I

105TH CONGRESS
1ST SESSION

H. R. 1093

To amend the medical device provisions of the Federal Food, Drug, and Cosmetic Act.

IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 1997

Mr. FOX of Pennsylvania introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the medical device provisions of the Federal Food, Drug, and Cosmetic Act.

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

SECTION 1. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Life Extending and Life Saving Device 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 a section or other provi-

sion of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.).

SEC. 2. DEFINITIONS.

Section 201 (21 U.S.C. 321) is amended—

(1) in paragraph (h), by striking ''reagent'' and inserting ''in vitro diagnostic test system, special purpose reagent,'', and

(2) by adding at the end the following:

''(gg) The term 'special purpose reagent' means any monoclonal or polyclonal antibody, antigen, genetic probe, or other similar or related article that is a component of an in vitro diagnostic test system.

''(hh) The term 'in vitro diagnostic test system' means a system intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae.''.

SEC. 3. MISSION OF THE FOOD AND DRUG ADMINISTRATION.

Section 903 (21 U.S.C. 393) is amended by adding at the end the following:

''(d) The mission of the Food and Drug Administration (with respect to drugs, biological products, and devices) is to promote and protect the health of the American people. This mission should be achieved by—

''(1) facilitating the timely availability of safe and effective products that benefit the American public,

''(2) encouraging the efficient development of new products in the United States,

''(3) taking prompt and appropriate action where postmarketing surveillance demonstrated that products present a health risk to the American public,

''(4) ensuring that human drugs, biological products, and devices are tested and manufactured consistent with the goal of harmonization of international standards,

''(5) facilitating the flow of information to educate health professionals and the American public, and

''(6) enforcing the applicable statutes and regulations in a timely, fair, and decisive manner.''.

SEC. 4. HARMONIZATION.

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

''(c)(1) The Secretary shall take such action as may be appropriate to harmonize the requirements of this Act for good manufacturing practice regulations with requirements of similar laws in foreign countries through the

International Conference on Harmonization by December 1996.

''(2) The Secretary shall regularly participate in meetings with other foreign governments to discuss methods and approaches to harmonize international regulatory requirements. The office shall forward any proposed agreements resulting from such meetings to the appropriate officials in each participating country for consideration in the formulation of agreements to harmonize international regulatory requirements. The office shall have the responsibility of ensuring that the process of harmonizing international regulatory requirements for devices and drugs is continuous.

''(3) The Commissioner shall initially report to committees of the United States Congress with oversight responsibilities for the United States Food and Drug Administration regarding the efforts and accomplishments of the office no later than 18 months after the date of enactment of this paragraph. Thereafter, the Commissioner shall report to such committees biennially.''.

SEC. 5. PREMARKET NOTIFICATION.

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

(1) in subsection (k), by inserting ''excluding any device classified into class I under section 513 or 520, or any device classified into class II under

section 513 or 520, if such class II device has been exempted from the requirements of this subsection under paragraph (1),'' after ''a device intended for human use'',

(2) in subsection (k), by striking ''report'' and inserting ''have the option of reporting'',

(3) in subsection (k), by striking ''or any person who is not an employee of the United States, and who is accredited by the Secretary or the Secretary's designee to receive and review notifications required under this subsection and to make recommendations under subsection 513(f)(1) about such notifications'' after ''report to the Secretary'', and

(4) by inserting after subsection (k) the following:

''(l) Within 3 months after the date of the enactment of this subsection, the Secretary shall publish a notice in the Federal Register soliciting from the public the identification of class II devices that should not be subject to the notification requirements of subsection (k) because such notification is unnecessary to ensure public health. The notice shall provide no more than 30 days for submission of information to the Secretary, and the Secretary shall by regulation exempt specified class II devices from

notification under subsection (k). The proposal for such a regulation shall permit 30 days for comment. The Secretary shall publish a final regulation in the Federal Register no later than 45 days after the end of the comment period. If the Secretary fails to promulgate a final regulation 45 days after the end of the comment period, each class II device proposed for exemption from subsection (k) shall be deemed to be exempt from that subsection.

''(m) The Secretary may not withhold a determination of the initial classification of a device under section 513(f)(1) for any reason, including that the facility in which a device may be manufactured is not in compliance with good manufacturing practice requirements set forth in regulations promulgated under the authority of section 520(f).''.

(b) NOTICE.—Section 513(f) (21 U.S.C. 360c(f)) is amended by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively, and by inserting after paragraph (1) the following:

''(2)(A) If the Secretary fails to make a determination under paragraph (1)(A) within 90 days of receipt of a notification required by subsection (k), the Secretary shall send a letter by registered mail to the submitter of such notification stating that additional time is necessary to determine the initial classification of the device. Addi-

tionally, such letter shall state each reason necessitating the need for additional time and provide the submitter a date for completion.

''(B) Within 90 days of receiving a notification required under subsection (k) for devices identified as being substantially equivalent to a class II device, a person accredited to conduct reviews of such notifications shall make a determination of initial classification under paragraph (1)(A) of any such device which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section. Such determination of initial classification shall be final. The accredited person shall immediately, by registered mail, provide to the submitter of such notification an order classifying the device. If the accredited person determines that the device should be classified into class III, such person shall refer the premarket notification submission to the Secretary. The Secretary shall have 30 days to review the submission and issue an order initially classifying the device. If the Secretary fails to make a classification decision within 30 days, the Secretary shall send a letter to the submitter of the notification which conforms to the requirements of subparagraph (A).

''(C) Within 60 days of receiving a notification required under subsection (k) for a device identified as being

substantially equivalent to a class III device, a person accredited to conduct reviews of such notification shall make a determination of the initial classification under paragraph (1)(A) of any such device which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section, and within such time period submit a recommendation to the Secretary and to the submitter of the premarket notification which contains such determination. The recommendation by such person of initial classification of a device shall be binding upon the Secretary, unless the Secretary within 30 calendar days of receipt of the recommendation finds that the recommendation is clearly erroneous, issues an order under this subsection initially classifying the device and provides, as part of the order, a detailed explanation of the basis for the finding that the classification recommendation of the accredited person is clearly erroneous. If within 90 days from the date of receipt of the notification the Secretary does not issue an order that differs from the recommendation of the accredited person, the Secretary shall promptly send by registered mail to the submitter of the notification such recommendation as the Secretary's order of initial classification. If the Secretary does not provide the submitter such notification by registered mail as specified herein, the rec-

ommendation of classification provided to the submitter of the premarket notification shall become the Secretary's order of initial classification of the device. Such classification may only be charged pursuant to the procedures specified in paragraph (3) of this subsection.

''(D) Any change or modification to a device initially classified under this subsection, other than a major change (including any major modification) in the intended use, shall not require an additional submission under subsection (k) if such change or modification is supported by appropriate data or information, and the change or modification can be shown to not adversely affect the safety or effectiveness of the device which was initially classified under this subsection. All data or information relied upon to document that a change to (including any modification of) such device does not require an additional notification under subsection (k) shall be made a part of the good manufacturing practice document file required by regulations promulgated under section 520(f) and shall be maintained for a period of time equal to the commercial life of the device, at a minimum.''.

(c) Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding after subparagraph (B) the following:

''(C) For the purpose of determining the intended use of a predicate device under subparagraph (A), each use

reasonably included within a general use for the predicate device shall be deemed a legally marketed use of the predicate device and shall be available in premarket notifications required under subsection (k).

''(D) For the purpose of determining substantial equivalence, the Secretary shall not consider any uses or indications of a device that are not specifically identified in a premarket market notification submission under subsection (k).''.

SEC. 6. THE RISK/BENEFIT DETERMINATION.

Section 513(a)(2)(A) is amended by striking the comma following the word ''intended'' and adding to the end of the paragraph the following: ''by the person legally responsible for labeling the device,''.

SEC. 7. EFFECTIVENESS DETERMINATION.

(a) Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A)) is amended by adding at the end the following: ''Well-controlled clinical investigations shall not be appropriate, unless the Secretary determines, after consultation with an advisory committee constituted under subsection (b) that such investigations are necessary to demonstrate that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device. Any person may submit well-controlled clinical investigations

to the Secretary to demonstrate that a device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended as suggested in the labeling of the device, and, without reliance on an advisory committee, the Secretary may determine that such studies are appropriate for such purpose.''.

(b) Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end the following:

''(C) The determination of effectiveness shall not include any of the following:

''(i) The evaluation of clinical outcomes, if the use of a device provides a medical contribution to the diagnosis or treatment of the persons for whom the device is intended, unless the device is represented in the labeling of the device to provide a therapeutic effect to the persons for whom the device is intended.

''(ii) The evaluation of relative effectiveness, unless the performance of a device is compared to that of another device through labeling or other representations by the person legally responsible for the labeling of the device.

''(iii) The evaluation of cost effectiveness representations.

''(iv) The evaluation of any indication for use not included in the labeling of a device, unless the person legally responsible for the labeling of the device promotes such indications for use.''.

SEC. 8. PREMARKET APPROVAL.

(a) Section 515(c)(1) (21 U.S.C. 360e(c)(1)) is amended by inserting '', or may file such application with a person or organization authorized to review applications for premarket approval'' after ''class III device'' and by redesignating paragraph (2) as paragraph (4) and by adding after paragraph (1) the following:

''(2)(A) Persons or organizations authorized to receive and review applications for approval of class III devices shall review such applications in accordance with the schedule of events identified in subsection (d)(2), unless such organization or person by contract with an applicant alters the schedule of events or eliminates any such event other than the requirements to file an application before undertaking a substantive review, refer an application under subparagraph (C) to an advisory committee constituted under the authority of section 513(b), and complete the review of an application in a timely manner.

''(B) The review standard for a premarket approval application applicable to such persons or organizations

shall be identical in all respects to the standard of review the Secretary is required to follow under this section.

''(C) The scope of review responsibility of such persons or organizations authorized to conduct reviews of premarket approval applications shall include—

''(i) the filing of applications for substantive review,

''(ii) the review of applications to determine whether there is a reasonable assurance that a device is safe and effective for its labeled uses,

''(iii) the presentation, when appropriate, of such applications to an advisory committee constituted under section 513(b), and

''(iv) the evaluation of advisory committee recommendations and premarket approval applications and the formulation of reports and recommendations to be submitted to the Secretary no later than 30 days after receipt of an advisory committee's recommendation.

Recommendations to the Secretary shall specify whether an application should be approved or denied and shall state the basis for the recommendation.

''(D) If an advisory committee is not required to review a premarket approval application, such person or organization shall no later than 120 days after filing, or at

such other designated time determined by the applicant and the accredited person, provide the Secretary with a report and recommendation in accordance with the requirements of subparagraph (C).

''(E) The Secretary shall approve or deny an application reviewed by an accredited person within 180 days of receipt of an application which has been accepted for filing under subsection (c), unless the accredited person submits its report and recommendation to the Secretary later than 150 days after such receipt. If the report and recommendation of an accredited person is submitted to the Secretary later than 150 days after receipt of an application which has been accepted for filing under subsection (c), the Secretary shall have 30 days from the date of receipt to approve or deny the application.

''(F) The recommendation of an accredited person to approve or deny an application shall be binding upon the Secretary, unless the Secretary finds that such recommendation is clearly erroneous. In the event that the Secretary makes such a finding, the Secretary shall provide a detailed explanation of the basis therefor.

''(G) The Secretary shall approve or deny applications for premarket approval of class III devices pursuant to the requirements of subsection (d).

''(3) The Secretary may use experts qualified by training and experience in addition to employees of the United States Government to review applications. Reviews by such experts may relate to portions of an application or entire applications. Each such review shall be in writing and submitted to the Secretary for consideration of whether to approve a device for commercial distribution.''.

(b) Section 515(c) (21 U.S.C. 360e(c)), as amended by subsection (a), is amended by adding the following at the end of paragraph (4): ''Such panel shall be scheduled to meet at least 4 times each calendar year to consider among other things the approval of applications submitted to the Secretary under this subsection. Such meetings shall, to the extent possible, be scheduled at equal intervals throughout the year.''.

(c) Section 515(d) (21 U.S.C. 360e(d)) is amended by redesignating paragraphs (2) and (3) as paragraphs (5) and (6), respectively, and by inserting after paragraph (1) the following:

''(2) Each application received under subsection (c) shall be reviewed in the following manner to achieve final action on such applications within 180 days of their receipt:

''(A) The Secretary shall make a determination within 30 days of receipt of an application submitted

under subsection (c) of whether the application satisfies the content requirements of subsection (c)(1) and applicable regulations.

''(B) The Secretary shall meet with an applicant within 90 days of receipt of an application that has been accepted for filing to discuss the review status of the application. If the application does not appear in a form that would necessitate an approval under this subsection, the Secretary shall, in writing and prior to the meeting, present to the applicant a description of any deficiencies with the application and what information would be necessary to bring the application into a form that would require an approval.

''(C) The Secretary shall provide an applicant the opportunity for a meeting 115 days after receipt of an application which has been accepted for filing under subsection (c) to inform the applicant of the status of the application, advise the applicant of any deficiencies in the application not previously communicated to the applicant, review proposed labeling for the device, and review the actions taken to correct deficiencies identified at the meeting held on the 90th day after receipt of the filed application.

''(D) The Secretary shall refer an application to a panel established under section 513 for review and for an approval recommendation, unless a panel is not required under subsection (c)(2), within 30 days of the meeting referenced in subparagraph (B) or at the next scheduled panel meeting following such meeting, whichever is later.

''(E) The Secretary shall meet with the applicant within 30 days of the panel review if the Secretary has determined that the application is not in a form that would require approval under this subsection. Prior to the meeting, the Secretary shall, in writing, present to the applicant each basis for denying approval of the application and the additional information necessary to bring the application into a form that could be approved.

''(F) The Secretary shall meet within 10 days of the panel review to present to an applicant a description of all additional information necessary to require an approval of an application under this subsection if the Secretary has determined that the application appears to be in a form that would receive approval within 180 days of receipt of such application. The applicant may waive such meeting and in-

stead receive in writing from the Secretary, within 30 days of the panel review, such information.

''(G) The Secretary shall meet with the applicant no later than 150 days after receipt of an application which has been accepted for filing under subsection (c), if an advisory panel is not required under subsection (c)(2), and inform the applicant whether or not the application is in a form that could be approved under this subsection. If the application is in such form, the Secretary shall, at or prior to the meeting, present in writing a description of all additional information necessary to require an approval of an application under this subsection. If the application is not in such form, the Secretary shall, prior to the meeting, present in writing to the applicant each basis for denying the approval of the application and the additional information necessary to bring the application into a form that could be approved.

''(H) The Secretary shall issue an order either approving or denying an application within 180 days of receipt of an application that has been accepted for filing.

''(3)(A) The time for the Secretary's review of an application under this subsection shall not be enlarged by

any amendment to the application and shall take no more than 180 days.

''(B) The Secretary shall ensure that each time frame under paragraph (2) is met. For each instance in which a review requirement under paragraph (2) is not met, a report to the Secretary is required no later than 10 days after the date of the scheduled event set forth in paragraph (2) fully explaining the reason that the scheduled time frame was not met. Within 10 days after receipt of such report, the Secretary shall provide an explanation to the applicant regarding the failure to comply with paragraph (2) and set the date for satisfying the scheduled review program obligation.

''(C) On January 1 of each calendar year, the Secretary shall submit to the committees of Congress with substantive oversight responsibility for the Food and Drug Administration a report summarizing each instance in the previous fiscal year in which the requirements of paragraph (2) were not met. This report shall include reasons for the failures to meet the requirements of paragraph (2) and proposals to ensure that such requirements will be met.

''(4) In order to better treat or diagnose life-threatening or irreversibly debilitating diseases or conditions of

man, the Secretary shall promulgate regulations to create 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 public health.

Such regulations shall include criteria for identifying devices which merit preferential review and shall specify procedures for implementing such reviews. The Secretary shall publish in the Federal Register a proposed regulation no later than 6 months after the date of enactment of the paragraph, allowing 60 days for comment. The Secretary shall publish a final regulation no later than 60 days after the last day of the comment period.''.

(d) Section 515(d) (21 U.S.C. 360e(d)) is amended by adding before the semicolon at the end of paragraph (5)(B) the following: ''(the determination of a reasonable assurance that a device is effective under the conditions of use prescribed, recommended, or suggested in proposed labeling shall not include uses or indications for use not identified in the application)''.

(e) The Secretary of Health and Human Services shall revise, through notice and comment procedures, the

regulations appearing in title 21 of the Code of Federal Regulations, part 814, to conform the regulations to the amendments of section 515 of the Federal Food, Drug, and Cosmetic Act made by this section and to eliminate premarket approval of supplements which relate to manufacturing changes and other changes which do not actually affect device safety or effectiveness.

SEC. 9. INVESTIGATIONAL DEVICE EXEMPTIONS.

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

''(6) The Secretary of Health and Human Services shall, within 120 days of the date of enactment of this paragraph, by regulation amending the content of parts 812 and 813 of title 21 of the Code of Federal Regulations, update the procedures and conditions under which devices intended for human use may upon application be granted an exemption from certain requirements under the Act. Such regulation shall—

''(A) permit the use of investigational devices, outside of the investigational protocol, in the diagnosis or treatment of diseases or conditions that are life threatening or could be irreversibly debilitating, when the risk of not using the investigational device exceeds the probable risk of using such device as determined by the local institutional review board;

''(B) require that prior to submitting an application to the Secretary, any person intending to investigate the safety or effectiveness of a class III device or an implant may submit an investigational plan, including clinical protocol, to the Secretary for review; and

''(C) provide a submitter who disputes the Secretary's response under subparagraph (B) a right to appear before an advisory committee of the investigational plan and the Secretary's evaluation of such plan.

Within 30 days of receipt of an investigational plan under subparagraph (B), the Secretary shall respond in writing to the submitter identifying each deficiency with the plan and such other information that will facilitate the review and approval of an application.''.

SEC. 10. CLASSIFICATION AND RECLASSIFICATION OF IN VITRO DIAGNOSTIC TEST SYSTEMS.

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

''INITIAL CLASSIFICATION AND RECLASSIFICATION OF IN VITRO DIAGNOSTIC TEST SYSTEMS

''(j) Any class III in vitro diagnostic test system intended for human use which was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this para-

graph is deemed to be automatically reclassified by the Secretary in class II on the date 1 year after the date of enactment of this subsection unless the Secretary, by regulation, finds that classification of the device in class III is necessary to provide reasonable assurance of its safety and effectiveness. Any such device that the Secretary classifies in class III shall remain in class III for 3 years after the effective date of the regulation classifying the device in class III. At the end of the 3-year period, the device is deemed to be automatically reclassified by the Secretary in class II unless the Secretary, by notice and comment rulemaking, extends the class III designation for an additional period of time. Any proposed regulation issued under this subsection finding that a device shall be classified in class III shall be accompanied by a full statement of the reasons (and supporting documentation and data) of the Secretary for finding that classification of the device in class III is necessary to provide reasonable assurance of its safety and effectiveness and that reclassification in class II will not provide such assurance.

''CLASSIFICATION

''(k) Any in vitro diagnostic test system intended for human use which is intended to be introduced or delivered for introduction into interstate commerce for commercial distribution on or after the date of enactment of this subsection is deemed to be classified by the Secretary in class

II unless the Secretary, by regulation, finds that classification of the device in class III is necessary to provide reasonable assurance of its safety and effectiveness. Any such device that the Secretary classifies in class III shall remain in class III for 3 years after the effective date of the regulation classifying the device in class III. At the end of that 3-year period, the device is deemed to be automatically reclassified by the Secretary in class II unless the Secretary, by notice and comment rulemaking, extends the class III designation for an additional period of time. Any proposed regulation issued under this subsection finding that a device shall be classified in class III shall be accompanied by a full statement of the reasons (and supporting documentation and data) of the Secretary for finding that classification in class II will not provide such assurance.''.

(b) Section 520(l)(1) (21 U.S.C. 360j(l)(1)) is amended by adding after ''has classified such device in class I or II'' the following: '', except that any device intended for human use described in subparagraphs (A) through (F) which is an in vitro diagnostic test system is deemed to be classified by the Secretary in class II on the date 1 year after the date of enactment of this paragraph unless the Secretary in response to a petition submitted under paragraph (2) has classified such device in

class I, or the Secretary, by regulation, finds that classification of the device in class III is necessary to provide reasonable assurance of its safety and effectiveness. Any such device that the Secretary classifies in class III shall remain in class III for 3 years after the effective date of the regulation classifying the device in class III. Any such device that the Secretary classifies in class III shall remain in class III for 3 years after the effective date of the regulation classifying the device in class III unless the Secretary, by notice and comment rulemaking, extends the class III designation for an additional period of time. At the end of that 3-year period, the device is deemed to be automatically reclassified by the Secretary in class II. Any proposed regulation issued under this paragraph finding that a device shall be classified in class III shall be accompanied by a full statement of the reasons (and supporting documentation and data) of the Secretary for finding that classification of the device in class III is necessary to provide reasonable assurance of its safety and effectiveness and that reclassification in class II will not provide such assurance''.

SEC. 11. REGULATION OF SPECIAL PURPOSE REAGENTS.

Section 513 (21 U.S.C. 360c), as amended by section 8, is amended by adding at the end the following:

''SPECIAL PURPOSE REAGENTS

''(l) Any special purpose reagent is deemed to be classified by the Secretary in class I, subject to the 'general controls' defined in subsection (h), except the premarket notification requirement of section 510(k), if—

''(1) the labeling complies with all requirements that the Secretary, by regulation, establishes for in vitro diagnostic test systems, including a requirement that a certificate of analysis provided by the manufacturer of the special purpose reagent shall be limited to a description of the physical and chemical properties of the device, the quantity provided, appropriate storage instruction, expiration date, and the results of any quality or purity testing conducted by the manufacturer;

''(2) the label for the device bears the statement 'For manufacturing or laboratory use only,'; and

''(3) distribution of the device is restricted to laboratories licensed by the Secretary under section 353 of the Public Health Service Act to perform 'high complexity' testing as the Secretary, by regulation, defines.

''IN VITRO DIAGNOSTIC TEST SYSTEM

''(m) Any laboratory licensed by the Secretary under section 353 of the Public Health Services Act to perform 'high complexity' testing which uses a special purpose rea-

gent to manufacture an in vitro diagnostic test system only for use in that laboratory shall validate the in vitro diagnostic test system. The laboratory shall include the following statement on all labeling and any patent test report: 'Proprietary assay developed and validated by [name of laboratory]. The performance characteristics of this assay have not been cleared or approved by the Food and Drug Administration'.''.

SEC. 12. AUTHORIZATION OF NONGOVERNMENTAL ORGANIZATIONS AND PERSONS TO CONDUCT GOOD MANUFACTURING PRACTICE INSPECTIONS AND RESPONSES TO ADVERSE FINDINGS.

Section 704 (21 U.S.C. 374) is amended—

(1) in subsection (a)(1), by inserting ''or organizations and individuals receiving accreditation to conduct good manufacturing practice inspections under section 712'' after ''Secretary'';

(2) in subsection (a)(3), by inserting ''or an accredited organization or individual under section 712'' after ''employee'';

(3) in subsection (b), by inserting '', or the accredited organization or individual under section 712,'' after ''employee'';

(4) in subsection (b), by inserting ''(1)'' after ''(b)'', redesignating clauses (1) and (2) as clauses (A) and (B), respectively, and adding at the end the following:

''(2) The Secretary shall provide at least 10 days from the date of presentation of the findings in paragraph (1) for the person receiving such findings to respond. The Secretary shall take no regulatory action against a person or article subject to the requirements of the Act until completing a review of such a response, which is timely submitted to the Secretary, except the Secretary may take immediate action when the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, or that any regulated article could present an unreasonable and substantial risk of injury or illness to the public health. The Secretary shall provide to the regulated person, within 30 days of receiving a response to findings identified in paragraph (1), a detailed assessment of the response.

''(3) At the time an accredited organization or individual shall identify in writing each inspectional finding observed during such inspection which suggests a deviation from requirements under the Act. Within 30 days from the date of presentation of such findings, the person

receiving the findings shall respond in writing to the accredited organization or individual stating the response of such person to each finding. Within 30 days of receipt of such response, the accredited organization or individual shall prepare and submit a written report to the Secretary, including inspectional findings, the regulated person's response to the findings, an assessment of the adequacy of the response and conclusions, and a copy of the conflict of interest assessment prepared in accordance with the requirement set forth in section 712(c). Such accredited organization or individual shall immediately submit to the Secretary the inspectional findings when the device to which such findings relate is intended for human use and presents a reasonable probability that such device would cause serious, adverse health consequences or death, or that any regulated article could present an unreasonable and substantial risk of injury or illness to the public health.''; and

(5) by adding after subsection (e) the following:

''(f) Persons duly designated by the Secretary to conduct inspections under this section shall not request any information not permitted under subsections (a) and (e) unless such person states with specificity and in writing the identification of the information subject to the request, the reason for the request, and that the written request

seeks to obtain information not required to be produced under this section.''.

SEC. 13. ACCREDITATION OF NONGOVERNMENTAL ORGANIZATIONS OR INDIVIDUALS.

Subchapter A of chapter VII is amended by adding the following:

''ACCREDITATION OF NONGOVERNMENTAL ORGANIZATIONS OR INDIVIDUALS

''SEC. 712. (a) The Secretary shall, within 180 days after the date of enactment of this section, by regulation establish procedures and criteria to accredit any organization or individuals for purposes of—

''(1) conducting good manufacturing practice inspections authorized under section 704 to determine the conformance of a facility with regulations promulgated under section 520(f);

''(2) reviewing notifications required under section 510(k) and making written recommendations of initial classification under section 513(f)(1) of devices; and

''(3) reviewing applications under section 515(c) and providing written reviews to the Secretary determine, within 120 days from the receipt of a submission requesting accreditation, whether the organization or individual submitting such application is fit to undertake some or all of the activities specifies

herein. The Secretary shall notify the applicant in writing of the Secretary's determination within such time period.

''(b) The Secretary shall take into account the training and experience of organizations and individuals who apply for accreditation, including formal education, certifications, work experience, ability to protect the confidentiality of trade secret and confidential commercial and financial information, lack of bias and other related information necessary to determine the fitness of an applicant to undertake activities on behalf of the Department of Health and Human Services.

''(c) Notwithstanding the credentials or qualifications of any applicant, the Secretary shall, after accreditation require each person who chooses to use an accredited organization or individual to determine whether such organization or individual has a significant personal or financial interest in a device, other than compensation for reviews or inspections, that would influence decisions regarding such device.''.

SEC. 14. RESEARCH ACTIVITIES.

(a) ACTIVITIES.—Chapter IX, as amended by section 11, is amended by adding after section 906 the following:

''RESEARCH ACTIVITIES

''SEC. 907. Research activities of the Food and Drug Administration relating to drugs, devices, and biological

products, which are authorized under section 903(b)(2)(D) and section 352 of the Public Health Service Act, shall directly relate to the review and approval of drugs, devices, and biological products. In conducting such research activities, the Food and Drug Administration may collaborate with the National Institutes of Health, academic health centers, and other scientific institutions and the drug and device industry.''.

(b) PURPOSE.—Section 903 (21 U.S.C. 393), as amended by section 3, is amended by adding at the end the following:

''(e) Any research conducted by or for the Food and Drug Administration shall be solely related directly to (1) the regulatory mission or (2) professional staff development related to that mission and shall be limited to the minimum necessary to achieve such purposes.''.

SEC. 15. POLICY AND PERFORMANCE REVIEW.

Section 514 (21 U.S.C. 360d) is amended by adding the following:

''(c)(1) The Secretary shall recognize applicable nationally or internationally recognized consensus standards to determine whether there is a reasonable assurance that a device is safe or effective or to determine compliance with any requirement under the Act, except that, any person may elect to submit data other than that required by

such standards to demonstrate a reasonable assurance of device safety or effectiveness or compliance with requirements under the Act.

''(2) The Secretary in lieu of receiving data demonstrating conformance to standards referenced in paragraph (1) shall accept certifications from regulated persons that devices conform with each standard identified in each such certification.

''(d) The Secretary shall not rely upon informal agency statements, including guidance documents, policy statements, points to consider documents, or any other statements intended for a similar purpose, to require any action be taken to satisfy a requirement under the Act, unless such statement is first subject to the rulemaking procedure set forth in section 5 U.S.C. e 553.''.

SEC. 16. EXPORT OF NEW DRUGS AND DEVICES.

Section 801(e) (21 U.S.C. 381(e)) is amended—

(1) in paragraph (1), by inserting after ''under this Act'' the following: ''or in violation of section 505 or section 351 of the Public Health Service Act'',

(2) in paragraph (1), by striking the last sentence, and

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

''(2) Paragraph (1) does not apply to the export of—

''(A) any device—

''(i) which does not comply with an applicable requirement under section 514 or 515,

''(ii) which under section 520(g) is exempt from either such section, or

''(iii) which is a banned device under section 516, or

''(B) any drug (including a biological product) which does not comply with an applicable requirement under section 505 or 512 or section 351 of the Public Health Service Act,

unless the device or drug is in compliance with the requirements of paragraph (1). In the case of a device or drug for which an export notice is required under this paragraph, the Secretary may prohibit the export of such device or drug if the Secretary determines that the possibility of the reimportation of the device or drug into the United States presents an imminent hazard to the public health and safety of the United States and the only means of limiting the hazard is to prohibit the export of the device or drug.''.

SEC. 17. RECLASSIFICATION OF CERTAIN DEVICES.

Section 515 (21 U.S.C. 360e) is amended by adding at the end the following new subsection:

''RECLASSIFICATION

''(j) The Secretary shall, within 18 months of the date of enactment of this subsection, publish in the Federal Register a proposed regulation reclassifying all devices identified in subsection (i)(2) into class II, unless the Secretary has already published a proposed regulation required under subsection (i) for each such device. The Secretary shall provide 60 days for comment on the proposed regulation, and shall publish a final regulation in the Federal Register within 60 days after the last day for comment reclassifying into class II each such device not included in a regulation required under subsection (i), or maintaining, where appropriate, the original classification of such devices.''.

SEC. 18. TRACKING.

(a) Section 519(e) is amended to read as follows:

''(e) Every person who registers under section 510 and is engaged in the manufacture of a class II or class III device the failure of which would be reasonably likely to have life threatening or permanently debilitating health consequences attributable to the device and which is a permanently implantable device, or a life sustaining or life supporting device used outside a device user facility, or may designate, shall adopt a method of device tracking. Manufacturers subject to tracking may satisfy the require-

ments of this subsection by relying exclusively on social security numbers as a method of device tracking.''.

(b) The Secretary of Health and Human Services shall, within 12 months of the date of the enactment of this Act, revise regulations appearing in part 821 of title 21 of the Code of Federal Regulations, to conform to section 519 of the Federal Food, Drug, and Cosmetic Act as amended by subsection (a).

(c) Section 205(c)(2)(C)(vii) (42 U.S.C. e 405(c)(2)(C)(viii)) of the Social Security Act is amended by redesignating subclauses (II), (III), and (IV) as (III), (IV), and (V), and inserting after subclause (I) the following new subclause:

''(II) Section 519(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)) is exempted from subclause (I). Social Security account numbers and related records obtained or maintained by authorized persons shall be available for use under section 519(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)) for purposes of device tracking. The requirements under section 7(b) of the Privacy Act of 1974 (Public Law No. 93–579, 88 Stat. 1896), shall not apply to any Federal, State, or local government agency requesting a person to disclose his/her social security account number for pur-

poses of device tracking under section 519(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)).''.

SEC. 19. POSTMARKET SURVEILLANCE.

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

''POSTMARKET SURVEILLANCE

''SEC. 522. (a) The Secretary may require a manufacturer to conduct postmarket surveillance for any device of the manufacturer first introduced or delivered for introduction into interstate commerce after January 1, 1991, that is a class III device the failure of which would be reasonably likely to have life threatening or permanently debilitating consequences attributable to the device and which is (1) a permanently implantable device, or (2) a life sustaining or life supporting device used outside a device user facility.

''(b) Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving notice from the Secretary that the manufacturer is required under this section to conduct such surveillance and submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection

of useful data or other information necessary to protect the public health and to provide safety and effectiveness information for the device. The Secretary may not approve such a protocol until it has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary.''.

SEC. 20. MISCELLANEOUS.

(a) Chapter III of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 et seq.) is amended by adding at the end thereof the following new sections:

''DISSEMINATION OF TREATMENT INFORMATION ON DRUGS AND BIOLOGICAL PRODUCTS

''SEC. 311. (a)(1) Notwithstanding sections 301(d), 502(f), 505, and 507 and section 351 of the Public Health Service Act (42 U.S.C. 262), and subject to the requirements of paragraph (2) and subsection (b), a person may disseminate to any person that is a health care practitioner or other provider of health care goods or services, a pharmacy benefit manager, a health maintenance organization or other managed health care organization, or a health care insurer or governmental agency, written information, or an oral or written summary of the written information, concerning—

''(A) a treatment use for an investigational new drug or an investigational biological product approved by the Secretary for such treatment use; or

''(B) a use (whether or not such use is contained in the official labeling) of a new drug (including any antibiotic drug) or a biological product for which an approval of an application filed under section 505(b), 505(j), or 507, or a product license issued under the Public Health Service Act, is in effect.

''(2) A person may disseminate information under paragraph (1)(B) only if—

''(A) the information is an unabridged—

''(i) reprint or copy of a peer-reviewed article from a scientific or medical journal that is published by an organization that is independent of the pharmaceutical industry; or

''(ii) chapter, authored by an expert or experts in the disease to which the use relates, from a recognized reference textbook that is published by an organization that is independent of the pharmaceutical industry;

''(B) the text of the information has been approved by a continuing medical education accrediting agency that is independent of the pharmaceutical industry as part of a scientific or medical educational program approved by such agency;

''(C) the information relates to a use that is recognized under Federal law for purposes of third-party coverage or reimbursement, and—

''(i) the text of the information has been approved by an organization referred to in such Federal law; or

''(ii) the information is part of a disease management program or treatment guideline with respect to such use; or

''(D) the information is an accurate and truthful summary of the information described in subparagraph (A), (B), or (C).

''(b) In order to afford a full and fair evaluation of the information described in subsection (a), a person disseminating the information shall include a statement that discloses—

''(1) if applicable, that the use of a new drug or biological product described in subparagraph (A) or (B) of subsection (a)(1) and the information with respect to the use have not been approved by the Food and Drug Administration;

''(2) if applicable, that the information is being disseminated at the expense of the sponsor of the drug or biological product;

''(3) if applicable, that one or more authors of the information being disseminated are employees of or consultants to the sponsor of the drug or biological product; and

''(4) the official labeling for the drug and biological product, or in the case of a treatment use of an investigational drug or biological product, the investigator brochure and all updates thereof.

''(c) As used in this section, the term 'expense' includes financial, in-kind, and other contributions provided for the purpose of disseminating the information described in subsection (a).

''(d) In the case of a professional disagreement between the Secretary and other qualified experts with respect to the application of section 502(a), the Secretary may not use section 502 to prohibit the dissemination of information in the types of circumstances and under the conditions set forth in subsections (a) and (b).

''DISSEMINATION OF INFORMATION ON DEVICES

SEC. 312. (a) Notwithstanding sections 301, 501(f), 501(i), 502(a), 502(f), and 502(o), or any other provision of law, and subject to subsections (b) and (c), a person may disseminate to any person that is a health care practitioner or other provider of health care goods or services, a pharmacy benefit manager, a health maintenance organization or other managed health care organization, or a

health care insurer or governmental agency, written or oral information (including information exchanged at scientific and educational meetings, workshops, or demonstrations) relating to a use, whether or not the use is described in the official labeling, of a device produced by a manufacturer registered pursuant to section 510.

''(b)(1) To the extent practicable, the requirement with respect to a statement of disclosure under subsection (b) of section 311 shall apply to the dissemination of written and oral information under this section, except that this paragraph shall not apply to the dissemination of written or oral information with respect to the intended use described in the labeling of a device.

''(2) A person may disseminate information under subsection (a) only if—

''(A) the information is an unabridged—

''(i) reprint or copy of a peer-reviewed article from a scientific or medical journal that is published by an organization that is independent of the medical device industry; or

''(ii) chapter, authored by an expert or experts in the medical specialty to which the use relates, from a recognized reference textbook that is published by an organization that is independent of the medical device industry;

''(B) the information has been approved by a continuing medical education accrediting agency that is independent of the medical device industry as part of a scientific or medical educational program approved by such agency;

''(C) the information relates to a use that is recognized under Federal law for purposes of third-party reimbursement, and—

''(i) the text of the information has been approved by an organization referred to in such Federal law; or

''(ii) the information is part of a disease management program or treatment guideline with respect to such use; or

''(D) the oral or written information is—

''(i) part of an exchange of information solely among health care practitioners, health care reimbursement officials, and the industry;

''(ii) exchanged for educational or scientific purposes; and

''(iii) presented at continuing medical education programs, seminars, workshops, or demonstrations.

''(3) The requirements under subsection (a)(1)(A) and (B) of section 311 shall not apply with respect to devices.

''(c) Notwithstanding section 502(a), 502(f), 502(o), or any other provision of law, the written or oral dissemination of information relating to a new use of a device, in accordance with this section, shall not be construed by the Secretary as evidence of a new intended use of the device that is different from the intended use of the device set forth on the official labeling of the device. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the device.''.

(b) Section 519 (21 U.S.C. 360i) is amended to read as follows:

''RECORDS AND REPORTS ON DEVICES

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

''(1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes

aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury;

''(2) shall define the term 'serious injury' to mean an injury that—

''(A) is life threatening,

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

''(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure;

''(3) shall require reporting of other significant adverse device experiences as determined by the Secretary to be necessary to be reported;

''(4) shall not impose requirements unduly burdensome to a device manufacturer or importer taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this Act;

''(5) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary

state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

''(6) which require submission of a report or information to the Secretary shall state the reason or purpose for the submission of such report or information and identify to the fullest extent practicable such report or information;

''(7) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this Act;

''(8) may not require a manufacturer, importer, or distributor of a class I device to—

''(A) maintain for such a device records respecting information not in the possession of the manufacturer or importer, or

''(B) to submit for such a device to the Secretary any report or information—

''(i) not in the possession of the manufacturer or importer, or

''(ii) on a periodic basis,

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded; and

''(b) Subsection (a) shall not apply to—

''(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

''(2) any person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 520(g)); and

''(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety and effectiveness.

''(c) Each manufacturer and importer required to make reports under subsection (a) shall submit to the Secretary annually a statement certifying that—

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

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

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

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

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

shall adopt a method of device tracking.''.

(b) Within 120 days after the enactment of this section, the Secretary shall delete all regulations in title 21, part 800 requiring distributors, other than importers, to make reports of deaths, serious injuries or illness, and malfunctions related to devices.

(c) Section 303(c) (21 U.S.C. 333) is amended by striking the period at the end of subsection (c) and inserting ''; or for having violated 301(a), (b), (c), and (k), by failure to comply with either subsections 502(t)(2) or 501(h), or having violated subsection 301(g)(1)(B) by fail-

ing to furnish material or information required under subsection 519(a) if such person acted in good faith, had no reason to believe that the person's acts violated the law, and had no prior notice from the Secretary that the acts constituted violations of the Act.''.

(d) Section 201(h) (21 U.S.C. 321(h)) is amended by striking paragraph (1), and renumbering paragraphs (2), and (3) as paragraphs (1) and (2), respectively.

(e) The Secretary of Health and Human Services within 120 days of the enactment of this section shall revise all regulations appearing in part 800 of title 21 of the Code of Federal Regulations to delete any requirement to report device malfunctions.

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