Union Calendar No. 178

105TH CONGRESS
1ST SESSION

H. R. 1710

[Report No. 105–307]

A BILL

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.

OCTOBER 6, 1997

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

Union Calendar No. 178

105TH CONGRESS
1ST SESSION

H. R. 1710

[Report No. 105–307]

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.

IN THE HOUSE OF REPRESENTATIVES

MAY 22, 1997

Mr. BARTON of Texas (for himself, Ms. ESHOO, Mr. BLILEY, Mr. BILIRAKIS, Mr. GREENWOOD, Mr. DAN SCHAEFER of Colorado, Mr. HALL of Texas, Mr. HASTERT, Mr. MANTON, Mr. TAUZIN, Mr. TOWNS, Mr. OXLEY, Ms. FURSE, Mr. UPTON, Mr. RUSH, Mr. STEARNS, Mr. PAXON, Mr. GILLMOR, Mr. KLUG, Mr. CRAPO, Mr. COX of California, Mr. DEAL of Georgia, Mr. LARGENT, Mr. BURR of North Carolina, Mr. BILBRAY, Mr. WHITFIELD, Mr. GANSKE, Mr. NORWOOD, Mr. WHITE, Mr. COBURN, Mr. LAZIO of New York, Mrs. CUBIN, Mr. ROGAN, Mr. SHIMKUS, Mr. GORDON, Mr. EHRLICH, Mr. RAMSTAD, Mr. WYNN, Ms. MCCARTHY of Missouri, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Commerce

OCTOBER 6, 1997

Additional sponsors: Mr. FAZIO of California, Mr. GEKAS, Mr. HOLDEN, Mr. SAWYER, Mr. PETERSON of Minnesota, Mr. CUNNINGHAM, Mr. MCGOVERN, Mr. CAMPBELL, Mr. BUYER, Mr. ARCHER, Mr. GUTKNECHT, Mr. FARR of California, Mr. FROST, Mr. FRANK of Massachusetts, Mr. CANADY of Florida, Mr. CRAMER, Mr. MCHALE, Mr. FOLEY, Mr. NEAL of Massachusetts, Mr. HAYWORTH, Mr. MCKEON, Mr. STUMP, Mr. TAYLOR of North Carolina, Mr. HORN, Mr. BOEHNER, Mr. FRANKS of New Jersey, Mr. HOSTETTLER, Mr. WATTS of Oklahoma, Mr. LUCAS of Oklahoma, Mr. DOOLITTLE, Mr. THORNBERRY, Mr. ROYCE, Mr. BURTON of Indiana, Mr. SAXTON, Mr. DELAY, Mr. BRADY, Mr. MOAKLEY, Mr. MEEHAN, Mr. BAESLER, Mr. BALLENGER, Mr. SESSIONS, Mr. BONILLA, Mr. HUTCHINSON, Ms. GRANGER, Mrs. JOHNSON of Connecticut, Mr. PORTER, Mr. DOOLEY of California, Mr. COMBEST, Mr. MCINTOSH, Mrs. MYRICK, Mr. DUNCAN, Mr. GIBBONS, Mr. SHAYS, Mr. KLECZKA, Mr.

FORBES, Mr. SAM JOHNSON, Mr. LUTHER, Mr. HERGER, Mr. KOLBE, Mr. SMITH of Texas, Mr. CALVERT, Mr. SENSENBRENNER, Mr. WELDON of Florida, Mr. CLYBURN, Mr. EHLERS, Mr. TALENT, Mrs. TAUSCHER, Mrs. ROUKEMA, Mr. SPENCE, Mr. STENHOLM, Mr. KIND of Wisconsin, Mr. TANNER, Mr. DREIER, Ms. DANNER, Mr. PASCRELL, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. MINGE, Mr. PICKERING, Mr. MENENDEZ, Mrs. KELLY, Ms. DUNN of Washington, Mr. GRAHAM, Mr. BUNNING of Kentucky, Mr. ROTHMAN, Mr. ETHERIDGE, Mr. PACKARD, Mr. HOEKSTRA, Mr. HANSEN, Mr. COOK, Mr. KIM, Mr. FRELINGHUYSEN, Mr. REYES, Ms. SANCHEZ, Mr. CAPPS, Mrs. CHENOWETH, Mr. MILLER of Florida, Mr. HUNTER, Mr. GOODLING, Mr. BISHOP, Mr. ROHRABACHER, Mr. SOLOMON, Mr. SUNUNU, Mr. CHRISTENSEN, Mr. THOMAS, Mrs. NORTHUP, Mr. PITTS, Mr. SOUDER, Mr. BERMAN, Mr. FAWELL, Mr. ADERHOLT, Mr. CANNON, Mr. WAMP, and Mr. MATSUI

OCTOBER 6, 1997

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on May 22, 1997]

A BILL

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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. 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 sub-

paragraph 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.".

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 manu-

facturing 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 preced-

ing 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 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.".

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.