

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

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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. CAPP, 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.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*
 3 **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-**
 4 **TENTS.**

5 (a) *SHORT TITLE.*—*This Act may be cited as the*
 6 *“Medical Device Regulatory Modernization Act of 1997”.*

7 (b) *REFERENCE.*—*Whenever in this Act an amend-*
 8 *ment or repeal is expressed in terms of an amendment to,*

1 or repeal of, a section or other provision, the reference shall
 2 be considered to be made to that section or other provision
 3 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 4 321 et seq.).

5 (c) *TABLE OF CONTENTS.*—The table of contents for
 6 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.*

7 **SEC. 2. FDA MISSION AND ANNUAL REPORT.**

8 (a) *MISSION.*—Section 903 (21 U.S.C. 393) is amend-
 9 ed by redesignating subsections (b) and (c) as subsections
 10 (c) and (d), respectively, and by adding after subsection (a)
 11 the following:

12 “(b) *MISSION.*—The Food and Drug Administration
 13 shall promote the public health by promptly and efficiently
 14 reviewing clinical research and taking appropriate action

1 *on the marketing of regulated products in a timely manner,*
2 *and with respect to such products shall protect the public*
3 *health by ensuring that—*

4 “(1) *foods are safe, wholesome, sanitary, and*
5 *properly labeled;*

6 “(2) *human and veterinary drugs are safe and*
7 *effective;*

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

10 “(4) *cosmetics are safe and properly labeled; and*

11 “(5) *public health and safety are protected from*
12 *electronic product radiation.*

13 *The Food and Drug Administration shall participate with*
14 *other countries to reduce the burden of regulation, har-*
15 *monize regulatory requirements, and achieve appropriate*
16 *reciprocal arrangements.”.*

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

20 **(e) ANNUAL REPORT.**—*The Secretary shall, simulta-*
21 *neously with the submission each year of the budget for the*
22 *Food and Drug Administration, submit to the Committee*
23 *on Commerce of the House of Representatives and the Com-*
24 *mittee on Labor and Human Resources of the Senate an*
25 *annual report which shall—*

1 “(1) review the performance of the Food and
2 *Drug Administration in meeting its mission and the*
3 *development of Food and Drug Administration poli-*
4 *cies to implement such mission;*

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

10 “(3) describe the staffing and resources of the
11 *Food and Drug Administration;*

12 “(4)(A) list each bilateral and multinational
13 *meeting held by the Food and Drug Administration*
14 *to address methods and approaches to reduce the bur-*
15 *den of regulation, to harmonize regulation, and to*
16 *seek appropriate reciprocal arrangements,*

17 “(B) describe the goals, activities, and accom-
18 *plishments of the Food and Drug Administration in*
19 *such meetings, and*

20 “(C) list issues that the Food and Drug Admin-
21 *istration is considering or has presented for each such*
22 *meeting; and*

23 “(5) summarize and explain each instance in the
24 *previous fiscal year in which an application received*
25 *under section 515(c) was not reviewed in a manner*

1 to achieve final action on such application within
2 180 days of its receipt.”.

3 **SEC. 3. DISPUTE RESOLUTION.**

4 Chapter V (21 U.S.C. 351 et seq.) is amended by in-
5 serting after section 506 the following:

6 “DISPUTE RESOLUTION

7 “SEC. 506A. If, regarding an obligation under this
8 Act, there is a scientific controversy between the Secretary
9 and a person who is a sponsor, applicant, or manufacturer,
10 and no specific provision of this Act or regulation promul-
11 gated under this Act provides a right of review of the matter
12 in controversy, the Secretary shall, by regulation, establish
13 a procedure under which such sponsor, applicant, or manu-
14 facturer may request a review of such controversy by an
15 appropriate scientific advisory panel under section
16 515(g)(2)(B). Such review shall take place in a timely man-
17 ner. The Secretary shall promulgate such regulations not
18 later than 180 days after the date of the enactment of the
19 Medical Device Regulatory Modernization Act of 1997.”.

20 **SEC. 4. INVESTIGATIONAL DEVICE EXEMPTIONS; EX-**
21 **PANDED ACCESS.**

22 Section 520(g) (21 U.S.C. 360j(g)) is amended by add-
23 ing at the end the following:

24 “(6)(A) Not later than 120 days after the date of the
25 enactment of the Medical Device Regulatory Modernization
26 Act of 1997, the Secretary shall by regulation establish, with

1 *respect to a device for which an exemption under this sub-*
2 *section is in effect, the following:*

3 “(i) *Procedures and conditions under which the*
4 *Secretary will, without requiring an additional ap-*
5 *proval of an application for an exemption or the ap-*
6 *proval of a supplement to such an application, per-*
7 *mit—*

8 “(I) *developmental changes in the device*
9 *that do not constitute a significant change in de-*
10 *sign or in basic principles of operation and that*
11 *are made in response to information gathered*
12 *during the course of an investigation; and*

13 “(II) *changes or modifications to clinical*
14 *protocols that do not affect the validity of data*
15 *or information resulting from the completion of*
16 *an approved protocol and do not alter the rela-*
17 *tionship of likely patient risk to benefit relied*
18 *upon to approve a protocol.*

19 “(ii) *Procedures and conditions under which the*
20 *Secretary will, outside of an approved investigational*
21 *protocol (subject to compliance with regulations for*
22 *the protection of patients), permit uses of the device*
23 *in the diagnosis, monitoring, or treatment of diseases*
24 *or conditions that are life-threatening or could be ir-*
25 *reversibly debilitating, when—*

1 “(I) the treating physician determines that
2 the investigational use of the device likely will
3 provide a benefit; that the risk of not using the
4 device exceeds the probable risk of using the de-
5 vice; and that there is no legally marketed device
6 alternative for the satisfactory treatment or diag-
7 nosis of such disease or condition;

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

12 “(III) the Secretary determines that the in-
13 vestigational use of the device will not interfere
14 with the initiation, conduct, or completion of
15 clinical investigations to support marketing ap-
16 proval; and

17 “(IV) the sponsor, or clinical investigator,
18 of the investigational use of the device submits to
19 the Secretary a clinical protocol consistent with
20 the provisions of paragraph (3) and any regula-
21 tions promulgated under such paragraph de-
22 scribing the investigational use of devices in a
23 single patient or a small group of patients.

24 “(B) Regulations under subparagraph (A)(i) shall pro-
25 vide that a change or modification described in such sub-

1 *paragraph is not permitted unless, not later than 5 days*
2 *after making the change or modification, a notice of the*
3 *change or modification is submitted to the Secretary.*

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

10 “(7)(A) *In the case of a person intending to investigate*
11 *the safety or effectiveness of a class III device or an*
12 *implantable device, the Secretary shall ensure that the per-*
13 *son has an opportunity, prior to submitting an application*
14 *to the Secretary or to an institutional review board, to sub-*
15 *mit to the Secretary, for review, an investigational plan*
16 *(including a clinical protocol). If the applicant requests a*
17 *meeting with the Secretary regarding such review, the Sec-*
18 *retary shall meet with the applicant not later than 30 days*
19 *after receiving the request for the meeting.*

20 “(B) *Agreements regarding the parameters of an inves-*
21 *tigational plan (including clinical protocol) that are*
22 *reached between the Secretary and a sponsor or applicant*
23 *shall be reduced to writing and made part of the adminis-*
24 *trative record by the Secretary. Such agreements shall not*
25 *be changed, except—*

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

3 “(ii) pursuant to a decision, made in accordance
4 with subparagraph (C) by the director of the office in
5 which the device involved is reviewed, that a substan-
6 tial scientific issue essential to determining the safety
7 or effectiveness of the device involved has been identi-
8 fied.

9 “(C) A decision under subparagraph (B)(ii) by the di-
10 rector shall be in writing, and may be made only after the
11 Secretary has provided to the sponsor or applicant an op-
12 portunity for a meeting at which the director and the spon-
13 sor or applicant are present and at which the director docu-
14 ments the scientific issue involved.”.

15 **SEC. 5. SPECIAL REVIEW FOR CERTAIN DEVICES.**

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

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

19 (2) by adding at the end the following:

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

24 “(A) representing breakthrough technologies,

25 “(B) for which no approved alternatives exist,

1 “(C) which offer significant advantages over ex-
2 isting approved alternatives, or

3 “(D) the availability of which is in the best in-
4 terest of the patients.”.

5 **SEC. 6. EXPANDING HUMANITARIAN USE OF DEVICES.**

6 (a) SECTION 520(m).—Section 520(m) (21 U.S.C.
7 360j(m)) is amended—

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

10 “The request shall be in the form of an application to the
11 Secretary. Within 60 days of the date of the receipt of an
12 application, the Secretary shall issue an order approving
13 or denying the application, except that if the Secretary con-
14 venes a scientific advisory panel, the Secretary shall within
15 120 days of the receipt of an application issue such order.”;

16 (2) by amending paragraph (5) to read as fol-
17 lows:

18 “(5) The Secretary may suspend or withdraw an ex-
19 emption from the effectiveness requirements of sections 514
20 and 515 for a humanitarian device, after providing notice
21 and an opportunity for an informal hearing, if any condi-
22 tion for granting such exemption for such device set forth
23 in paragraphs (2) through (4) no longer is met.”; and

24 (3) by amending paragraph (6) to read as fol-
25 lows:

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

8 (b) *REGULATIONS.—Any provision in a regulation in-*
9 *cluded in title 21 of the Code of Federal Regulations per-*
10 *taining to humanitarian devices which is inconsistent with*
11 *the amendments made by subsection (a) shall be deemed re-*
12 *scinded on the date of the enactment of this Act. The Sec-*
13 *retary shall amend regulations pertaining to humanitarian*
14 *devices to conform with the amendments made by subsection*
15 *(a).*

16 **SEC. 7. DEVICE STANDARDS.**

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

20 *“Listing of Recognized Standards*

21 “(c)(1) *The Secretary shall issue notices identifying*
22 *and adopting applicable nationally or internationally rec-*
23 *ognized standards (or portions of such standards) to which*
24 *a person may self-certify compliance for the purpose of dem-*
25 *onstrating a reasonable assurance that a device is safe or*

1 *effective or to determine compliance with any requirement*
2 *of this Act. Such notices shall be published in the Federal*
3 *Register, and the Secretary shall provide an opportunity*
4 *for public comment on the standards involved.*

5 “(2) *The Secretary shall accept a certification that a*
6 *device conforms with each type of standard referenced in*
7 *subsection (a) and identified in such certification to the ex-*
8 *tent such standard applies, except that the Secretary may,*
9 *at any time, require the person who submitted the certifi-*
10 *cation to submit the data and information which such per-*
11 *son relied upon in making such certification, and may re-*
12 *ject the certification if the Secretary determines that the*
13 *data and information do not demonstrate compliance with*
14 *the standards identified in the certification. Such person*
15 *shall maintain the data and information for a period of*
16 *2 years after the submission of the certification, or for the*
17 *expected design life of the device, whichever is later.*

18 “(3) *The Secretary may remove from the list of stand-*
19 *ards adopted under subsection (a) a standard (or portion*
20 *of a standard) which the Secretary determines is not reli-*
21 *able for the purpose set out in such subsection.*

22 “(4) *In the case of a person who does not self-certify*
23 *compliance pursuant to paragraph (1) regarding a device,*
24 *the person may elect to utilize data other than those re-*
25 *quired by standards under paragraph (1) to demonstrate*

1 *a reasonable assurance of the safety or effectiveness of the*
2 *device.”.*

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

5 *“(x) The falsification of a certification under section*
6 *514(c) or the failure or refusal to provide data or informa-*
7 *tion required by the Secretary under such section.”.*

8 *(c) ADULTERATED DEVICES.—Section 501(e) (21*
9 *U.S.C. 351(e)) is amended by striking “subject to a per-*
10 *formance standard” and all that follows and inserting the*
11 *following: “subject to a performance standard established*
12 *under subsection (b) of section 514, unless such device is*
13 *in all respects in conformity with such standard; or subject*
14 *to a standard listed under subsection (c) of such section (in*
15 *the case of a person who has self-certified to such standard),*
16 *unless such device is in all respects in conformity with such*
17 *standard.”.*

18 *(d) CONFORMING AMENDMENTS.—*

19 *(1) DEFINITION OF CLASS II DEVICE.—Section*
20 *513(a)(1)(B) (21 U.S.C. 360c(a)(1)(B)) is amended*
21 *by inserting after “performance standards,” the fol-*
22 *lowing: “the listing of standards under section*
23 *514(c),”.*

1 (2) *RELATIONSHIP TO PERFORMANCE STAND-*
2 *ARDS.—Section 514(a) (21 U.S.C. 360d(a)) is amend-*
3 *ed—*

4 (A) *in paragraph (1), in the second sen-*
5 *tence, by striking “under this section” and in-*
6 *serting “under subsection (b)”;*

7 (B) *in paragraph (2), in the matter preced-*
8 *ing subparagraph (A), by striking “under this*
9 *section” and inserting “under subsection (b)”;*

10 (C) *in paragraph (3), by striking “under*
11 *this section” and inserting “under subsection*
12 *(b)”;* and

13 (D) *in paragraph (4), in the matter preced-*
14 *ing subparagraph (A), by striking “this section”*
15 *and inserting “this subsection and subsection*
16 *(b)”.*

17 **SEC. 8. SCOPE OF REVIEW.**

18 (a) *SECTION 513(a).—Section 513(a)(3) (21 U.S.C.*
19 *360c(a)(3)) is amended—*

20 (1) *in subparagraph (A) by inserting “one or*
21 *more” before “clinical investigations”;* and

22 (2) *by adding at the end the following:*

23 “(C) *In making a determination of a reasonable assur-*
24 *ance of the effectiveness of a device for which an application*
25 *under section 515 has been submitted, the Secretary shall*

1 *consider whether the extent of data that otherwise would*
2 *be required for approval of the application with respect to*
3 *effectiveness can be reduced through reliance on postmarket*
4 *controls.*

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

16 “(ii) *Agreements under section 515 regarding the pa-*
17 *rameters of valid scientific evidence for a device that are*
18 *reached between the Secretary and a sponsor or applicant*
19 *shall be reduced to writing and made part of the adminis-*
20 *trative record by the Secretary. Such agreements shall not*
21 *be changed, except—*

22 “(I) *with the written agreement of the sponsor or*
23 *applicant; or*

24 “(II) *pursuant to a decision, made in accordance*
25 *with clause (iii) by the director of the office in which*

1 *the device involved is reviewed, that a substantial sci-*
2 *entific issue essential to determining the safety or ef-*
3 *fectiveness of the device has been identified.*

4 *“(iii) A decision under clause (ii) by the director shall*
5 *be in writing, and may be made only after the Secretary*
6 *has provided to the sponsor or applicant an opportunity*
7 *for a meeting at which the director and the sponsor or ap-*
8 *plicant are present and at which the director documents*
9 *the scientific issue involved.”.*

10 *(b) SECTION 513(i).—Section 513(i)(1) (21 U.S.C.*
11 *360c(i)(1)) is amended by adding at the end the following:*

12 *“(C) To facilitate reviews of reports submitted to the*
13 *Secretary under section 510(k), the Secretary shall consider*
14 *the extent to which reliance on postmarket controls may ex-*
15 *pedite the classification of devices under subsection (f)(1)*
16 *of this section.*

17 *“(D) Whenever the Secretary requests information to*
18 *demonstrate that devices with differing technological char-*
19 *acteristics are substantially equivalent, the Secretary shall*
20 *only request information that is necessary to making sub-*
21 *stantial equivalence determinations. In making such re-*
22 *quest, the Secretary shall consider the least burdensome*
23 *means of demonstrating substantial equivalence and request*
24 *information accordingly.*

1 “(E)(i) Any determination by the Secretary of the in-
2 tended use of a device shall be based upon the proposed la-
3 beling submitted in a report for the device under section
4 510(k), unless the director of the organizational unit re-
5 sponsible for regulating devices (in this subparagraph re-
6 ferred to as the ‘Director’), after providing an opportunity
7 for consultation with the person who submitted such report,
8 determines and states in writing (I) that there is a reason-
9 able likelihood that the device will be used for an intended
10 use not identified in the proposed labeling for the device,
11 and (II) on the basis of data or the absence of data, that
12 such use could cause harm.

13 “(ii) Such determination shall—

14 “(I) be provided to the person who submitted the
15 report within 10 days from the date of the notifica-
16 tion of the Director’s concerns regarding the proposed
17 labeling;

18 “(II) specify limitations on the device’s labeling
19 which proscribe the use not included in proposed la-
20 beling; and

21 “(III) find the device substantially equivalent
22 when the labeled intended use and the technological
23 characteristics of the device relative to a legally mar-
24 keted device conform with the requirements of sub-
25 paragraph (A).

1 “(iii) *The responsibilities of the Director under this*
2 *subparagraph may not be delegated.*”

3 “(iv) *This subparagraph has no legal effect after the*
4 *expiration of the five-year period beginning on the date of*
5 *the enactment of the Medical Device Regulatory Moderniza-*
6 *tion Act of 1997.*”

7 (c) *SECTION 515(d).—Section 515(d) (21 U.S.C.*
8 *360e(d)) is amended—*

9 (1) *in paragraph (1)(A), by adding after and*
10 *below clause (ii) the following:*

11 *“In making the determination whether to approve or deny*
12 *the application, the Secretary shall rely on the conditions*
13 *of use included in the proposed labeling as the basis for*
14 *determining whether or not there is a reasonable assurance*
15 *of safety and effectiveness, if the proposed labeling is neither*
16 *false nor misleading. In determining whether or not such*
17 *labeling is false or misleading, the Secretary shall fairly*
18 *evaluate all material facts pertinent to the proposed label-*
19 *ing.”; and*

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

22 “(6)(A)(i) *A supplemental application shall be re-*
23 *quired for any change to a device subject to an approved*
24 *application under this subsection that affects safety or effec-*
25 *tiveness, unless such change is a modification in a manu-*

1 *facturing procedure or method of manufacturing and the*
2 *holder of the approved application submits a written notice*
3 *to the Secretary that describes in detail the change, summa-*
4 *rizes the data or information supporting the change, and*
5 *informs the Secretary that the change has been made under*
6 *the requirements of section 520(f).*

7 “(i) *The holder of an approved application who sub-*
8 *mits a notice under clause (i) with respect to a manufactur-*
9 *ing change of a device may distribute the device 30 days*
10 *after the date on which the Secretary receives the notice,*
11 *unless the Secretary within such 30-day period notifies the*
12 *holder that the notice is not adequate and describes such*
13 *further information or action that is required for accept-*
14 *ance of such change. If the Secretary notifies the holder that*
15 *a premarket approval supplement is required, the Secretary*
16 *shall review the supplement within 135 days after the re-*
17 *ceipt of the supplement. The time used by the Secretary to*
18 *review the notice of the manufacturing change shall be de-*
19 *ducted from the 135-day review period if the notice meets*
20 *appropriate content requirements for premarket approval*
21 *supplements.*

22 “(B)(i) *Subject to clause (ii), in reviewing a supple-*
23 *ment to an approved application, for an incremental*
24 *change to the design of a device that affects safety or effec-*
25 *tiveness, the Secretary shall approve such supplement if—*

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

4 “(II) clinical data from the approved applica-
5 tion and any supplement to the approved application
6 provide a reasonable assurance of safety and effective-
7 ness for the changed device.

8 “(ii) The Secretary may require, when necessary, ad-
9 ditional clinical data to evaluate the design modification
10 of the device to provide a reasonable assurance of safety and
11 effectiveness.”.

12 **SEC. 9. PREMARKET NOTIFICATION.**

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

15 (1) in subsection (k)—

16 (A) in the matter preceding paragraph (1),
17 by adding after “report to the Secretary” the fol-
18 lowing: “or person who is accredited under sec-
19 tion 712(a)”; and

20 (B) by adding after and below paragraph

21 (2) the following:

22 “Such a report is not required for a device intended for
23 human use that is exempted from the requirements of this
24 subsection under subsection (l) or is classified into class I
25 under section 513. The exception established in the preced-

1 *ing sentence does not apply to any class I device that is*
2 *intended to be life supporting or life sustaining or is in-*
3 *tended for a use which is of substantial importance in pre-*
4 *venting impairment of human health, or to any class I de-*
5 *vice that presents a potential unreasonable risk of illness*
6 *or injury. With respect to a person who is accredited under*
7 *section 712(a), such accredited person shall review a report*
8 *under this subsection that is received by such person and*
9 *shall submit, not later than 60 days after receiving the re-*
10 *port, to the Secretary such person's recommendation for ac-*
11 *tion to be taken by the Secretary on the report.”; and*

12 (2) *by adding after subsection (k) the following*
13 *subsection:*

14 “(l) *Not later than 30 days after the date of the enact-*
15 *ment of the Medical Device Regulatory Modernization Act*
16 *of 1997, the Secretary shall publish in the Federal Register*
17 *a list of each type of class II device that does not require*
18 *a report under subsection (k) to provide reasonable assur-*
19 *ance of safety and effectiveness. Each type of class II device*
20 *listed by the Secretary shall be exempt from the requirement*
21 *to file a report under subsection (k) as of the date of the*
22 *publication of the list in the Federal Register. Beginning*
23 *on the date that is 1 day after the date of the publication*
24 *of the list, any person may petition the Secretary to exempt*
25 *a type of class II device from the reporting requirement of*

1 subsection (k). The Secretary shall publish in the Federal
2 Register notice of the intent of the Secretary to exempt the
3 device, or of the petition, and provide a 30-day period for
4 public comment. If the Secretary fails to respond to a peti-
5 tion within 120 days of receiving it, the petition shall be
6 deemed to be granted.”.

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

9 (1) in the second sentence of paragraph (1) by
10 striking the period at the end and inserting the fol-
11 lowing: “unless within 30 days of receiving an order
12 classifying the device into class III the person who
13 submits a report under section 510(k) for such device
14 requests review with respect to the classification of the
15 device and a final order of classification from the Sec-
16 retary. Such person shall submit to the Secretary
17 data and information supporting the classification of
18 the device into class I or II. After the request, a device
19 classified into class III under this paragraph remains
20 in class III, but shall not be deemed to be finally clas-
21 sified until the Secretary has determined the classi-
22 fication of the device based on the classification cri-
23 teria set forth in subparagraphs (A) through (C) of
24 subsection (a)(1), within 60 days of receiving the re-
25 quest to review and classify a device. Any device

1 *found under this paragraph not to be substantially*
2 *equivalent to a device described in subparagraph*
3 *(A)(i) and which is classified by the Secretary into*
4 *class III may not be commercially distributed in com-*
5 *merce before it is approved under section 515.”; and*

6 *(2) by adding at the end the following:*

7 *“(4) The Secretary may not withhold a determination*
8 *of the initial classification of a device under paragraph (1)*
9 *because of a failure to comply with any provision of this*
10 *Act unrelated to a substantial equivalence decision, includ-*
11 *ing a finding that the facility in which the device is manu-*
12 *factured is not in compliance with good manufacturing re-*
13 *quirements as set forth in regulations of the Secretary under*
14 *section 520(f) (other than a finding that the failure to com-*
15 *ply with such regulations is directly related to the safety*
16 *or effectiveness of the device).”.*

17 *(c) SECTION 513.—Section 513(i)(1) (21 U.S.C.*
18 *360c(i)), as amended by section 8(b), is amended—*

19 *(1) in subparagraph (A)(ii)(I), by striking “clin-*
20 *ical data” and inserting “appropriate clinical or sci-*
21 *entific data” and by inserting “or a person accredited*
22 *under section 712” after “Secretary”;*

23 *(2) in subparagraph (A)(ii)(II), by striking “ef-*
24 *ficacy” and inserting “effectiveness”; and*

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

3 “(F) *For purposes of subparagraph (A), the term ‘leg-*
4 *ally marketed device’ includes any device introduced into*
5 *interstate commerce for commercial distribution before May*
6 *28, 1976, and any device determined to be substantially*
7 *equivalent to such device which has not been removed from*
8 *the market by an order of the Secretary or a judicial order*
9 *because it is not safe or not effective.*

10 “(G) *Not later than 270 days after the date of the en-*
11 *actment of the Medical Device Regulatory Modernization*
12 *Act of 1997, the Secretary shall issue guidance specifying*
13 *the general principles that the Secretary will consider in*
14 *determining when a specific intended use of a device is not*
15 *reasonably included within a general use of such device for*
16 *purposes of a determination of substantial equivalence*
17 *under subsection (f) or section 520(l).”.*

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

1 **SEC. 10. CLASSIFICATION PANELS.**

2 *Section 513(b) (21 U.S.C. 360c(b)) is amended by add-*
3 *ing at the end the following:*

4 *“(5) Classification panels covering each type of device*
5 *shall be scheduled to meet at such times as may be appro-*
6 *priate for the Secretary to meet applicable statutory dead-*
7 *lines.*

8 *“(6)(A) Any person whose device is specifically the*
9 *subject of review by a classification panel shall have the*
10 *same rights as the Secretary regarding—*

11 *“(i) access to data and information submitted to*
12 *a classification panel (except for data and informa-*
13 *tion that are not available for public disclosure under*
14 *section 552 of title 5, United States Code);*

15 *“(ii) the submission, for review by a classifica-*
16 *tion panel, of information that is based on the data*
17 *or information provided in the application submitted*
18 *under section 515 by the person, which information*
19 *shall be submitted to the Secretary for prompt trans-*
20 *mittal to the classification panel; and*

21 *“(iii) the participation of the persons at meet-*
22 *ings of the panel.*

23 *“(B) Any meetings of a classification panel shall pro-*
24 *vide adequate time for initial presentations and for re-*
25 *sponse to any differing views by persons whose devices are*
26 *specifically the subject of a classification panel review, and*

1 *shall encourage free and open participation by all interested*
2 *persons.*

3 “(7) *After receiving from a classification panel the*
4 *conclusions and recommendations of the panel on a matter*
5 *that the panel has reviewed, the Secretary shall review the*
6 *conclusions and recommendations, shall make a final deci-*
7 *sion on the matter in accordance with section 515(d)(2),*
8 *and shall notify the affected persons of the decision in writ-*
9 *ing and, if the decision differs from the conclusions and*
10 *recommendations of the panel, shall include the reasons for*
11 *the difference.*

12 “(8) *A scientific advisory panel under this subsection*
13 *shall not be subject to the annual chartering and annual*
14 *report requirements of the Federal Advisory Committee*
15 *Act.”.*

16 **SEC. 11. PREMARKET APPROVAL.**

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

20 “(2) *Each application received under subsection (c)*
21 *shall be reviewed in a manner to achieve final action on*
22 *such application within 180 days of its receipt. At the re-*
23 *quest of the applicant, the Secretary shall meet with an ap-*
24 *plicant under such an application within 90 days of the*
25 *date of the application’s submission.”.*

1 **SEC. 12. ACCREDITATION FOR ACCREDITED PERSONS.**

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

4 “ACCREDITED PERSONS

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

14 “(b) *ACCREDITATION.*—

15 “(1) *PROGRAMS.*—The Secretary shall provide
16 for such accreditation through programs administered
17 by the Food and Drug Administration, other govern-
18 ment agencies, or by other qualified nongovernment
19 organizations.

20 “(2) *ACCREDITATION.*—

21 “(A) *GENERAL RULE.*—Not later than 180
22 days after the date of the enactment of the Medi-
23 cal Device Regulatory Modernization Act of
24 1997, the Secretary shall establish and publish
25 in the Federal Register requirements to accredit
26 or deny accreditation to persons who request to

1 *perform the duties specified in subsection (a).*
2 *The Secretary shall respond to a request for ac-*
3 *creditation within 60 days of the receipt of the*
4 *request. The accreditation of such person shall*
5 *specify the particular activities under subsection*
6 *(a) for which such person is accredited.*

7 “(B) *WITHDRAWAL OF ACCREDITATION.*—
8 *The Secretary may withdraw accreditation of*
9 *any person accredited under this paragraph,*
10 *after providing notice and an opportunity for an*
11 *informal hearing, when such person acts or fails*
12 *to act in a manner that is inconsistent with the*
13 *purposes of this section or poses a threat to pub-*
14 *lic health.*

15 “(C) *PERFORMANCE AUDITING.*—*To ensure*
16 *that persons accredited under this section will*
17 *continue to meet the standards of accreditation,*
18 *the Secretary shall—*

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

22 “(ii) *take such additional measures as*
23 *the Secretary determines to be appropriate.*

24 “(D) *ANNUAL REPORT.*—*The Secretary*
25 *shall include in the annual report required*

1 *under section 903(e)(2) the names of all accred-*
2 *ited persons and the particular activities under*
3 *subsection (a) for which each such person is ac-*
4 *credited and the name of each accredited person*
5 *whose accreditation has been withdrawn during*
6 *the year.*

7 “(3) *QUALIFICATIONS.—An accredited person*
8 *shall, at a minimum, meet the following require-*
9 *ments:*

10 “(A) *Such person shall be an independent*
11 *organization which is not owned or controlled by*
12 *a manufacturer, supplier, or vendor of devices*
13 *and which has no organizational, material, or fi-*
14 *nancial affiliation with such a manufacturer,*
15 *supplier, or vendor.*

16 “(B) *Such person shall be a legally con-*
17 *stituted entity permitted to conduct the activities*
18 *for which it seeks accreditation.*

19 “(C) *Such person shall not engage in the de-*
20 *sign, manufacture, promotion, or sale of devices.*

21 “(D) *Such person shall be operated in ac-*
22 *cordance with generally accepted professional*
23 *and ethical business practices and shall agree in*
24 *writing that as a minimum it will—*

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

3 “(ii) limit work to that for which com-
4 petence and capacity are available;

5 “(iii) treat information received,
6 records, reports, and recommendations as
7 proprietary information;

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

11 “(v) protect against the use, in carry-
12 ing out subsection (a) with respect to a de-
13 vice, of any officer or employee of the person
14 who has a financial conflict of interest re-
15 garding the device, and annually make
16 available to the public disclosures of the ex-
17 tent to which the person, and the officers
18 and employees of the person, have main-
19 tained compliance with requirements under
20 this clause relating to financial conflicts of
21 interest.

22 “(4) *SELECTION OF ACCREDITED PERSONS.*—The
23 Secretary shall provide each person who chooses to use
24 an accredited person to receive a section 510(k) report
25 a panel of at least 2 or more accredited persons from

1 *which the regulated person may select 1 for a specific*
2 *regulatory function.”.*

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

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

7 “(1) *the submission of a report or recommenda-*
8 *tion by a person accredited under section 712 that is*
9 *false or misleading in any material respect;*

10 “(2) *the disclosure by a person accredited under*
11 *section 712 of confidential commercial information or*
12 *any trade secret without the express written consent*
13 *of the person who submitted such information or se-*
14 *cret to such person; or*

15 “(3) *the receipt by a person accredited under sec-*
16 *tion 712 of a bribe in any form or the doing of any*
17 *corrupt act by such person associated with a respon-*
18 *sibility delegated to such person under this Act.”.*

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

24 **(d) REPORT.**—*Not later than 5 years after the date*
25 *of the enactment of this Act, the Comptroller General of the*

1 *United States shall report to the Committee on Commerce*
2 *of the House of Representatives and the Committee on*
3 *Labor and Human Resources of the Senate on the use of*
4 *accredited persons under section 712 of the Federal Food,*
5 *Drug, and Cosmetic Act, the extent to which such use was*
6 *helpful in the implementation of such Act, and the extent*
7 *to which such use promoted actions which were contrary*
8 *to the purposes of such Act.*

9 **SEC. 13. PREAMENDMENT DEVICES.**

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

12 *“Revision*

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

23 **SEC. 14. DEVICE TRACKING.**

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

1 “*Device Tracking*

2 “(e) *The Secretary may by order require a manufac-*
3 *turer to adopt a method of tracking a class II or class III*
4 *device—*

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

7 “(2) *which is—*

8 “(A) *intended to be an implantable device,*

9 *or*

10 “(B) *a life sustaining or life supporting de-*
11 *vice used outside a device user facility.”.*

12 **SEC. 15. POSTMARKET SURVEILLANCE.**

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

15 “*POSTMARKET SURVEILLANCE*

16 “*SEC. 522. (a) IN GENERAL.—The Secretary may by*
17 *order require a manufacturer to conduct postmarket sur-*
18 *veillance for any device of the manufacturer which is a class*
19 *II or class III device the failure of which would be reason-*
20 *ably likely to have serious adverse health consequences or*
21 *which is intended to be—*

22 “(1) *an implantable device, or*

23 “(2) *a life-sustaining or life-supporting device*
24 *used outside a device user facility.*

25 “(b) *SURVEILLANCE APPROVAL.—Each manufacturer*
26 *required to conduct a surveillance of a device shall, within*

1 30 days of receiving an order from the Secretary prescribing
2 that the manufacturer is required under this section to con-
3 duct such surveillance, submit, for the approval of the Sec-
4 retary, a plan for the required surveillance. The Secretary,
5 within 60 days of the receipt of such plan, shall determine
6 if the person designated to conduct the surveillance has ap-
7 propriate qualifications and experience to undertake such
8 surveillance and if such plan will result in information nec-
9 essary to determine the occurrence of unforeseen events. The
10 Secretary, in consultation with the manufacturer, may by
11 order require a prospective surveillance period of up to 36
12 months. Any determination by the Secretary that a longer
13 period is necessary shall be made by mutual agreement be-
14 tween the Secretary and the manufacturer or, if no agree-
15 ment can be reached, after the completion of a dispute reso-
16 lution process as described in section 506A.”.

17 **SEC. 16. HARMONIZATION.**

18 (a) SECTION 520(f).—Section 520(f)(1)(B) (21 U.S.C.
19 360j(f)(1)(B)) is amended by striking “and” at the end of
20 clause (i), by striking the period at the end of clause (ii)
21 and inserting “; and” and by adding after clause (ii) the
22 following:

23 “(iii) ensure that such regulation conforms, to
24 the extent practicable, with internationally recognized

1 *standards defining quality systems, or parts thereof,*
2 *for medical devices.”.*

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

5 *“(c)(1) The Secretary shall participate in meetings*
6 *with representatives of other countries to discuss methods*
7 *and approaches to reduce the burden of regulation and har-*
8 *monize regulatory requirements if the Secretary determines*
9 *that such harmonization continues consumer protections*
10 *consistent with the purposes of this Act. The Secretary shall,*
11 *not later than 180 days after the date of enactment of the*
12 *Medical Device Regulatory Modernization Act of 1997,*
13 *make public a plan that establishes a framework for achiev-*
14 *ing mutual recognition of good manufacturing practices in-*
15 *spections.*

16 *“(2) The Secretary shall report to the Committee on*
17 *Commerce of the House of Representatives and the Commit-*
18 *tee on Labor and Human Resources of the Senate at least*
19 *60 days before executing any bilateral or multilateral agree-*
20 *ment under paragraph (1).”.*

21 **SEC. 17. REPORTS.**

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

24 (1) *in subsection (a)—*

1 (A) in the matter preceding paragraph (1),
2 by striking “manufacturer, importer, or distribu-
3 tor” and inserting “manufacturer or importer”;
4 and

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

7 “(9) shall require distributors to keep records
8 and make such records available to the Secretary
9 upon request.”;

10 (2) by striking subsection (d); and

11 (3) in subsection (f), by striking “, importer, or
12 distributor” each place it appears and inserting “or
13 importer”.

14 (b) *REGISTRATION*.—Section 510(g) (21 U.S.C.
15 360(g)) is amended—

16 (1) by redesignating paragraph (4) as para-
17 graph (5);

18 (2) by inserting after paragraph (3) the follow-
19 ing:

20 “(4) any distributor who acts as a wholesale dis-
21 tributor of devices, and who does not manufacture, re-
22 package, process, or relabel a device; or”; and

23 (3) by adding at the end the following flush sen-
24 tence:

1 *“In this subsection, the term ‘wholesale distributor’ means*
2 *any person who distributes a device from the original place*
3 *of manufacture to the person who makes the final delivery*
4 *or sale of the device to the ultimate consumer or user.”.*

5 *(c) DEVICE USER FACILITIES.—*

6 *(1) IN GENERAL.—Section 519(b) (21 U.S.C.*
7 *360i(b)) is amended—*

8 *(A) in paragraph (1)(C)—*

9 *(i) in the first sentence, by striking “a*
10 *semi-annual basis” and inserting “an an-*
11 *annual basis”;*

12 *(ii) in the second sentence, by striking*
13 *“and July 1”; and*

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

16 *(B) in paragraph (2)—*

17 *(i) in subparagraph (A), by inserting*
18 *“or” after the comma at the end;*

19 *(ii) in subparagraph (B), by striking*
20 *“, or” at the end and inserting a period;*
21 *and*

22 *(iii) by striking subparagraph (C).*

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

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

3 (B) by inserting after paragraph (4) the fol-
4 lowing paragraph:

5 “(5) With respect to device user facilities that are hos-
6 pitals or nursing homes:

7 “(A) The Secretary shall by regulation plan and
8 implement a program under which the Secretary lim-
9 its user reporting under paragraphs (1) through (4)
10 to a subset of hospitals and nursing homes that con-
11 stitutes a representative profile of user reports for de-
12 vice deaths and serious illnesses or serious injuries.

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

16 “(C) During the period in which the Secretary
17 is providing for a transition to the full implementa-
18 tion of the program, paragraphs (1) through (4)
19 apply to such facilities except to the extent that the
20 Secretary determines otherwise.

21 “(D) On and after the date on which the pro-
22 gram is fully implemented, paragraphs (1) through
23 (4) do not apply to such a facility unless the facility
24 is included in the subset referred to in subparagraph
25 (A).

1 “(E) Not later than one year after the date of the
2 enactment of the Medical Device Regulatory Mod-
3 ernization Act of 1997, the Secretary shall submit to
4 the Committee on Commerce of the House of Rep-
5 resentatives, and to the Committee on Labor and
6 Human Resources of the Senate, a report describing
7 the plan developed by the Secretary under subpara-
8 graph (A) and the progress that has been made to-
9 ward the implementation of the plan.”.

10 **SEC. 18. INFORMATION SYSTEM.**

11 Chapter IX is amended by adding at the end the fol-
12 lowing section:

13 **“SEC. 906. INFORMATION SYSTEM.**

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

20 **SEC. 19. PRACTICE OF MEDICINE.**

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

23 **“SEC. 907. PRACTICE OF MEDICINE.**

24 “Nothing in this Act shall be construed to limit or
25 interfere with the authority of a health care practitioner

1 to prescribe or administer any legally marketed device to
2 a patient for any condition or disease within a legitimate
3 health care practitioner-patient relationship. This section
4 shall not limit any existing authority of the Secretary to
5 establish and enforce restrictions on the sale or distribution,
6 or in the labeling, of a device that are part of a determina-
7 tion of substantial equivalence, established as a condition
8 of approval, or promulgated through regulations. Further,
9 this section shall not change any existing prohibition on
10 the promotion of unapproved uses of legally marketed de-
11 vices.”.

12 **SEC. 20. CLARIFICATION OF DEFINITION.**

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

18 **SEC. 21. LABELING AND ADVERTISING REGARDING COMPLI-**

19 **ANCE WITH STATUTORY REQUIREMENTS.**

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

22 **SEC. 22. NONINVASIVE BLOOD GLUCOSE METER.**

23 (a) *FINDINGS.*—The Congress finds that—

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

1 (2) *diabetes affects approximately 16,000,000*
2 *Americans and another 650,000 will be diagnosed in*
3 *1997;*

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

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

8 (5) *the failure to properly control and manage*
9 *diabetes results in costly and often fatal complications*
10 *including but not limited to blindness, coronary ar-*
11 *tery disease, and kidney failure;*

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

16 (7) *the pain associated with existing blood test-*
17 *ing devices creates a disincentive for people with dia-*
18 *betes to test blood glucose levels, particularly children;*

19 (8) *a safe and effective noninvasive blood glucose*
20 *meter would likely improve control and management*
21 *of diabetes by increasing the number of tests con-*
22 *ducted by people with diabetes, particularly children;*
23 *and*

1 (9) *the Food and Drug Administration is re-*
2 *ponsible for reviewing all applications for new medi-*
3 *cal devices in the United States.*

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

9 **SEC. 23. RULE OF CONSTRUCTION.**

10 *Nothing in this Act or the amendments made by this*
11 *Act shall be construed to affect the question of whether the*
12 *Secretary of Health and Human Services has any authority*
13 *to regulate any tobacco product, tobacco ingredient, or to-*
14 *bacco additive. Such authority, if any, shall be exercised*
15 *under the Federal Food, Drug, and Cosmetic Act as in effect*
16 *on the day before the date of the enactment of this Act.*