105TH CONGRESS, 1st Session | HOUSE OF REPRESENTATIVES | REPORT 105–307

MEDICAL DEVICE REGULATORY MODERNIZATION ACT OF 1997

OCTOBER 6, 1997.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BLILEY, from the Committee on Commerce, submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 1710]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (H.R. 1710) to amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, clearance, and use of devices to maintain and improve the public health and quality of life of the citizens of the United States, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

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

(a) SHORT TITLE.—This Act may be cited as the "Medical Device Regulatory Modernization Act of 1997".

(b) REFERENCE.—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. 321 et seq.).

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

Sec. 1. Short title; references; table of contents.
Sec. 2. FDA mission and annual report.
Sec. 3. Dispute resolution.
Sec. 4. Investigational device exemptions; expanded access.
Sec. 5. Special review for certain devices.
Sec. 6. Expanding humanitarian use of devices.
Sec. 7. Device standards.
Sec. 8. Scope of review.
Sec. 9. Premarket notification.
Sec. 10. Classification panels.
Sec. 11. Premarket approval.
Sec. 12. Accreditation for accredited persons.
Sec. 13. Preamendment devices.
Sec. 14. Device tracking.
Sec. 15. Postmarket surveillance.
Sec. 16. Harmonization.
Sec. 17. Reports.
Sec. 18. Information system.
Sec. 19. Practice of medicine.
Sec. 20. Clarification of definition.
Sec. 21. Labeling and advertising regarding compliance with statutory requirements.
Sec. 22. Noninvasive blood glucose meter.
Sec. 23. Rule of construction.

SEC. 2. FDA MISSION AND ANNUAL REPORT.

(a) MISSION.—Section 903 (21 U.S.C. 393) is amended by redesignating subsections (b) and (c) as subsections (c) and (d), respectively, and by adding after subsection (a) the following:

"(b) MISSION.—The Food and Drug Administration shall 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 with respect to such products shall protect the public health by ensuring that—

"(1) foods are safe, wholesome, sanitary, and properly labeled;

"(2) human and veterinary drugs are safe and effective;

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

"(4) cosmetics are safe and properly labeled; and

"(5) public health and safety are protected from electronic product radiation.

The Food and Drug Administration shall participate with other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.".

(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393), as amended by subsection (a), is amended by adding at the end the following:

"(e) ANNUAL REPORT.—The Secretary shall, simultaneously with the submission each year of the budget for the Food and Drug Administration, submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an annual report which shall—

"(1) review the performance of the Food and Drug Administration in meeting its mission and the development of Food and Drug Administration policies to implement such mission;

"(2) review the performance of the Food and Drug Administration in meeting its own performance standards, including its own outcome measurements, and statutory deadlines for the approval of products or for other purposes contained in this Act;

"(3) describe the staffing and resources of the Food and Drug Administration;

"(4)(A) list each bilateral and multinational meeting held by the Food and Drug Administration to address methods and approaches to reduce the burden

of regulation, to harmonize regulation, and to seek appropriate reciprocal arrangements, (B) describe the goals, activities, and accomplishments of the Food and Drug Administration in such meetings, and (C) list issues that the Food and Drug Administration is considering or has presented for each such meeting; and

"(5) summarize and explain each instance in the previous fiscal year in which an application received under section 515(c) was not reviewed in a manner to achieve final action on such application within 180 days of its receipt.".

SEC. 3. DISPUTE RESOLUTION.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 506 the following:

"DISPUTE RESOLUTION

"SEC. 506A. If, regarding an obligation under this Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer, and no specific provision of this Act or regulation promulgated under this Act provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy by an appropriate scientific advisory panel under section 515(g)(2)(B). Such review shall take place in a timely manner. The Secretary shall promulgate such regulations not later than 180 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997.".

SEC. 4. INVESTIGATIONAL DEVICE EXEMPTIONS; EXPANDED ACCESS.

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

"(6)(A) Not later than 120 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, the following:

"(i) Procedures and conditions under which the Secretary will, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

"(I) developmental changes in the device that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

"(II) changes or modifications to clinical protocols that do not affect the validity of data or information resulting from the completion of an approved protocol and do not alter the relationship of likely patient risk to benefit relied upon to approve a protocol.

"(ii) Procedures and conditions under which the Secretary will, outside of an approved investigational protocol (subject to compliance with regulations for the protection of patients), permit uses of the device in the diagnosis, monitoring, or treatment of diseases or conditions that are life-threatening or could be irreversibly debilitating, when—

"(I) the treating physician determines that the investigational use of the device likely will provide a benefit; that the risk of not using the device exceeds the probable risk of using the device; and that there is no legally marketed device alternative for the satisfactory treatment or diagnosis of such disease or condition;

"(II) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the investigational use of the device in the case described in subclause (I);

"(III) the Secretary determines that the investigational use of the device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

"(IV) the sponsor, or clinical investigator, of the investigational use of the device submits to the Secretary a clinical protocol consistent with the provisions of paragraph (3) and any regulations promulgated under such paragraph describing the investigational use of devices in a single patient or a small group of patients.

"(B) Regulations under subparagraph (A)(i) shall provide that a change or modification described in such subparagraph is not permitted unless, not later than 5 days after making the change or modification, a notice of the change or modification is submitted to the Secretary.

"(C) Regulations under subparagraph (A)(ii) shall provide that, under appropriate conditions described by the Secretary in the regulations, the Secretary will author-

ize the shipment of investigational devices (as defined in the regulations) for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

"(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or an implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review board, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant requests a meeting with the Secretary regarding such review, the Secretary shall meet with the applicant not later than 30 days after receiving the request for the meeting.

"(B) Agreements regarding the parameters of an investigational plan (including clinical protocol) that are 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 agreements shall not be changed, except—

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

"(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.

"(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has 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 documents the scientific issue involved.".

SEC. 5. SPECIAL REVIEW FOR CERTAIN DEVICES.

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

(1) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; 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,

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

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

SEC. 6. EXPANDING HUMANITARIAN USE OF DEVICES.

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

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

"The request shall be in the form of an application to the Secretary. Within 60 days of the date of the receipt of an application, the Secretary shall issue an order approving or denying the application, except that if the Secretary convenes a scientific advisory panel, the Secretary shall within 120 days of the receipt of an application issue such order.";

(2) by amending paragraph (5) to read as follows:

"(5) The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device, after providing notice and an opportunity for an informal hearing, if any condition for granting such exemption for such device set forth in paragraphs (2) through (4) no longer is met."; and

(3) by amending paragraph (6) to read as follows:

"(6) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.".

(b) REGULATIONS.—Any provision in a regulation included in title 21 of the Code of Federal Regulations pertaining to humanitarian devices which is inconsistent with the amendments made by subsection (a) shall be deemed rescinded on the date of the enactment of this Act. The Secretary shall amend regulations pertaining to humanitarian devices to conform with the amendments made by subsection (a).

SEC. 7. DEVICE STANDARDS.

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

"Listing of Recognized Standards

"(c)(1) The Secretary shall issue notices identifying and adopting applicable nationally or internationally recognized standards (or portions of such standards) to which a person may self-certify compliance for the purpose of demonstrating a reasonable assurance that a device is safe or effective or to determine compliance with any requirement of this Act. Such notices shall be published in the Federal Register, and the Secretary shall provide an opportunity for public comment on the standards involved.

"(2) The Secretary shall accept a certification that a device conforms with each type of standard referenced in subsection (a) and identified in such certification to the extent such standard applies, except that the Secretary may, at any time, require the person who submitted the certification to submit the data and information which such person relied upon in making such certification, and may reject the certification if the Secretary determines that the data and information do not demonstrate compliance with the standards identified in the certification. Such person shall maintain the data and information for a period of 2 years after the submission of the certification, or for the expected design life of the device, whichever is later.

"(3) The Secretary may remove from the list of standards adopted under subsection (a) a standard (or portion of a standard) which the Secretary determines is not reliable for the purpose set out in such subsection.

"(4) In the case of a person who does not self-certify compliance pursuant to paragraph (1) regarding a device, the person may elect to utilize data other than those required by standards under paragraph (1) to demonstrate a reasonable assurance of the safety or effectiveness of the device.".

(b) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(x) The falsification of a certification under section 514(c) or the failure or refusal to provide data or information required by the Secretary under such section.".

(c) ADULTERATED DEVICES.—Section 501(e) (21 U.S.C. 351(e)) is amended by striking "subject to a performance standard" and all that follows and inserting the following: "subject to a performance standard established under subsection (b) of section 514, unless such device is in all respects in conformity with such standard; or subject to a standard listed under subsection (c) of such section (in the case of a person who has self-certified to such standard), unless such device is in all respects in conformity with such standard.".

(d) CONFORMING AMENDMENTS.—

(1) DEFINITION OF CLASS II DEVICE.—Section 513(a)(1)(B) (21 U.S.C. 360c(a)(1)(B) is amended by inserting after "performance standards," the following: "the listing of standards under section 514(c)," .

(2) RELATIONSHIP TO PERFORMANCE STANDARDS.—Section 514(a) (21 U.S.C. 360d(a)) is amended—

(A) in paragraph (1), in the second sentence, by striking "under this section" and inserting "under subsection (b)";

(B) in paragraph (2), in the matter preceding subparagraph (A), by striking "under this section" and inserting "under subsection (b)";

(C) in paragraph (3), by striking "under this section" and inserting "under subsection (b)"; and

(D) in paragraph (4), in the matter preceding subparagraph (A), by striking "this section" and inserting "this subsection and subsection (b)".

SEC. 8. SCOPE OF REVIEW.

(a) SECTION 513(a).—Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended—

(1) in subparagraph (A) by inserting "one or more" before "clinical investigations"; and

(2) 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) Upon the request of any person intending to submit an application under section 515, the Secretary shall, not later than 30 days after receiving such request, meet with the person to determine the type of valid scientific evidence within the meaning of subparagraphs (A) and (B) that will be necessary to demonstrate the effectiveness of a device for the proposed conditions of use. Within 30 days of such meeting, the Secretary shall identify, and confirm in writing, the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the proposed conditions of use.

"(ii) Agreements under section 515 regarding the parameters of valid scientific evidence for a device that are 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 agreements shall not be changed, except—

"(I) with the written agreement of the sponsor or applicant; or

"(II) pursuant to a decision, made in accordance with clause (iii) 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 has been identified.

"(iii) A decision under clause (ii) by the director shall be in writing, and may be made only after the Secretary has 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 documents the scientific issue involved.".

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

"(C) 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 to demonstrate that devices 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), unless the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the 'Director'), after providing an opportunity for consultation with the person who submitted such report, 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) on the basis of data or the absence of data, that such use could cause harm.

"(ii) 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;

"(II) specify limitations on the device's labeling which proscribe the use not included in proposed labeling; and

"(III) find the device substantially equivalent when the labeled intended use and the technological characteristics of the device relative to a legally marketed device conform with the requirements of subparagraph (A).

"(iii) The responsibilities of the Director under this subparagraph may not be delegated.

"(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Medical Device Regulatory Modernization Act of 1997.".

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

(1) in paragraph (1)(A), by adding after and below clause (ii) the following: "In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling."; and

(2) by adding after paragraph (5) (as added by section 5(2)) the following:

"(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

"(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a premarket approval supplement

is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

"(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

"(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

"(II) clinical data from the approved application and any supplement to the approved application provide a 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. 9. PREMARKET NOTIFICATION.

(a) SECTION 510.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k)—

(A) in the matter preceding paragraph (1), by adding after "report to the Secretary" the following: "or person who is accredited under section 712(a)"; and

(B) by adding after and below paragraph (2) the following:

"Such a report is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (l) or is classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended to be life supporting or life sustaining or is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury. With respect to a person who is accredited under section 712(a), such accredited person shall review a report under this subsection that is received by such person and shall submit, not later than 60 days after receiving the report, to the Secretary such person's recommendation for action to be taken by the Secretary on the report."; and

(2) by adding after subsection (k) the following subsection:

"(l) Not later than 30 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, 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 listed by the Secretary shall be exempt from the requirement to file a report under subsection (k) as of the date of the publication of the list in the Federal Register. Beginning on the date that is 1 day after the date of the publication of the list, any person may petition the Secretary to exempt a type of class II device from the reporting requirement of subsection (k). The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. If the Secretary fails to respond to a petition within 120 days of receiving it, the petition shall be deemed to be granted.".

(b) INITIAL CLASSIFICATION.—Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in the second sentence of paragraph (1) by striking the period at the end and inserting the following: "unless within 30 days of receiving an order classifying the device into class III the person who submits a report under section 510(k) for such device requests review with respect to the classification of the device and a final order of classification from the Secretary. Such person shall submit to the Secretary data and information supporting the classification of the device into class I or II. After the request, a device classified into class III under this paragraph remains in class III, but shall not be deemed to be finally classified until the Secretary has determined the classification of the device based on the classification criteria set forth in subparagraphs (A) through (C) of subsection (a)(1), within 60 days of receiving the request to review and classify a device. Any device found under this paragraph not to be substantially equivalent to a device described in subparagraph (A)(i) and which is classified by the Secretary into class III may not be commercially distributed in commerce before it is approved under section 515."; and

(2) by adding at the end the following:

"(4) 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 a substantial equivalence decision, including a finding that

the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that the failure to comply with such regulations is directly related to the safety or effectiveness of the device).".

(c) SECTION 513.—Section 513(i)(1) (21 U.S.C. 360c(i)), as amended by section 8(b), is amended—

(1) in subparagraph (A)(ii)(I), by striking "clinical data" and inserting "appropriate clinical or scientific data" and by inserting "or a person accredited under section 712" after "Secretary";

(2) in subparagraph (A)(ii)(II), by striking "efficacy" and inserting "effectiveness"; and

(3) by adding at the end of paragraph (1) the following:

"(F) For purposes of subparagraph (A), the term 'legally marketed device' includes any device introduced into interstate commerce for commercial distribution before May 28, 1976, and any device determined to be substantially equivalent to such device which has not been removed from the market by an order of the Secretary or a judicial order because it is not safe or not effective.

"(G) Not later than 270 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).".

(d) SUNSET.—The amendments made by subsections (a)(1)(A) and (c)(1), to the extent that they relate to an accredited person under section 712 of the Federal Food, Drug, and Cosmetic Act, shall be of no force or effect upon the expiration of 7 years from the date of the enactment of this Act.

SEC. 10. 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 have the same rights as the Secretary regarding—

"(i) access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code);

"(ii) the submission, for review by a classification panel, of information that is based on the 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 participation of the persons at meetings of the panel.

"(B) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel review, and shall encourage free and open participation by all interested persons.

"(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

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

SEC. 11. PREMARKET APPROVAL.

Section 515(d) (21 U.S.C. 360e(d)), as amended by section 5(1), is amended by inserting after paragraph (1) the following:

"(2) Each application received under subsection (c) shall be reviewed in a manner to achieve final action on such application within 180 days of its receipt. At the request of the applicant, the Secretary shall meet with an applicant under such an application within 90 days of the date of the application's submission.".

SEC. 12. ACCREDITATION FOR ACCREDITED PERSONS.

(a) AMENDMENT.—Subchapter A of chapter VII is amended by adding at the end the following:

"ACCREDITED PERSONS

"SEC. 712. (a) IN GENERAL.—The Secretary shall, not later than 1 year after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, accredit persons for the purpose of reviewing and initially classifying devices under section 513(f)(1) that are subject to a report under section 510(k). An accredited person may not be used to perform a review of a class III device, or a class II device which is intended to be permanently implantable or life sustaining or life supporting.

"(b) ACCREDITATION.—

"(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) GENERAL RULE.—Not later than 180 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register requirements to accredit 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 such person is accredited.

"(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person acts or fails to act in a manner that is inconsistent with the purposes of this section or poses a threat to public health.

"(C) PERFORMANCE AUDITING.—To ensure that persons accredited under 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 determines to be appropriate.

"(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 903(e)(2) the names of all accredited persons and the particular 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.

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

"(A) 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.

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

"(C) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

"(D) Such person shall be operated 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 conflict of interest regarding the device, 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.

"(4) SELECTION OF ACCREDITED PERSONS.—The Secretary shall provide each person who chooses to use an accredited person to receive a section 510(k) report a panel of at least 2 or more accredited persons from which the regulated person may select 1 for a specific regulatory function.".

(b) CONFORMING AMENDMENT.—Section 301 (21 U.S.C. 321), as amended by section 7(b), is amended by adding at the end the following:

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

"(1) the submission of a report or recommendation by a person accredited under section 712 that is false or misleading in any material respect;

"(2) the disclosure by a person accredited under section 712 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 712 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.".

(c) SUNSET.—The amendments made by subsections (a) and (b) to the extent they relate to an accredited person under section 712 of the Federal Food, Drug, and Cosmetic Act shall be of no force or effect upon the expiration of 7 years from the date of the enactment of this Act.

(d) REPORT.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on the use of accredited persons under section 712 of the Federal Food, Drug, and Cosmetic Act, the extent to which such use was helpful in the implementation of such Act, and the extent to which such use promoted actions which were contrary to the purposes of such Act.

SEC. 13. PREAMENDMENT DEVICES.

Section 515(i) (21 U.S.C. 360e(i)) is amended to read as follows:

"Revision

"(i) Not later than 180 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of the types of devices classified into class III under section 513(d), which are not subject to a regulation under subsection (b), and for which the Secretary has determined after classification of such devices that premarket approval is unnecessary to protect the public health. Each such type of device listed in the Federal Register publication shall be reclassified into class II or class I, as appropriate.".

SEC. 14. DEVICE TRACKING.

Subsection (e) of section 519 (21 U.S.C. 360i) is amended to read as follows:

"Device Tracking

"(e) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

"(1) the failure of which would be reasonably likely to have serious adverse health consequences; or

"(2) which is—

"(A) intended to be an implantable device, or

"(B) a life sustaining or life supporting device used outside a device user facility.".

SEC. 15. POSTMARKET SURVEILLANCE.

Section 522 (21 U.S.C. 360l) is amended to read as follows:

"POSTMARKET SURVEILLANCE

"SEC. 522. (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

"(1) an implantable device, or

"(2) a life-sustaining or life-supporting device used outside a device user facility.

"(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such sur-

veillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if such plan will result in information necessary to determine the occurrence of unforeseen events. The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 506A.".

SEC. 16. HARMONIZATION.

(a) SECTION 520(f).—Section 520(f)(1)(B) (21 U.S.C. 360j(f)(1)(B)) is amended by striking "and" at the end of clause (i), by striking the period at the end of clause (ii) and inserting "; and" and by adding after clause (ii) the following:

"(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts thereof, for medical devices.".

(b) SECTION 803.—Section 803 (21 U.S.C. 383) is amended by adding at the end the following:

"(c)(1) The Secretary shall participate in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act. The Secretary shall, not later than 180 days after the date of enactment of the Medical Device Regulatory Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

"(2) The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least 60 days before executing any bilateral or multilateral agreement under paragraph (1).".

SEC. 17. REPORTS.

(a) REPORTS.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "manufacturer, importer, or distributor" and inserting "manufacturer or importer"; and

(B) by striking paragraph (9) and inserting the following:

"(9) shall require distributors to keep records and make such records available to the Secretary upon request.";

(2) by striking subsection (d); and

(3) in subsection (f), by striking ", importer, or distributor" each place it appears and inserting "or importer".

(b) REGISTRATION.—Section 510(g) (21 U.S.C. 360(g)) 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, repackage, process, or relabel a device; or"; and

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

"In this subsection, the term 'wholesale distributor' means any person 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) DEVICE USER FACILITIES.—

(1) IN GENERAL.—Section 519(b) (21 U.S.C. 360i(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) in subparagraph (B), by striking ", or" at the end and inserting a period; and

(iii) by striking subparagraph (C).

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

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

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

"(5) With respect to device user facilities that are hospitals or nursing homes:

"(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of hospitals and nursing homes that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

"(B) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply to such device user facilities.

"(C) During the period in which the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply to such facilities except to the extent that the Secretary determines otherwise.

"(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to such a facility unless the facility is included in the subset referred to in subparagraph (A).

"(E) Not later than one year after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.".

SEC. 18. INFORMATION SYSTEM.

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

"SEC. 906. INFORMATION SYSTEM.

"The Secretary shall, with respect to devices, establish and maintain an information system to track the status and progress of each application or submission submitted to the Secretary requesting agency action. The system shall permit access by the applicant under conditions specified by the Secretary.".

SEC. 19. PRACTICE OF MEDICINE.

Chapter IX, as amended by section 18, is amended by adding at the end the following:

"SEC. 907. PRACTICE OF MEDICINE.

"Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to 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 distribution, or in 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, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.".

SEC. 20. CLARIFICATION OF DEFINITION.

Section 201(h) (21 U.S.C. 321) is amended by adding at the end the following: "A computer software product shall not be considered a device under this paragraph solely on the basis that the primary use of such product is related to the provision of health care.".

SEC. 21. LABELING AND ADVERTISING REGARDING COMPLIANCE WITH STATUTORY REQUIREMENTS.

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

SEC. 22. NONINVASIVE BLOOD GLUCOSE METER.

(a) FINDINGS.—The Congress finds that—

(1) diabetes and its complications are a leading cause of death by disease in America;

(2) diabetes affects approximately 16,000,000 Americans and another 650,000 will be diagnosed in 1997;

(3) the total health care-related costs of diabetes total nearly $100,000,000,000 per year;

(4) diabetes is a disease that is managed and controlled on a daily basis by the patient;

(5) the failure to properly control and manage diabetes results in costly and often fatal complications including but not limited to blindness, coronary artery disease, and kidney failure;

(6) blood testing devices are a critical tool for the control and management of diabetes, and existing blood testing devices require repeated piercing of the skin;

(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; and

(9) the Food and Drug Administration is responsible for reviewing all applications for 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. 23. 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 day before the date of the enactment of this Act.

PURPOSE AND SUMMARY

The purpose of H.R. 1710, the Medical Device Regulatory Modernization Act of 1997, is to enact common-sense improvements in the current regulatory system that will enable the U.S. Food and Drug Administration (FDA) to keep pace with medical innovation and enhance patient access to lifesaving, life-sustaining, and life-improving medical devices.

BACKGROUND AND NEED FOR LEGISLATION

H.R. 1710, the Medical Device Regulatory Modernization Act of 1997, is a compilation of reforms pertaining to existing statutory and regulatory requirements concerning medical devices. These reforms focus on a number of problems which are summarized below.

The U.S. medical device industry is diverse, consisting of thousands of product lines used by more than 50 medical specialties in numerous procedures and applications. Most product lines generate relatively modest revenues; in fact, only an estimated 7 percent of all product line groups have annual revenue potential of more than $150 million. As a result, the majority of device companies are small (80 percent of device firms have fewer than 50 employees; 98 percent have fewer than 500) and focus on a single clinical area.

During this century, major strides in medical technology have revolutionized the practice of medicine. In light of achievements in such fields as fiber optics, imaging, biomaterials, electronics, and biotechnology, today's medical technology is faster, more efficient, and more productive than ever. These achievements have provided benefits to individual patients and to society at large—including better health, more cost effective medical treatments, and the return of patients to productive lives more quickly.

However, in many areas, the current regulatory system is not keeping pace with medical innovation. For FDA approval, a medical device company must submit one of two applications: a 510(k), or a premarket approval (PMA). A 510(k) is submitted for devices that are "substantially equivalent to" a device placed on the market prior to 1976. A PMA application, which must often be supported by extensive clinical data, is required when a device is unlike an already marketed device or represents a breakthrough medical technology. In a number of cases, for both 510(k) and PMA products, increased requirements that are burdensome, expensive, and time-consuming have delayed patients' access to promising new devices.

A total of 5,297 510(k) applications were filed with the FDA in FY 1996, down significantly from 6,056 in FY 1995 and 7,022 in FY 1989. In FY 1996, it took the FDA an average of 110 days to carry out a 510(k) review, not including the time when a review was put on hold for manufacturer input of additional information. However, the total average review time, including such holds (FDA time), was 145 days. The FDA has made recent progress in improving review times. For FY 1997, the average 510(k) review time was 130 days total time (97 days "FDA time"). 5,049 510(k) applications were submitted in FY 1997. In addition, the review backlog has been eliminated. However, 510(k) total review times remain longer than the 90 days called for under the Federal Food, Drug, and Cosmetic Act (FFDCA).

510(k) AVERAGE REVIEW TIMES

[In days]

	Fiscal years—					
	1991	1992	1993	1994	1995	1996
Statutory Review Time	90	90	90	90	90	90
FDA Time	81	102	162	184	137	110
Total Time	102	126	195	216	178	145
Applications Submitted	5,770	6,509	6,288	6,434	6,056	5,297

With regard to breakthrough devices, 44 PMA applications were submitted to the FDA in FY 1996, up from 39 in 1995, but down significantly from 84 in 1989. Between 1990 and 1996, review times for PMAs of breakthrough devices nearly doubled. In FY 1996, it took the FDA an average total time (i.e., actual time elapsed from application to approval) of 786 days to approve these advanced devices, or more than four times longer than the 180 days allowed under the FFDCA. Recent progress has been made. In FY 1997, the FDA approved 48 PMAs, taking an average total review time of 498 days (375 days "FDA time"), a decline of nearly 37 percent. However, this still is more than double the statutory 180-day deadline.

PMA Average Review Times

[In days]

	Fiscal years—					
	1991	1992	1993	1994	1995	1996
Statutory Review Time	180	180	180	180	180	180
FDA Time	335	236	547	649	606	572
Total Time	633	310	799	823	773	786
Applications Submitted	75	65	40	43	39	44

The net result of these delays is that American patients do not have access to technologies that are often available to patients in other countries. This is occurring as companies are able to market their products in foreign countries, such as in the European Union, before being able to gain FDA approval to market them in the United States.

HEARINGS

In preparation for action on modernization of the Food and Drug Administration, the Committee held 17 hearings over the last 30 months, including an April 30, 1997, hearing entitled, "Medical Devices: Technological Innovation and Patient/Provider Perspectives." The Subcommittee on Health and Environment received testimony from the following witnesses: Dr. Michael A. Friedman, Lead Deputy Commissioner, Food and Drug Administration; Dr. John F. Hansbrough, Director of the Regional Burn Center, University of California, San Diego Medical Center; Dr. Robert A. Schmidt, Section Chief of Mammography, University of Chicago Hospitals; Dr. Joseph M. Smith, Assistant Professor of Medicine, Washington University School of Medicine; Dr. C. Warren Olanow, Professor and Chairman, Department of Neurology, Mount Sinai School of Medicine; and Ms. Joy Vaas, Washington, D.C.

COMMITTEE CONSIDERATION

On September 17, 1997, the Subcommittee on Health and Environment met in an open markup session and approved H.R. 1710 for Full Committee consideration, amended, by a voice vote. On September 26, 1997, the Full Committee met in an open markup session and ordered H.R. 1710 reported to the House, amended, by a voice vote, a quorum being present.

ROLLCALL VOTES

Clause 2(l)(2)(B) of rule XI of the Rules of the House requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto. There were no recorded votes taken in connection with ordering H.R. 1710 reported or in adopting the amendments. The following are the voice votes that were taken in Committee:

VOICE VOTES—SEPTEMBER 26, 1997

Bill: H.R. 1710, Medical Device Regulatory Modernization Act of 1997

Amendment: Amendment in the Nature of a Substitute by Mr. Barton.

Disposition: Agreed to, amended, by a voice vote.

Amendment: Amendment to the Barton Amendment in the Nature of a Substitute by Mr. Waxman re: limiting the role of manufacturers in determining the length of postmarket surveillance.

Disposition: Withdrawn, by unanimous consent.

Amendment: Amendment to the Barton Amendment in the Nature of a Substitute by Mr. Barton re: labeling and advertising regarding compliance with statutory requirements.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Barton Amendment in the Nature of a Substitute by Ms. Eshoo re: establishing safeguards in the scope of 510(k) application review.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Barton Amendment in the Nature of a Substitute by Ms. Furse re: add a sense of Congress with respect to a noninvasive blood glucose meter.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Barton Amendment in the Nature of a Substitute by Mr. Klug re: maintaining the classification of Class I devices.

Disposition: Withdrawn, by unanimous consent.

Amendment: Amendment to the Barton Amendment in the Nature of a Substitute by Mr. Markey re: striking the provision on device tracking and postmarket surveillance.

Disposition: Withdrawn, by unanimous consent.

Amendment: Amendment to the Barton Amendment in the Nature of a Substitute by Mr. Waxman re: defining the role of the FDA in regulating the practice of medicine.

Disposition: Withdrawn, by unanimous consent.

Amendment: Amendment to the Barton Amendment in the Nature of a Substitute by Mr. Waxman re: limiting the devices eligible for accredited party review.

Disposition: Withdrawn, by unanimous consent.

Motion: Motion by Mr. Bliley to order H.R. 1710 reported to the House, amended.

Disposition: Agreed to, by a voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee has held oversight hearings on issues addressed in this legislation.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform and Oversight.

NEW BUDGET AUTHORITY AND TAX EXPENDITURES

In compliance with clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, the Committee finds that H.R. 1710, would result in no new or increased budget authority or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 1, 1997.

Hon. TOM BLILEY,
Chairman, Committee on Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1710, the Medical Device Regulatory Modernization Act of 1997.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Anne Hunt.

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

H.R. 1710—Medical Device Regulatory Modernization Act of 1997

Summary: H.R. 1710 would amend the Food, Drug and Cosmetic Act (FD&CA) and the Public Health Service Act to reform the Food and Drug Administration's (FDA's) regulatory and approval processes for devices. The bill would also require the FDA to meet statutory deadlines for approving some device applications. Finally, the FDA would be directed to accredit independent entities to review certain device applications. CBO estimates that enacting H.R. 1710 would result in net additional discretionary spending of $13 million in 1998 and $70 million over the 1998–2002 period, assuming appropriation of the authorized amounts.

H.R. 1710 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act and would impost no costs on state, local, or tribal governments. The bill would reduce the costs of existing private-sector mandates.

Estimated cost of the Federal Government: The estimated budgetary impact of H.R. 1710 is shown in the following table. For the purposes of this estimate, CBO assumes that all amounts authorized in the bill would be appropriated by the start of each fiscal year and that outlays would follow the historical spending patterns for the FDA. The costs of this legislation fall within budget function 550 (Health).

	By fiscal years, in millions of dollars—						
	1996	1997	1998	1999	2000	2001	2002
SPENDING SUBJECT TO APPROPRIATION							
Spending by FDA Under Current Law:							
Estimated Authorization Level	877	887	919	949	982	1,016	1,050
Estimated Outlays	866	895	914	937	971	1,005	1,038
Proposed Changes:							
Estimated Authorization Level	0	0	13	14	13	14	16
Estimated Outlays	0	0	9	13	13	14	15
Spending by FDA Under H.R. 1710:							
Estimated Authorization Level [1]	877	887	932	963	995	1,030	1,066
Estimated Outlays	866	895	923	950	984	1,019	1,053

[1] The 1996 and 1997 levels are the amounts appropriated for those years.

Basis of estimate: H.R. 1710 would amend the FDA's approval and regulatory processes with the intent of accelerating product approvals and reducing regulatory requirements. Under this bill,

manufacturers of class III devices could petition for the reclassification of their products. The bill would direct the FDA to comply with statutory deadlines for reviewing certain device applications and to accredit third-party reviewers. Finally, the proposal would require the FDA to establish an information system to track device applications and submissions. Other provisions of the bill would have no significant budgetary impact.

Reclassification of Class III Devices. H.R. 1710 would change the FDA's current practice of automatically designating as class III products new devices that are not substantially equivalent to a legally marketed predicate device. Sponsors of devices designated as class III could submit to the FDA information supporting a class I or II determination, and could make a recommendation about the classification of their product. The FDA would have 60 days to make a final determination on the sponsor's recommendation. This provision would reduce the number of premarket applications reviewed by the FDA, saving $2 million in 1998 and $12 million over five years.

Enforced Deadlines for FDA Action on Submissions. Under this provision, the FDA would be directed to complete action on applications for premarket approval (PMA) of class III devices within 180 days. This provision would therefore bring the FDA into compliance with the statutory deadline for reviewing PMA applications.

Assuming that the volume and quality standards for reviews were to remain constant, the FDA would require additional staff and resources to reduce its current device review times significantly. Because H.R. 1710 would somewhat relax current FDA regulations, the number of product applications could increase, placing further demands on the agency's resources. CBO estimates that the additional personnel and resources necessary to meet the proposed deadlines would exceed any savings realized through regulatory relief offered by H.R. 1710. This provision would cost the federal government an estimated $11 million in 1998 and $66 million over five years.

Third-Party Review of Applications. This provision would require the FDA to accredit independent entities for reviewing and making initial classification recommendations on section 510(k) device submissions. Devices that are life-sustaining or life-supporting, intended for permanent implantation, or designated as class III devices would be exempted from this provision. The FDA could evaluate the performance of accredited reviewers and rescind their accreditation status when necessary. CBO estimates that this proposal would save approximately $1 million over five years.

Application Tracking System. H.R. 1710 would direct the FDA to establish an information system to track device applications and submissions. Based on information from the FDA, CBO estimates that the cost of developing and maintaining this system would be $4 million in 1998, and $17 million over five years.

Estimated impact on State, local, and tribal governments: H.R. 1710 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

Estimated impact on the private sector: In general, H.R. 1710 reduces the costs of existing private-sector mandates. In at least one

instance (section 8, Scope of Review) it would replace an existing private-sector mandate with new, less burdensome requirements. CBO is uncertain whether other sections would add to the cost of complying with regulations governing the use of unapproved devices for humanitarian purposes. In total, however, CBO concludes that the direct cost of all private-sector mandates in this bill would be minimal and the total effect could be a net reduction in costs imposed on the private sector.

Estimate prepared by: Federal Cost: Anne Hunt. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Anna Cook.

Estimate approved by: Robert A. Sunshine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation. The bill provides that a device classification panel shall not be subject to annual chartering and annual reporting requirements under the Federal Advisory Committee Act.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title; references; table of contents

The short title for this Act is the "Medical Device Regulatory Modernization Act of 1997." All references are to sections or provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321 et seq.), unless otherwise specified.

Sec. 2. FDA mission and annual report

This section establishes a mission statement under section 903 for the Food and Drug Administration (FDA). The FDA's mission is to promote public health by promptly and efficiently reviewing and taking action on regulated products and by ensuring that (a) foods are safe, wholesome, sanitary and properly labeled; (b)

human and veterinary drugs are safe and effective; (c) there is a reasonable assurance of 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.

The FDA is required to work with other countries to reduce regulatory burdens, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.

Under section 903, the Secretary of Health and Human Services (the Secretary) must submit to the House Committee on Commerce and the Senate Committee on Labor and Human Resources an annual report containing the following: a review of the FDA's performance in meeting its mission and in meeting its own performance standards and statutory deadlines for the approval of products or other activities under the FFDCA; a description of staffing and resources of the FDA; and a list of each bilateral and multinational meeting the FDA held to address issues pertinent to reducing regulatory burdens, harmonizing regulation, and seeking appropriate reciprocal arrangements. The annual report must also contain a summary explaining each instance in the previous fiscal year in which final action on a premarket approval application, filed under section 515(c) of the FFDCA, was not achieved within 180 days.

In addition, the Committee requests that the Secretary, in keeping with this legislation's focus on improved FDA performance, consider the creation of the position of Chief Operating Office at the agency. Such a role could facilitate the administration of the agency's operations, with possible responsibilities including the establishment of standards of performance, determination of performance reviews and employee compensation, and oversight of audits of the performance of reviewers at the FDA.

Sec. 3. Dispute resolution

Section 3 amends Chapter V by adding a new section 506A to require the Secretary to publish regulations relating to procedures for resolving a scientific controversy between the Secretary and a regulated person for cases where the FFDCA does not provide a right of review. The regulations must include procedures under which the regulated person may request a review of the controversy by an FDA scientific advisory panel. The Secretary must promulgate the regulations within 180 days of enactment.

Sec. 4. Investigational device exemptions; expanded access

This section amends Section 520(g) to provide that within 120 days of enactment, the Secretary must publish regulations relating to investigational device exemptions (IDEs), which establish procedures under which the Secretary will, without requiring an additional approval of an application, permit (1) developmental changes in the device that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation, and (2) changes or modifications to clinical protocols that do not affect the validity of data and do not alter the relationship of likely patient risk to benefit that was relied upon to approve a protocol.

The Secretary must also establish, by regulation, procedures and conditions under which the Secretary will permit uses of an investigational device for a single patient or a small group of patients where (1) a treating physician determines that the investigational use of the device likely will provide a benefit, that the risk of not using the device exceeds the probable risk of using the device, and that there is no legally marketed satisfactory alternative; (2) the Secretary determines that there is sufficient evidence of safety and effectiveness and that the investigational use of the device will not interfere with clinical investigations to support marketing approval; and (3) the sponsor or investigator has filed an appropriate clinical protocol. The Committee notes that the FDA's recently issued treatment-IDE regulations provide another means for expanded access.

The regulations under subparagraph (A)(ii) must provide that changes to the IDE as established under new subparagraph (A)(i) are permitted only if the Secretary is notified within five days of the modification. The regulations must also provide that, under appropriate conditions, the Secretary will authorize the shipment of investigational devices in a medical emergency. For class III or implantable devices, the Secretary must ensure that the device sponsor has an opportunity to preview an investigational plan or clinical protocol with the Secretary before submitting it to an institutional review board or the Secretary for review. If a preview consultation is requested, the Secretary must meet with the applicant within 30 days of receiving a request. Any agreements that the Secretary and device sponsor reach during the consultation must be reduced to writing and made part of the Secretary's administrative record. Such agreements may be changed with the written agreement of the sponsor, or pursuant to a written decision by the reviewing office director, after providing the sponsor with an opportunity for a meeting, that a substantial scientific issue essential to determining the safety or effectiveness of the device has been identified.

In requiring that the Secretary meet with a sponsor to discuss a planned protocol, the Committee recognizes that valuable resources will be expended by technical experts at the FDA and representing the sponsor. The Committee expects, therefore, that any such meeting be a productive one. To ensure this, the sponsor must have provided the FDA with sufficient background and other information so the appropriate FDA personnel can be available and prepared for the meeting. The FDA is not expected to agree to any meeting requests where sponsors have not provided the necessary information.

Sec. 5. Special review for certain devices

Section 5 amends Section 515 to require the Secretary to establish a priority system for reviewing medical devices (A) representing breakthrough technologies, (B) for which no approved alternatives exist, (C) which offer significant advantages over existing approved therapies, or (D) the availability of which is in the best interest of patients.

Sec. 6. Expanding humanitarian use of devices

This section amends Section 520(m) to require that applicants seeking a humanitarian exemption for a device must submit an application which the Secretary must review and approve or disapprove within 60 days, unless a scientific advisory panel is convened. If the Secretary convenes a scientific advisory panel, the final decision must occur within 120 days of the submission of the application to the Secretary. The Secretary may suspend or withdraw a humanitarian device exemption if any of the conditions for granting the exemption are not being met. Also, the Secretary may require a person to demonstrate continued compliance with the requirements for the exemption.

Provisions of current regulations pertaining to humanitarian device exemptions which are inconsistent with section 6 are rescinded upon enactment, and the Secretary must modify these regulations to accord with this section.

Sec. 7. Device standards

Section 7 of the bill creates a process whereby the Secretary will identify and list in the *Federal Register* all or parts of nationally or internationally recognized standards upon which regulated persons may rely to satisfy requirements under the FFDCA to which such standards are applicable. Conformance with listed standards may be demonstrated with certifications that devices conform with standards. For example, in a premarket notification, a submitter may satisfy an electrical safety requirement by certifying conformance to IEC–601, assuming such standard is identified and listed by the Secretary. Because standards are of substantially greater importance in the international regulatory community than before, and because they present opportunities for more efficient premarket reviews and a greater potential for use of accredited organizations, the Committee believes this provision will assist the FDA and device manufacturers in facilitating premarket clearances. The Committee believes that integration of nationally and internationally recognized standards into the Secretary's regulatory approach to devices will improve the efficiency and the effectiveness of device regulation, without expenditure of significant resources.

An important feature of this provision is that it does not create an obligation that any regulated person rely on a listed standard. If a regulated person chooses to rely on a listed standard to support the clearance of a premarket notification device, that device must conform to any listed standard upon which the 510(k) submitter relies. Listed standards may be compared to guidance documents, since they do not create an obligation for either the FDA or the regulated person. However, if a person certifies conformance to such a standard, legal responsibility will result. The Committee wishes to emphasize that regulated persons may rely on other data or information to demonstrate compliance with the FFDCA, including other data or information that can be used to establish substantial equivalence, notwithstanding the existence of an applicable listed standard.

While the Secretary is required to accept self-certifications, the Secretary may at any time request that the underlying data and information be submitted to support the certifications and may re-

ject the certification if the submitted data and information do not demonstrate compliance with the standards identified in the certification. Regulated persons are required to preserve data and information relied upon in making a certification for a period of two years or for the expected design life of the device, whichever is later. The Secretary may remove a standard from the list of adopted standards if the Secretary determines that the standard is not reliable.

In addition, section 301 is amended to prohibit regulated persons from falsifying certifications or withholding information that the Secretary might require under new section 514(c). Also, the Secretary may enforce the FFDCA against persons who represent that a device conforms to a listed standard and it does not. Such incorrect representations would adulterate a device under section 501(e).

Finally, the Committee wishes to emphasize that listed standards are not necessarily special controls within the meaning of section 513(a)(1)(B), and they are not special controls when non-substantially-equivalent devices are initially classified into class II under section 513(f).

Sec. 8. Scope of review

This section amends Section 513(a)(3), pertaining to device classification. For premarket approval applications (PMAs), the Secretary shall evaluate the effectiveness of a device on the basis of well-controlled investigations, including one or more clinical investigations where appropriate. In reviewing PMAs under section 515, the Secretary must consider the extent to which data that might otherwise be required to determine effectiveness might be reduced through reliance on postmarket controls.

Also, the Secretary must meet with a device sponsor within 30 days of receiving a request to discuss the type of valid scientific evidence needed to demonstrate the effectiveness of a device. Within 30 days of the meeting, the Secretary must provide the applicant with a written specification of the type of evidence needed to provide a reasonable assurance that a device is effective under the proposed conditions of use. Agreements reached between the Secretary and the applicant must be reduced to writing and made part of the Secretary's administrative record. The written agreement may not be changed unless the applicant agrees or the reviewing office director makes a written determination, after providing the sponsor with an opportunity for a meeting, that a substantial scientific issue essential to determining the safety or effectiveness of the device has been identified.

The amendments to section 513(a)(3) are intended to facilitate early and binding determinations of the type of scientific evidence necessary to establish a reasonable assurance of effectiveness for class III devices which require premarket approval. As introduced on May 22, 1997, the original H.R. 1710 provision stated, in relevant part: "Any clinical data * * * specified by the Secretary for demonstrating a reasonable assurance of device effectiveness shall reflect the Secretary's determination that such data are necessary to establish device effectiveness *and that no other less burdensome means of evaluating effectiveness are available that would have a reasonable likelihood of resulting in approval.*" (Emphasis added).

The intention of this original language, which also would not have changed the effectiveness standard, was to make clear that the FDA should avoid unnecessary over-regulation of the approval of breakthrough medical devices. In deciding to delete the "no other less burdensome" language, the Committee did not disagree with the intent of the original provision; rather the Committee agreed that clear legislative history would ensure the same result without creating a perception in statute that avoiding a perceived regulatory "burden" is as important as ensuring the safety and effectiveness of a medical device.

The Committee believes that the amendments to section 513(a)(3) are 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. In particular, the Committee is aware of examples where the FDA has requested inappropriate types of clinical testing for certain breakthrough devices and is concerned about instances in which the agency has required sponsors to conduct unnecessary randomized clinical studies to demonstrate device effectiveness. Although randomized clinical testing may be the best means of demonstrating device effectiveness for some products, the Committee is informed that such testing is often unnecessary to demonstrate effectiveness for many devices.

Section 513(i) is amended to direct the Secretary to consider the extent to which postmarket controls may expedite medical device classification. The provision clarifies that whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. Also, in making such a request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence.

New section 513(i)(1)(E) provides that the Secretary's determination of the intended use of a device for purposes of determining substantial equivalence with a legally marketed device must be based upon the proposed labeling submitted by the manufacturer in a 510(k) report unless there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Under such circumstances, this provision requires the Director of the Office of Device Evaluation to provide an opportunity to the submitter of the report for consultation about these concerns and to notify the submitter within 10 days following that consultation of the Director's determination that the unlabeled use could cause harm. The provision also clarifies the authority of the Secretary to require the label of the device to carry a warning or contraindication with respect to the unlabeled use the Director has determined could cause harm. Finally, the provision requires the Secretary to clear the device for the labeled intended use, so long as that labeled use and the technological characteristics of the device satisfy the requirements for establishing substantial equivalence under section 513(i)(1)(A).

Section 513(i)(1)(E) is most likely to apply to situations where a technological change in the device provides the Director responsible for clearing the device with reason to believe that the device will

be used for a use that has not been identified on the proposed label, and for which there are no, or insufficient, data to establish the safety and effectiveness of that device for the unlabeled use.

Under section 513(i)(1)(E), a device that is substantially equivalent to a legally marketed predicate for its labeled intended use cannot be kept off the market merely because the agency has concerns about the harm that could result from an unlabeled use. The Director may, however, require limitations in the labeling that proscribe the unlabeled use. The Committee believes this provision strikes the proper balance between getting devices to the market efficiently and protecting the public from harm that may be associated with other uses of the device for which there are not data establishing safety and effectiveness. The determination that limitations about an unlabeled use should be included in labeling for a device must be made by the Director of the Office of Device Evaluation or a higher level official and cannot be delegated to any employee of lesser authority. The Committee believes this level of review is essential to ensure that such limitations are required only in those circumstances when there is reason to believe, either on the basis of data or because of the absence of data, that the use of the device for its unlabeled use could cause harm. If the manufacturer of the device wishes to have the limiting language removed from the label, the manufacturer will be required to file an additional report under section 510(k) or a premarket approval application, depending upon the nature of the unlabeled use.

The provision establishing new section 513(i)(1)(E) sunsets in five years. At the end of that time period, Congress, the industry, the FDA, and the public will be able to determine whether this provision has helped to get devices to market more efficiently and with adequate public health protection.

Section 515(d) is amended to specify conditions for determining whether to approve or deny a premarket approval application (PMA). In making the determination whether to approve or deny a PMA, the Secretary must rely on the conditions of use included in the proposed labeling unless the proposed labeling is false or misleading.

Under new section 515(d)(6)(A)(i), a supplemental application shall be required for any change to a device subject to an approved PMA that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under good manufacturing practices. The holder of an approved application who submits a notice to modify a device under clause (i) may distribute the device within 30 days of notifying the Secretary unless the Secretary notifies the applicant that further action is required to accept the change. If a premarket approval supplement is required, the Secretary must review the supplement within 135 days.

Under new section 515(d)(6)(B), if a supplement for an incremental change to the design of a device affects the safety and effectiveness of a device, the supplement must be approved if nonclinical data demonstrate that the design modification enhances device

function, and clinical data provide a reasonable assurance of safety and effectiveness for the changed device.

This section is intended by the Committee to provide for a predictable and dependable structure through which the FDA and sponsors of applications for marketing of new products can communicate effectively regarding requirements that must be met to secure marketing clearance or approval. The Committee believes that meetings between the appropriate FDA experts and their industry counterparts may provide one avenue to successful communication that may result in agreements that can expedite a manufacturer's understanding of what information, data, or investigations may be needed for any particular product. The legislation requires that such meetings be held upon the reasonable request of a sponsor or applicant, within a specified time frame after such request. By "reasonable request," the Committee means that the person requesting the meeting must be adequately prepared so that the meeting can be productive. Specifically, the person requesting the meeting must provide to the FDA a detailed description of the person's proposal (whether for clinical protocols or for other studies), a detailed description of the person's intended use of the product, a proposed plan for completion of studies to demonstrate the safety and effectiveness of the product, and any other available information about the product that will assist FDA experts in providing useful advice and guidance. In addition, the person requesting the meeting should provide the FDA with the names of all individuals who will represent the sponsor or applicant at the meeting, and the position those individuals hold in the company or institution.

The provisions of this section also make clear that the FDA, when it has been provided with sufficient information by the sponsor or applicant, must respond to meeting requests promptly and be prepared to participate in such meetings with a view toward reaching the desired conclusion—an agreement between the agency and the sponsor or applicant about the data, information, or studies needed before marketing approval or clearance can be achieved. The Committee intends that when FDA officials, including reviewers, provide advice during such meetings, and such advice results in an agreement between the agency and the sponsor or applicant, the agreement should be communicated in writing by the FDA to the sponsor or applicant, and should be made part of the agency's administrative record related to the particular application or product.

Although the Committee believes that such agreements should be binding on both parties, the Committee also recognizes that changes in medical or scientific information, which have a direct impact on issues that may have been part of the agreement, may occur after the agreement has been reached. In addition, the Committee recognizes that, despite everyone's best efforts to provide and consider all available information at the time of the meeting, there may have been information not known to or considered by the FDA (or to the sponsor or applicant) which has direct bearing on a decision or agreement made at the meeting. This is why the legislation allows for changes in any such agreements, based on the fact that a substantial scientific issue has come to light after an agreement has been reached, which has a direct bearing on the de-

termination of the safety or effectiveness of the product. In general, changes also can be made if there is agreement between the agency and the sponsor or applicant.

Sec. 9. Premarket notification

Section 9 amends Section 510(k) to provide device applicants with the option of submitting a medical device notification to either the Secretary or a person accredited under new section 712(a). An accredited person must review 510(k) notifications and submit a recommendation to the Secretary within 60 days. The accreditation program established under section 712 expires seven years from the date of enactment.

If a device is exempted from reporting requirements under new section 510(l) or is classified into class I under section 513, a notification is not required. Class I devices which are intended to be life-supporting, life-sustaining, substantially important to preventing impairment of human health, or which present an unreasonable risk of injury, shall not be excluded from requirements or reports under section 510(k).

Within 30 days of enactment, the Secretary must publish a list of each type of class II device that is exempt from the 510(k) requirement. After the notice is published, any person may petition the Secretary to exempt a class II device from the reporting requirement under section 510(k). The Secretary must respond to the petition and allow a 30-day public comment period. If the Secretary fails to respond to the petition within 120 days, the petition shall be deemed to be granted.

Section 513(f) directs the Secretary to recognize a request for reclassification from an applicant whose device is assigned to class III pursuant to a not substantially equivalent order and who has filed a 510(k) report, providing that such requests are received within 30 days of the initial classification order. Upon receiving that request, the Secretary must use classification criteria set forth in the FFDCA under subsections (A) through (C) of 513(a)(1) within 60 days of receiving the request to review and classify the device. Any device that is not substantially equivalent to an existing device and which is classified into class III may not be distributed before it is approved under section 515.

A determination of initial classification of a device may not be withheld because of the applicant's failure to comply with any provision of the FFDCA that is unrelated to a substantial equivalence decision, including noncompliance with good manufacturing practices as set forth in regulations under section 520(f) (unless such noncompliance is directly related to the safety or effectiveness of the device).

Section 513(i) is amended such that the Secretary or accredited organizations may make a determination of substantial equivalence on the basis of "appropriate clinical scientific data."

The term "legally marketed device" includes any device marketed before May 28, 1976, and any device found substantially equivalent to a device that has not been removed from the market for safety or effectiveness reasons.

Within 270 days of enactment, the Secretary must issue guidance specifying the principles that will be considered in determining

when a specific intended use of a device is not reasonably included within a general use of such device for purposes of determining substantial equivalence.

Sec. 10. Classification panels

Under amended section 513(b), the Secretary must convene classification panels at such times as to maintain compliance with applicable statutory deadlines. Device sponsors have the same rights as the Secretary for (i) accessing data and information submitted to the classification panel (except for information unavailable to the public under section 552 of Title 5, United States Code); (ii) submitting written information to a classification panel for an application submitted under section 515, so long as the information is based on the application being considered by the panel (such information will be submitted to the Secretary for prompt transmittal to the panel); and (iii) participating at panel meetings. Classification panels must provide adequate time for initial presentations and for responses to different views by sponsors. After receiving recommendations and conclusions from the classification panel, the Secretary must make a final decision on the matter in accordance with section 515(d)(2), and must provide written notification to the regulated persons affected by the decision. A scientific advisory panel shall not be subject to annual chartering and annual reporting requirements under the Federal Advisory Committee Act.

Sec. 11. Premarket approval

Section 11 amends section 515(d) (as amended by section 5) by inserting after paragraph (1) a provision for timely medical device review. Upon request, the Secretary must meet with an applicant who files a premarket approval application within 90 days of the date the application is submitted. The Secretary must review the application and achieve final action within 180 days of receipt.

Sec. 12. Accreditation for accredited persons

Section 12 amends Subchapter A of Chapter VII by adding a new section 712 which establishes requirements for accreditation. Under new section 712, the Secretary must, within one year of enactment, accredit persons who will review and initially classify devices that are subject to a report under section 510(k) of the FFDCA. An accredited person may not review a class III device, or class II device that is permanently implantable, life-sustaining or life-supporting.

New section 712(b)(1) directs the Secretary to establish through the FDA, or other government agencies or other qualified non-government agencies, a program for accreditation. The Committee emphasizes that the numbers of accredited bodies and the kinds of expertise of such bodies will be a function of the Secretary's ability to complete the accreditation process, as well as of the numbers and kinds of organizations that seek accreditation. The Committee does not anticipate that accredited organizations will immediately be available for the review of every type of medical device eligible under this bill for review by accredited bodies. However, the Committee does expect the Secretary to proceed promptly and diligently with accrediting appropriate, qualified organizations so that this

pilot program can provide the broadest and most useful information.

Within 180 days of enactment, the Secretary must establish and publish in the Federal Register requirements to accredit or deny accreditation to persons who request such accreditation. The Secretary must respond to a request for accreditation within 60 days of receiving the request and include a specification of the activities for which the person is accredited. When an accredited person acts in a manner inconsistent with accreditation purposes or poses a threat to public health, accreditation status may be withdrawn from the person after that person has been served notice and provided with an opportunity for an informal hearing. To ensure that accredited persons meet standards of accreditation, the Secretary is required to (i) make periodic onsite visits to the accredited persons to conduct performance audits, and (ii) take additional measures as deemed appropriate.

Minimum qualifications for accredited persons are (A) independence from ownership of or control by a medical device affiliate; (B) legal authority to conduct the activities for which they seek accreditation; (C) no engagement in the design, manufacture, promotion, or sale of devices; and (D) operation in accordance with generally accepted professional and ethical business practices. The accredited person must agree in writing that it will (i) certify that reported information accurately reflects data reviewed; (ii) confine its work to those areas in which it is competent; (iii) treat information received through the pilot program, such as records, reports, and recommendations, as proprietary information; (iv) promptly respond to and resolve complaints for the activities for which it is accredited; and (v) take steps to protect against the use of employees who have a financial conflict of interest regarding a device, and each year publicly disclose the extent to which the organization has complied with financial conflict of interest requirements.

The Secretary must provide applicants with a choice of at least two or more accredited persons from which to choose. The Committee recognizes that such choices may not be available immediately for all types of products, and will be available when and to the extent that it has been possible for the Secretary to promptly and diligently accredit appropriate expert organizations.

Section 12(b) amends section 301 as amended by new section 7(b) with a conforming amendment. Additional prohibited acts relating to the accreditation program under the FFDCA include (A) the submission of a false or misleading report or recommendation by an accredited person; (B) the unauthorized disclosure of confidential commercial information or any trade secrets; and (C) the receipt of a bribe in any form or the doing of any corrupt act by an accredited person.

The amendments establishing the accreditation program under the FFDCA shall remain in effect for a period of seven years from the date of enactment. Within five years of enactment, the Comptroller General of the United States must report to House Committee on Commerce and the Senate Committee on Labor and Human Resources on the service of accredited persons and the extent to which such service was beneficial and/or contrary to the purposes of the FFDCA.

Sec. 13. Preamendment devices

Section 13 amends section 515(i) to direct the Secretary to publish in the Federal Register within six months of enactment a list of the types of devices classified into class III under section 513(d) which are not subject to regulation under section 515(b) (that is, which have not been required to submit a premarket approval application). Each type of device listed in the Federal Register shall be reclassified into class II or class I, as appropriate.

Sec. 14. Device tracking

Section 14 amends section 519 to authorize the Secretary to require a manufacturer to track a class II or class III device (1) the failure of which would be reasonably likely to have serious adverse health consequences, or (2) which is intended to be an implantable device or is a life-sustaining or life-supporting device used outside of a device user facility.

Sec. 15. Postmarket surveillance

Section 15 amends section 522 of the FFDCA to establish that the Secretary has the discretion to order a manufacturer to conduct postmarket surveillance for any class II or class III device (1) the failure of which would be reasonably likely to have serious adverse health consequences, or (2) which is intended to be an implantable device or is a life-sustaining or life-supporting device used outside of a device user facility.

Each manufacturer who is required to conduct postmarket surveillance of a device must submit a plan within 30 days of receiving an order from the Secretary. Within 60 days of receiving the postmarket surveillance plan from the manufacturer, the Secretary shall determine if the person designated to conduct the surveillance is qualified to do so, and if the plan will yield the information needed to determine the occurrence of unforeseen events. The Secretary, in consultation with the manufacturer, may order a surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 3 ("Dispute Resolution") of the bill.

Sec. 16. Harmonization

This section amends Section 520(f)(1)(B) to ensure that regulations for good manufacturing practices conform, to the extent practicable, with internationally recognized standards defining quality systems, or parts thereof, for medical devices.

Section 803 is amended to require that the Secretary participate in multinational meetings to discuss methods and approaches to reduce the burden of regulation, harmonize regulatory requirements, and seek appropriate reciprocal arrangements consistent with the purposes of the FFDCA. Within 180 days of enactment, the Secretary must publish a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

The Secretary shall report to the House Committee on Commerce and the Senate Committee on Labor and Human Resources at least 60 days before executing any bilateral or multilateral agreement.

Sec. 17. Reports

Section 17 amends Section 519 to reduce the reporting requirements for all distributors of devices. Manufacturers and importers, however, are required to comply with the existing requirements for medical device reporting. The amendment to section 519(a)(9) requires 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 would also not be sent to the manufacturers. This is not intended to provide the FDA with any new statutory authority to require distributors to keep additional records; it merely clarifies that existing record keeping requirements of section 519(a) continue to apply. This provision also removes the registration, listing, and reporting requirements for distributors under section 510. Since user facilities and manufacturers submit medical device reports to the FDA, there is no need for additional reporting by distributors. The FDA is urged to allow all record keeping, including distributor record keeping, to be accomplished through either electronic means or written documentation. The FDA is also urged to revise its current regulations on distributor record keeping (21 C.F.R. § 804.35(b)) to provide that distributors need only keep records of complaints for six years from the date a complaint is received by the distributor, consistent with the longest statutes of limitations under State tort laws. Currently, FDA regulations require distributors to keep records for two years from the date of the record of complaint or the expected life of the device, whichever is greater. It is the intent of the Committee to simplify these requirements, since distributors, unlike manufacturers, are not able to determine the expected life of a device. Since these records will be kept by manufacturers as well, it is unnecessarily burdensome for distributors to keep these records for other than a fixed period of time.

The Committee expects the FDA to modify its regulations under section 519(f) to ensure 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 Control for Health and Safety Act of 1968 (21 U.S.C. 360ll).

Section 519(b) is amended by changing user reporting requirements from semi-annual to annual, and by adding a requirement that the Secretary plan and implement a sentinel system under which the Secretary limits user reporting to a subset of hospitals and nursing homes that constitute a representative profile of user reports for device deaths and serious illnesses or serious injuries. Within one year of enactment, the Secretary must submit a report to the House Committee on Commerce and the Senate Committee on Labor and Human Resources describing the plan for the sentinel system and the progress that has been made toward its implementation. The Committee expects the Secretary to proceed promptly and diligently toward establishing such a sentinel system.

The Committee requests that the Secretary, in consultation with the National Institute for Occupational Safety and Health, the

FDA, medical experts, and manufacturers, conduct a study of topically applied allergenic products used for the diagnosis of Type IV allergies (patch tests). To the extent feasible, the report should: (1) examine the extent of allergic skin reactions and contact dermatitis in the workplace; (2) assess the current availability of topically applied allergenic products used for the diagnosis of Type IV allergies (patch tests), compared with their availability in the 1980s and with availability in other countries; and (3) list by year, since 1970, the number of adverse reaction reports filed with the FDA resulting from the use of topically applied allergenic products used for the diagnosis of Type IV allergies and describe, to the extent possible, whether those adverse reactions resulted from commercial allergens or allergens that were individually prepared by a patient, physician, pharmacist, or other person. The Committee requests that the Secretary submit a report on the results of this study to the House Committee on Commerce and the Senate Committee on Labor and Human Resources not later than one year after enactment of this bill.

Sec. 18. Information system

Section 18 amends Chapter IX by adding new section 906 ("Information System") which requires the Secretary to establish an information system to track the status and progress of each application or submission that is submitted to the FDA for action. Device applicants shall be granted access to that system under conditions specified by the Secretary. The Committee recognizes that access to such a system must be carefully constructed to avoid inappropriate disclosure of confidential commercial information.

Sec. 19. Practice of medicine

Section 19 adds to Chapter IX a new section, Sec. 907. Practice of Medicine, to clarify that provisions in the FFDCA do not limit or interfere with the authority of a licensed health care practitioner to prescribe or administer any legally marketed drug or device in the context of a legitimate health care practitioner-patient relationship. This section does not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in 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, this section does not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

The Committee intends by this provision to emphasize that the FDA should not interfere in the practice of medicine. Specifically, the Committee notes that the uses of a medical device not covered by the label, by a physician using best medical judgment in determining how and when to use a medical product for the care of a particular patient, is not the province of the FDA. The Committee has clarified that the FDA's current authority to place restrictions on the labeling of a product, which may deal with the training or other requirements needed to use the device safely and effectively, is not limited by this provision. However, the Committee does not intend by this clarification to sanction or encourage the involvement of the FDA in disputes or differences among medical special-

ists about who may or may not use specific medical products. Further, the Committee notes that promotion restrictions do not apply to physicians' publishing articles regarding off-label uses of products, or presenting information at scientific or medical meetings. Finally, the Committee notes that with respect to products already on the market, any restrictions on such products which may be in their labeling or which may have been placed on the products by virtue of conditions of approval or regulations issued by the Secretary are not affected by this provision.

Sec. 20. Clarification of definition

This section amends Section 201(h) to clarify that a computer software product is not to be regulated as a device solely on the basis that the primary use of the product is related to the provision of health care. Software that is used simply to archive patient record information or to serve a similar library function will not be considered to be a medical device, even when such software is used in a hospital and other health care settings. However, nothing in this provision is intended to limit the FDA's authority to regulate software that is used to diagnose, treat, or prevent diseases or other conditions. For example, software that would be used in a hospital to identify compatible blood prior to transfusion would continue to be considered to be a medical device, as would other software that modifies information in patient records, such as picture archiving and compression systems. It is not the Committee's intention to shift the burden from the manufacturer to the FDA to demonstrate that a device, including stand-alone software, is safe and effective.

Sec. 21. Labeling and advertising regarding compliance with statutory requirements

Section 21 repeals section 301(l), which prohibits the use of any representation or suggestion that a device or drug is approved in accordance with the FFDCA.

Sec. 22. Noninvasive blood glucose meter

This section expresses the sense of 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. 23. Rule of construction

Whether and to what extent, if any, the FDA has authority under the FFDCA to regulate tobacco products, tobacco product ingredients, or tobacco product additives are questions currently under review by the courts. See *Coyne Beahm, Inc.* v. *United States Food & Drug Administration,* 958 F. Supp. 1060 (M.D. N.C. 1997), appeals pending, No. 97–1604 (and consolidated cases) (4th Cir.). During the deliberations on H.R. 1710, concern was expressed that the amendments to the FFDCA made by the legislation might be deemed to affect the extent of any FDA authority with respect to tobacco products, if the courts ultimately uphold the agency's assertion of authority to regulate tobacco products. To respond to that concern, a section stating a "rule of construction" has been included

in H.R. 1710 to make clear that Congress, through this legislation, is taking no position regarding either whether the FDA has any authority under the FFDCA to regulate any tobacco product, or what the extent of any such authority may be. Further, this section ensures that, if the courts ultimately determine that the FDA has authority under existing law to regulate tobacco products, this legislation does not alter any such authority as it may have existed when the FDA adopted its tobacco rule, as any such authority may ultimately be construed by the courts.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER II—DEFINITIONS

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SEC. 201. For the purposes of this Act—

(a) * * *

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(h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) * * *

* * * * * * *

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. *A computer software product shall not be considered a device under this paragraph solely on the basis that the primary use of such product is related to the provision of health care.*

* * * * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * * * *

[(l) The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 505, 515, or 520(g), as the

case may be, or that such drug or device complies with the provisions of such section.]

* * * * * * *

(x) The falsification of a certification under section 514(c) or the failure or refusal to provide data or information required by the Secretary under such section.

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

(1) the submission of a report or recommendation by a person accredited under section 712 that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 712 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 712 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.

* * * * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—

(a) * * *

* * * * * * *

(e) If it is, or purports to be or is represented as, a device which is [subject to a performance standard established under section 514, unless such device is in all respects in conformity with such standard.] *subject to a performance standard established under subsection (b) of section 514, unless such device is in all respects in conformity with such standard; or subject to a standard listed under subsection (c) of such section (in the case of a person who has self-certified to such standard), unless such device is in all respects in conformity with such standard.*

* * * * * * *

DISPUTE RESOLUTION

SEC. 506A. If, regarding an obligation under this Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer, and no specific provision of this Act or regulation promulgated under this Act provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy by an appropriate scientific advisory panel under section 515(g)(2)(B). Such review shall take place in a timely manner. The Secretary shall promulgate such regulations not later than 180 days after the date of

the enactment of the Medical Device Regulatory Modernization Act of 1997.

* * * * * * *

SEC. 510. (a) * * *

* * * * * * *

(g) The foregoing subsections of this section shall not apply to—

(1) * * *

* * * * * * *

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

[(4)**]** *(5)* such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

In this subsection, the term "wholesale distributor" means any person 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.

* * * * * * *

(k) Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary *or person who is accredited under section 712(a)* (in such form and manner as the Secretary shall by regulation prescribe)—

(1) * * *

* * * * * * *

Such a report is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (l) or is classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended to be life supporting or life sustaining or is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury. With respect to a person who is accredited under section 712(a), such accredited person shall review a report under this subsection that is received by such person and shall submit, not later than 60 days after receiving the report, to the Secretary such person's recommendation for action to be taken by the Secretary on the report.

(l) Not later than 30 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, 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 listed by the Secretary shall be exempt from the requirement to file a report under subsection (k) as of the date of the publication of the list in the Federal Register. Beginning on the date that

is 1 day after the date of the publication of the list, any person may petition the Secretary to exempt a type of class II device from the reporting requirement of subsection (k). The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. If the Secretary fails to respond to a petition within 120 days of receiving it, the petition shall be deemed to be granted.

* * * * * * *

CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

Device Classes

SEC. 513. (a)(1) There are established the following classes of devices intended for human use:

(A) * * *

(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, *the listing of standards under section 514(c),* postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

* * * * * * *

(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 514 and 515, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including *one or more* clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

* * * * * * *

(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) Upon the request of any person intending to submit an application under section 515, the Secretary shall, not later than 30 days after receiving such request, meet with the person to determine the type of valid scientific evidence within the meaning of subparagraphs (A) and (B) that will be necessary to demonstrate the effectiveness of a device for the proposed conditions of use. Within 30 days of such meeting, the Secretary shall identify, and confirm in writing, the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the proposed conditions of use.

(ii) Agreements under section 515 regarding the parameters of valid scientific evidence for a device that are 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 agreements shall not be changed, except—

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

(II) pursuant to a decision, made in accordance with clause (iii) 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 has been identified.

(iii) A decision under clause (ii) by the director shall be in writing, and may be made only after the Secretary has 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 documents the scientific issue involved.

(b)(1) * * *

* * * * * * *

(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 have the same rights as the Secretary regarding—

(i) access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code);

(ii) the submission, for review by a classification panel, of information that is based on the 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 participation of the persons at meetings of the panel.

(B) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel review, and shall encourage free and open participation by all interested persons.

(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the deci-

sion in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

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

* * * * * * *

(f)(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) classifying the device in class I or II**[.]** *unless within 30 days of receiving an order classifying the device into class III the person who submits a report under section 510(k) for such device requests review with respect to the classification of the device and a final order of classification from the Secretary. Such person shall submit to the Secretary data and information supporting the classification of the device into class I or II. After the request, a device classified into class III under this paragraph remains in class III, but shall not be deemed to be finally classified until the Secretary has determined the classification of the device based on the classification criteria set forth in subparagraphs (A) through (C) of subsection (a)(1), within 60 days of receiving the request to review and classify a device. Any device found under this paragraph not to be substantially equivalent to a device described in subparagraph (A)(i) and which is classified by the Secretary into Class III may not be commercially distributed in commerce before it is approved under section 515.*

* * * * * * *

(4) 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 a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that the failure to comply with such regulations is directly related to the safety or effectiveness of the device).

* * * * * * *

Substantial Equivalence

(i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including [clinical data] *appropriate clinical or scientific data* if deemed necessary by the Secretary *or a person accredited under section 712*, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and [efficacy] *effectiveness* than the predicate device.

* * * * * * *

(C) 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 to demonstrate that devices 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), unless the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the "Director"), after providing an opportunity for consultation with the person who submitted such report, 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) on the basis of data or the absence of data, that such use could cause harm.

(ii) 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;

(II) specify limitations on the device's labeling which proscribe the use not included in proposed labeling; and

(III) find the device substantially equivalent when the labeled intended use and the technological characteristics of the device relative to a legally marketed device conform with the requirements of subparagraph (A).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Medical Device Regulatory Modernization Act of 1997.

(F) For purposes of subparagraph (A), the term "legally marketed device" includes any device introduced into interstate commerce for commercial distribution before May 28, 1976, and any device determined to be substantially equivalent to such device which has not been removed from the market by an order of the Secretary or a judicial order because it is not safe or not effective.

(G) Not later than 270 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).

* * * * * * *

PERFORMANCE STANDARDS

Provisions of Standards

SEC. 514. (a)(1) The special controls required by section 513(a)(1)(B) shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device [under this section] *under subsection (b)* if the device has been reclassified as a class II device under a regulation under section 513(e) but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

(2) A performance standard established [under this section] *under subsection (b)* for a device—

(A) * * *

* * * * * * *

(3) The Secretary shall provide for periodic evaluation of performance standards established [under this section] *under subsection (b)* to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

(4) In carrying out his duties under [this section] *this subsection and subsection (b)*, the Secretary shall, to the maximum extent practicable—

(A) * * *

* * * * * * *

Listing of Recognized Standards

(c)(1) The Secretary shall issue notices identifying and adopting applicable nationally or internationally recognized standards (or portions of such standards) to which a person may self-certify compliance for the purpose of demonstrating a reasonable assurance that a device is safe or effective or to determine compliance with any

requirement of this Act. Such notices shall be published in the Federal Register, and the Secretary shall provide an opportunity for public comment on the standards involved.

(2) The Secretary shall accept a certification that a device conforms with each type of standard referenced in subsection (a) and identified in such certification to the extent such standard applies, except that the Secretary may, at any time, require the person who submitted the certification to submit the data and information which such person relied upon in making such certification, and may reject the certification if the Secretary determines that the data and information do not demonstrate compliance with the standards identified in the certification. Such person shall maintain the data and information for a period of 2 years after the submission of the certification, or for the expected design life of the device, whichever is later.

(3) The Secretary may remove from the list of standards adopted under subsection (a) a standard (or portion of a standard) which the Secretary determines is not reliable for the purpose set out in such subsection.

(4) In the case of a person who does not self-certify compliance pursuant to paragraph (1) regarding a device, the person may elect to utilize data other than those required by standards under paragraph (1) to demonstrate a reasonable assurance of the safety or effectiveness of the device.

PREMARKET APPROVAL

General Requirement

SEC. 515. (a) * * *

* * * * * * *

Action on an Application for Premarket Approval

(d)(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) (except as provided in section 520(l)(3)(D)(ii) or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary

shall fairly evaluate all material facts pertinent to the proposed labeling.

* * * * * * *

(2) Each application received under subsection (c) shall be reviewed in a manner to achieve final action on such application within 180 days of its receipt. At the request of the applicant, the Secretary shall meet with an applicant under such an application within 90 days of the date of the application's submission.

[(2)**]** *(3)* The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

(A) * * *

* * * * * * *

[(3)**]** *(4)* An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application.

(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,

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

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

(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a premarket approval supplement is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

(II) clinical data from the approved application and any supplement to the approved application provide a 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.

* * * * * * *

[Revision

[(i)(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

[(2) After the issuance of an order under paragraph (1) but before December 1, 1995, the Secretary shall publish a regulation in the Federal Register for each device—

[(A) which the Secretary has classified as a class III device, and

[(B) for which no final regulation has been promulgated under section 515(b),

revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a). Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this paragraph and provide reasonable opportunity for the submission of comments on any such regulation. No regulation requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of its publication in the Federal Register as a proposed regulation.

[(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the regulation requiring a device to remain in class III, establish a schedule for the promulgation of a section 515(b) regulation for each device

which is subject to the regulation requiring the device to remain in class III.]

Revision

(i) Not later than 180 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of the types of devices classified into class III under section 513(d), which are not subject to a regulation under subsection (b), and for which the Secretary has determined after classification of such devices that premarket approval is unnecessary to protect the public health. Each such type of device listed in the Federal Register publication shall be reclassified into class II or class I, as appropriate.

* * * * * * *

RECORDS AND REPORTS ON DEVICES

General Rule

SEC. 519. (a) Every person who is a [manufacturer, importer, or distributor] *manufacturer or importer* of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

(1) * * *

* * * * * * *

[(9) shall require distributors who submit such reports to submit copies of the reports to the manufacturer of the device for which the report was made.]

(9) shall require distributors to keep records and make such records available to the Secretary upon request.

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (7) of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

User Reports

(b)(1)(A) * * *

* * * * * * *

(C) Each device user facility shall submit to the Secretary on [a semi-annual basis] *an annual basis* a summary of the reports made under subparagraphs (A) and (B). Such summary shall be submitted on January 1 [and July 1] of each year. The summary shall be in such form and contain such information from such reports as the Secretary may require and shall include—

(i) sufficient information to identify the facility which made the reports for which the summary is submitted,

(ii) in the case of any product which was the subject of a report, the product name, serial number, and model number,

(iii) the name and the address of the manufacturer of such device, and

(iv) a brief description of the event reported to the manufacturer.

[The Secretary may by regulation alter the frequency and timing of reports required by this subparagraph.]

* * * * * * *

(2) The Secretary may not disclose the identity of a device user facility which makes a report under paragraph (1) except in connection with—

(A) an action brought to enforce section 301(q), *or*

(B) a communication to a manufacturer of a device which is the subject of a report under paragraph (1)[, or].

[(C) a disclosure required under subsection (a).]

This paragraph does not prohibit the Secretary from disclosing the identity of a device user facility making a report under paragraph (1) or any information in such a report to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

* * * * * * *

(5) With respect to device user facilities that are hospitals or nursing homes:

(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of hospitals and nursing homes that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

(B) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply to such device user facilities.

(C) During the period in which the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply to such facilities except to the extent that the Secretary determines otherwise.

(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to such a facility unless the facility is included in the subset referred to in subparagraph (A).

(E) Not later than one year after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.

[(5)] *(6)* For purposes of this subsection:

(A) The term "device user facility" means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office. The Secretary may by

regulation include an outpatient diagnostic facility which is not a physician's office in such term.

(B) The terms "serious illness" and "serious injury" mean illness or injury, respectively, that—

(i) is life threatening,

(ii) results in permanent impairment of a body function or permanent damage to a body structure, or

(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

* * * * * * *

[Certification

[(d) Each manufacturer, importer, and distributor required to make reports under subsection (a) shall submit to the Secretary annually a statement certifying that—

[(1) the manufacturer, importer, or distributor did file a certain number of such reports, or

[(2) the manufacturer, importer, or distributor did not file any report under subsection (a).

[Device Tracking

[(e) Every person who registers under section 510 and is engaged in the manufacture of—

[(1) a device the failure of which would be reasonably likely to have serious adverse health consequences and which is (A) a permanently implantable device, or (B) a life sustaining or life supporting device used outside a device user facility, or

[(2) any other device which the Secretary may designate,

shall adopt a method of device tracking.]

Device Tracking

(e) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

(1) the failure of which would be reasonably likely to have serious adverse health consequences; or

(2) which is—

(A) intended to be an implantable device, or

(B) a life sustaining or life supporting device used outside a device user facility.

Reports of Removals and Corrections

(f)(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer[, importer, or distributor] *or importer* of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer[, importer, or distributor] *or importer* if the removal or correction was undertaken—

(A) to reduce a risk to health posed by the device, or

(B) to remedy a violation of this Act caused by the device which may present a risk to health.

A manufacturer[, importer, or distributor] *or importer* of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

(3) For purposes of paragraphs (1) and (2), the terms "correction" and "removal" do not include routine servicing.

GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

General Rule

SEC. 520. (a) * * *

* * * * * * *

Good Manufacturing Practice Requirements

(f)(1)(A) * * *

(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated, [and]

(ii) afford opportunity for an oral hearing[.]*; and*

(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts thereof, for medical devices.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

* * * * * * *

Exemption for Devices for Investigational Use

(g)(1) It is the purpose of this subsection to encourage to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

* * * * * * *

(6)(A) Not later than 120 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, the following:

(i) Procedures and conditions under which the Secretary will, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

(I) developmental changes in the device that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

(II) changes or modifications to clinical protocols that do not affect the validity of data or information resulting from the completion of an approved protocol and do not alter the relationship of likely patient risk to benefit relied upon to approve a protocol.

(ii) Procedures and conditions under which the Secretary will, outside of an approved investigational protocol (subject to compliance with regulations for the protection of patients), permit uses of the device in the diagnosis, monitoring, or treatment of diseases or conditions that are life-threatening or could be irreversibly debilitating, when—

(I) the treating physician determines that the investigational use of the device likely will provide a benefit; that the risk of not using the device exceeds the probable risk of using the device; and that there is no legally marketed device alternative for the satisfactory treatment or diagnosis of such disease or condition;

(II) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the investigational use of the device in the case described in subclause (I);

(III) the Secretary determines that the investigational use of the device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

(IV) the sponsor, or clinical investigator, of the investigational use of the device submits to the Secretary a clinical protocol consistent with the provisions of paragraph (3) and any regulations promulgated under such paragraph describing the investigational use of devices in a single patient or a small group of patients.

(B) Regulations under subparagraph (A)(i) shall provide that a change or modification described in such subparagraph is not permitted unless, not later than 5 days after making the change or modification, a notice of the change or modification is submitted to the Secretary.

(C) Regulations under subparagraph (A)(ii) shall provide that, under appropriate conditions described by the Secretary in the regulations, the Secretary will authorize the shipment of investigational devices (as defined in the regulations) for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or an implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review board, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant requests a meeting with the Secretary regarding such review, the Secretary shall

meet with the applicant not later than 30 days after receiving the request for the meeting.

(B) Agreements regarding the parameters of an investigational plan (including clinical protocol) that are 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 agreements shall not be changed, except—

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

(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.

(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has 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 documents the scientific issue involved.

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Humanitarian Device Exemption

(m)(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 514 and 515 for a device for which the Secretary finds that—

(A) * * *

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(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devic or alternative forms of treatment.

The request shall be in the form of an application to the Secretary. Within 60 days of the date of the receipt of an application, the Secretary shall issue an order approving or denying the application, except that if the Secretary convenes a scientific advisory panel, the Secretary shall within 120 days of the receipt of an application issue such order.

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[(5) An exemption under paragraph (2) shall be for a term of 18 months and may only be initially granted in the 5-year period beginning on the date regulations under paragraph (6) take effect. The Secretary may extend such an exemption for a period of 18 months if the Secretary is able to make the findings set forth in paragraph (2) and if the applicant supplies information demonstrating compliance with paragraph (3). An exemption may be

extended more than once and may be extended after the expiration of such 5-year period.

[(6) Within one year of the date of the enactment of this subsection, the Secretary shall issue regulations to implement this subsection.]

(5) The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device, after providing notice and an opportunity for an informal hearing, if any condition for granting such exemption for such device set forth in paragraphs (2) through (4) no longer is met.

(6) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.

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[POSTMARKET SURVEILLANCE

[SEC. 522. (a) IN GENERAL.—

[(1) REQUIRED SURVEILLANCE.—The Secretary shall require a manufacturer to conduct postmarket surveillance for any device of the manufacturer first introduced or delivered for introduction into interstate commerce after January 1, 1991, that—

[(A) is a permanent implant the failure of which may cause serious, adverse health consequences or death,

[(B) is intended for a use in supporting or sustaining human life, or

[(C) potentially presents a serious risk to human health.

[(2) DISCRETIONARY SURVEILLANCE.—The Secretary may require a manufacturer to conduct postmarket surveillance for a device of the manufacturer if the Secretary determines that postmarket surveillance of the device is necessary to protect the public health or to provide safety or effectiveness data for the device.

[(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device under subsection (a)(1) shall, within 30 days of the first introduction or delivery for introduction of such device into interstate commerce, submit, for the approval of the Secretary, a protocol for the required surveillance. Each manufacturer required to conduct a surveillance of a device under subsection (a)(2) shall, within 30 days after receiving notice that the manufacturer is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information for the device. The Secretary may not approve such a protocol until it has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary.]

POSTMARKET SURVEILLANCE

SEC. 522. (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

(1) an implantable device, or

(2) a life-sustaining or life-supporting device used outside a device user facility.

(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if such plan will result in information necessary to determine the occurrence of unforeseen events. The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 506A.

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CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

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ACCREDITED PERSONS

SEC. 712. (a) IN GENERAL.—The Secretary shall, not later than 1 year after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, accredit persons for the purpose of reviewing and initially classifying devices under section 513(f)(1) that are subject to a report under section 510(k). An accredited person may not be used to perform a review of a class III device, or a class II device which is intended to be permanently implantable or life sustaining or life supporting.

(b) ACCREDITATION.—

(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) GENERAL RULE.—Not later than 180 days after the date of the enactment of the Medical Device Regulatory Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register requirements to accredit 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 such person is accredited.

(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person acts or fails to act in a manner that is inconsistent with the purposes of this section or poses a threat to public health.

(C) PERFORMANCE AUDITING.—To ensure that persons accredited under 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 determines to be appropriate.

(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 903(e)(2) the names of all accredited persons and the particular 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.

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

(A) 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.

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

(C) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

(D) Such person shall be operated 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 conflict of interest regarding the device, 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.

(4) SELECTION OF ACCREDITED PERSONS.—The Secretary shall provide each person who chooses to use an accredited person to receive a section 510(k) report a panel of at least 2 or more accredited persons from which the regulated person may select 1 for a specific regulatory function.

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CHAPTER VIII—IMPORTS AND EXPORTS

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OFFICE OF INTERNATIONAL RELATIONS

SEC. 803. (a) * * *

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(c)(1) The Secretary shall participate in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act. The Secretary shall, not later than 180 days after the date of enactment of the Medical Device Regulatory Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

(2) The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least 60 days before executing any bilateral or multilateral agreement under paragraph (1).

CHAPTER IX—MISCELLANEOUS

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SEC. 903. FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration").

(b) MISSION.—The Food and Drug Administration shall 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 with respect to such products shall protect the public health by ensuring that—

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

(2) human and veterinary drugs are safe and effective;

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

(4) cosmetics are safe and properly labeled; and

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

The Food and Drug Administration shall participate with other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.

[(b)] *(c)* COMMISSIONER.—

(1) * * *

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[(c)] *(d)* TECHNICAL AND SCIENTIFIC REVIEW GROUPS.—The Secretary through the Commissioner of Food and Drugs may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Administration, including functions under the Federal Food, Drug, and Cosmetic Act, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

(e) ANNUAL REPORT.—The Secretary shall, simultaneously with the submission each year of the budget for the Food and Drug Administration, submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an annual report which shall—

(1) review the performance of the Food and Drug Administration in meeting its mission and the development of Food and Drug Administration policies to implement such mission;

(2) review the performance of the Food and Drug Administration in meeting its own performance standards, including its own outcome measurements, and statutory deadlines for the approval of products or for other purposes contained in this Act;

(3) describe the staffing and resources of the Food and Drug Administration;

(4)(A) list each bilateral and multinational meeting held by the Food and Drug Administration to address methods and approaches to reduce the burden of regulation, to harmonize regulation, and to seek appropriate reciprocal arrangements, (B) describe the goals, activities, and accomplishments of the Food and Drug Administration in such meetings, and (C) list issues that the Food and Drug Administration is considering or has presented for each such meeting; and

(5) summarize and explain each instance in the previous fiscal year in which an application received under section 515(c) was not reviewed in a manner to achieve final action on such application within 180 days of its receipt.

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SEC. 906. INFORMATION SYSTEM.

The Secretary shall, with respect to devices, establish and maintain an information system to track the status and progress of each application or submission submitted to the Secretary requesting agency action. The system shall permit access by the applicant under conditions specified by the Secretary.

SEC. 907. PRACTICE OF MEDICINE.

Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to 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 distribution, or in 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, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

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ADDITIONAL VIEWS OF REPRESENTATIVE EDWARD J. MARKEY

Medical devices have the power to heal. But they also have the power to do great harm and to kill. The FDA has been strengthened over the years, in part, because of public outrage over medical device tragedies which resulted in unnecessary death and suffering. I am troubled by some of the provisions in the device bill.

First, I am disappointed with the provision that permits third-party review of devices. I question the need to allow private parties who may have a conflict-of-interest to perform regulatory reviews of new devices. Such a system invites abuses. Despite it's inherent flaws, this provision has managed to stay alive in this bill. Also disconcerting is the provision in the bill which would severely restrict the autonomy of the FDA to investigate those devices which are considered "substantially equivalent" to ones previously approved, even when the FDA detects "suspicious equivocation" on the part of the applicant.

Finally, the device bill contains two provisions that will change from mandatory to discretionary the requirement that device manufacturers do tracking and postmarket surveillance of their high-risk, life-sustaining or life-supporting devices. If these sections of the bill remain, we will actually have federal laws still on the books that require all automakers to track ignition switches in automobiles, while allowing device companies to fail to track the ignition switches in pacemakers. This would be laughable if it were not so close to becoming the law of the land.

I offered an amendment at the full Commerce Committee markup of H.R. 1710 that would strike Sections 14 and 15 of the bill, the sections titled "Device Tracking and Postmarket Surveillance," and maintain current law. For reasons impossible to fathom, Sections 14 and 15 would repeal mandatory tracking and postmarket surveillance of high-risk medical devices, enacted as part of the Safe Medical Devices Act of 1990, and make it optional. Without mandatory tracking of high risk devices like heart valves, pacemakers and implantable infusion pumps, it is impossible to find and warn patients whose lives are at risk from a faulty device.

This basic safety tool is widely appreciated and routine for automobile safety. Recalls that save lives are effective only because car companies are required to keep track of what machinery was sold to which customer. It is absurd to think, that without my amendment, we will have in our country a higher consumer protection standard on car parts than on implantable, life-sustaining or supporting medical devices.

Do we really want to place higher priority on the safety of car starters than on the safety of heart starters; a higher priority on tacking disk brakes than we do on tracking disc prostheses?

Mandatory postmarket surveillance by the manufacturer, approved by the FDA, provides a systematic method to look for and catch problems with these very high risk devices when they are put on the market. This process amounts to an "early-warning detection system" for threats to patients health and safety.

The device industry may think the tracking and surveillance provisions in current law are too onerous. But the fact is that repealing them is too dangerous.

If the engine in your Ford or Chevy poses a threat to your health and safety, the National Traffic and Motor Vehicle Safety Act empowers the government to require Ford or Chevy to track you down, have you bring your car in to the shop, and fix it. Shouldn't we require that same high standard for manufacturers of implantable, life-sustaining and life-supporting medical devices? The engine, if you will, implanted in a human being?

The Safe Medical Devices Act addressed this serious problem. The law was passed in direct response to the Bjork-Shiley heart valve fiasco. When the FDA detected a pattern of device failure in Bjork-Shiley heart valve patients, where the valves were prone to fracture and failure, it ordered the manufacturer to notify the recipients of this potential problem, what symptoms to look for, and how to take action if the symptoms were evident. The company claimed that it had no record of how to find half of the recipients. Hundreds died in the U.S., and nearly 1,000 people died worldwide. Congress put the Safe Medical Device Act on the books to make sure that this disaster would never be repeated. It is not our job to repeal it.

And to those who say that tracking doesn't work, I would like to share a story from this year to refute that claim. This past January doesn't work, I would like to share a story from this year to refute that claim. This past January, the FDA became aware that a "runaway pacing malfunction" in an implantable cardioverter defibrillator resulted in 3 patient deaths. Because of this tracking provision in current law, 97% of the 5,475 patients affected were notified to come in and have their devices reprogrammed.

Some may want this mandate repealed because they consider it "onerous." But the risk of this so-called reform is just too high.

A large coalition of patient rights and consumer groups, including the Consumer Federation of American, Public Citizen, Victim Against Lethal Valves, and many others, strongly supported this amendment.

I withdrew my amendment in full committee with after receiving assurances from the Chairman that these serious concerns would be addressed before the FDA bills came to the House floor. I believe that we must maintain current law and continue to make tracking and surveillance of implantable medical devices mandatory, and I hope we are able to reach a consensus on this matter before House floor action on this legislation.

These are a few of the problems that must be ironed out if we are to maintain a strong and effective Food and Drug Administration. There is no better protector of American consumers and pa-

tients in the world, and I am hopeful that this bill can be amended to strengthen and protect the FDA.

EDWARD J. MARKEY.

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