105TH CONGRESS
1ST SESSION

S. 870

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, approval, and use of medical devices to maintain and improve the public health and quality of life of individuals, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 10, 1997

Mr. WELLSTONE introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, approval, and use of medical devices to maintain and improve the public health and quality of life of individuals, and for other purposes.

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 ''Medical Technology, Public Health, and Innovation Act of 1997''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment

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

SEC. 2. FINDINGS; MISSIONS STATEMENT.

(a) FINDINGS.—The Congress finds the following:

(1) While the United States appropriately puts a top priority on the regulation of medical technologies to ensure the safety and efficacy of medical technologies that are introduced into the marketplace, the administration of such regulatory effort is causing the United States to lose its leadership role in producing innovative, top-quality medical devices.

(2) One of the key components of the medical device regulatory process that contributes to the United States losing its leadership role in medical device development is the inordinate amount of time it takes for medical technologies to be reviewed by the Food and Drug Administration.

(3) The most important result of the United States losing its leadership role is that patients in the United States do not have access to new medical technology in a timely manner.

(4) Delayed patient access to new medical technology results in lost opportunities to save lives, to

reduce hospitalization and recovery time, and to improve the quality of life of patients.

(5) The economic benefits that the United States medical device industry, which is composed principally of smaller companies, has provided through growth in jobs and global trade are threatened by the slow and unpredictable regulatory process at the Food and Drug Administration.

(6) The pace and predictability of the medical device regulatory process are in part responsible for the increasing tendency of United States medical device companies to shift research, product development, and manufacturing offshore, at the expense of American jobs, patients, and leading edge clinical research.

(b) MISSION STATEMENT.—This legislation seeks to improve the timeliness, effectiveness, and predictability of the medical device approval process for the benefit of United States patients and the United States economy by—

(1) providing for the use of nationally and internationally recognized performance standards to assist the Food and Drug Administration in determining the safety and effectiveness of medical devices;

(2) facilitating communication between medical device companies and the Food and Drug Administration;

(3) targeting the use of Food and Drug Administration resources on medical devices that are likely to have serious adverse health consequences; and

(4) requiring the Food and Drug Administration to determine the least costly, most efficient approach to reasonably assuring the safety and effectiveness of devices.

SEC. 3. DEVICE PERFORMANCE STANDARDS.

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

''RECOGNITION OF A PERFORMANCE STANDARD

''(c)(1)(A) The Secretary may, through publication in the Federal Register, issue notices identifying and listing nationally and internationally recognized performance standards for which persons may provide a certification of a device's conformity under paragraph (3) in order to meet the premarket submission requirements or other requirements under the Act to which the standards are applicable.

''(B) Any person may elect to utilize data other than data required by the standards described in subparagraph

(A) to meet any requirement under the Act to which the standards are applicable.

''(2) The Secretary may remove from the list of standards described in paragraph (1) a standard that the Secretary determines is no longer appropriate for making determinations with respect to the regulation of devices.

''(3)(A) A person may provide a certification that a device conforms to an applicable standard listed under paragraph (1) to meet the requirements described in paragraph (1) and the Secretary shall accept such certification.

''(B) The Secretary may, at any time, request a person who submits a certification described in subparagraph (A) to submit the data or information that the person relied on in making the certification.

''(C) A person who submits a certification described in subparagraph (A) shall maintain the data and information upon which the certification was made for a period of 2 years after the submission of the certification or a time equal to the expected design life of a device, whichever is longer.''.

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

''(x) The falsification of a certification submitted under section 514(c)(3) or the failure or refusal to provide

data or information requested by the Secretary under such section.''.

(c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e)) is amended by striking ''established'' and inserting ''established or listed''.

SEC. 4. PREMARKET APPROVAL.

(a) APPLICATION.—Section 515(c) (21 U.S.C. 360e(c)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (F), by striking ''; and'' and inserting a semicolon;

(B) in subparagraph (G), by striking ''require.'' and inserting ''require; and''; and

(C) by adding at the end the following:

''(H) an identifying reference to any performance standard listed under section 514(c) that is applicable to such device.''.

(2) by adding at the end the following:

''(3) The Secretary shall accept historical clinical data as a control for use in determining whether there is a reasonable assurance of safety and effectiveness of a device in a case in which the effects of the progression of a disease are clearly defined and well understood.

''(4) The Secretary may not require the sponsor of an application to conduct clinical trials for a device using randomized controls unless the controls—

''(A) are necessary;

''(B) are scientifically and ethically feasible; and

''(C) other less burdensome and controls, such as historical controls, are not available to permit a determination of a reasonable assurance of safety and effectiveness.''.

(b) ACTION ON APPLICATION.—Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A)—

(A) by striking ''paragraph (2) of this subsection'' each place it appears and inserting ''paragraph (8)''; and

(B) by adding at the end the following flush paragraph:

''In making a determination to approve or deny an application, the Secretary shall rely on the conditions of use proposed in the labeling of device as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness. If, based on a fair evaluation of all material facts, the proposed labeling of the device is neither false nor misleading in any particular, the Sec-

retary shall not consider conditions of use not included in such labeling in making the determination.'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (8) and (9), respectively; and

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

''(2) Each application received under subsection (c) shall be reviewed in a manner to achieve final action within the 180-day period described in subparagraph (A), and the 180-day period may not be altered for any reason without the written consent of an applicant.

''(3)(A) Not later than 100 days after the receipt of an application that has been filed by the Secretary because the application satisfies the content requirements of subsection (c)(1), the Secretary shall meet with the applicant and disclose each deficiency relating to the application that would preclude approval of the application under paragraph (1).

''(B) The applicant shall have the right to be informed in writing with respect to the information communicated to the applicant during the meeting.

''(4) To permit better treatment or better diagnoses of life-threatening or irreversibly debilitating diseases or conditions, the Secretary shall expedite the review for devices—

''(A) representing breakthrough technologies;

''(B) offering significant advantages over existing approved alternatives; or

''(C) for which accelerated availability is in the best interest of the public health.

''(5) The Secretary shall complete the review of all supplemental applicants to an application approved under paragraph (1) that do not contain clinical data within 90 days after the receipt of a supplemental that has been accepted for filing.''

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

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

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

''(II) clinical data from the approved application and any supplements to the approved application provide a reasonable assurance of safety and effectiveness.

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

''(7) Any representation in promotional materials for a device subject to an approved application under this subsection shall not be subject to premarket approval under this section, unless such representations establish new conditions of use. Any representations made in promotional materials for devices subject to an approved application shall be supported by appropriate data or information that can substantiate the representations at the time such representations are made.''.

(c) WITHDRAWAL OR TEMPORARY SUSPENSION OF APPROVAL OF APPLICATION.—Section 5155(e)(1) (21 U.S.C. 360e(1)) is amended in subparagraph (G) by inserting after the word ''effect'' the words ''or listed.''

SEC. 5. PREMARKET NOTIFICATION.

(a) EXEMPTION OF CERTAIN DEVICES.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k), by striking ''intended for human use'' and inserting ''intended for human use (except a device that is classified into class I under section 513 or 520 or a device that is classified into class II under section 513 or 520, and is exempt from the requirements of this subsection under subsection (l))'';

(2) by adding at the end of subsection (k) (as amended by paragraph (1)) the following flush sentence:

''The Secretary shall review the notification required by this subsection and make a determination under section 513(f)(1)(A) within 90 days after receiving the notification.''; and

(3) by adding at the end the following:

''(1)(A) Within 30 days after the date of enactment of this subsection, the Secretary shall develop and publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary not to require the report shall be exempt from the require-

ment to file a report under subsection (k) as of the date of the publication of the list in the Federal Register.

''(B) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, any person may petition the Secretary to exempt a type of class II device from the requirement of subsection (k). The Secretary shall respond to the petition within 120 days after the receipt of the petition and determine whether or not to grant the petition in whole or in part.''.

(b) SPECIAL RULE RELATING TO EXEMPTION OF CLASS I DEVICES FROM 510(k) NOTIFICATIONS.—The exemption of a class I device from the notification requirement of section 510(k) shall not apply to a class I device that is life sustaining or life saving or that is intended to be implanted into the human body.

SEC. 6. INVESTIGATIONAL DEVICE EXEMPTION.

(a) REGULATIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended—

(1) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

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

''(4) The Secretary shall, within 120 days after the date of enactment of this paragraph, by regulation, amending the content of part 812 of title 21 of the Code

of Federal Regulations, amend the procedures with respect to the approval of clinical studies under this subsection as follows:

''(A) The Secretary shall permit the sponsor of an investigation to meet with the Secretary prior to the submission of an application to develop a protocol for a clinical study subject to the regulation and require that the protocol be agreed upon in writing by the sponsor and the Secretary.

''(B)(i) The Secretary shall permit developmental changes to devices in response to information gathered during the course of an investigation without requiring an additional approval of an application for an investigational device exemption, or the approval of a supplement to the application, if the changes meet the following requirements:

''(I) The changes do not constitute a significant change in the design of the product or a significant change in basic principles of operation.

''(II) The changes do not adversely affect patient safety.

''(ii) The Secretary shall require that each such change shall be documented with information describing the change and the basis of the sponsor of

application for concluding that the change does not constitute a significant change in design or operating principles, and that the change does not adversely affect patient safety.''.

(b) CONFORMING AMENDMENTS.—Section 517(a)(7) (21 U.S.C. 360g(a)(7)) is amended—

(1) by striking ''section 520(g)(4)'' and inserting ''section 520(g)(5)''; and

(2) by striking ''section 520(g)(5)'' and inserting ''section 520(g)(6)''.

SEC. 7 PRODUCT REVIEW.

Section 513 (21 U.S.C. 360c) is amended by—

(1) in subsection (a)(3)(A)—

(A) by striking ''including clinical investigations where appropriate'' and inserting ''including 1 or more clinical investigations where appropriate'';

(B) by adding at the end the following: ''When evaluating the type and amount of data necessary to find a reasonable assurance of device effectiveness for an approval under section 515, the Secretary shall consider the extent to which reliance on postmarket controls may contribute to such assurance and expedite effectiveness determinations without increasing regu-

latory burdens on persons who submit applications under section 515(c).'';

(2) in subsection (a)(3), by adding at the end the following:

''(C)(i) The Secretary upon the request of any person intending to submit an application under section 515 shall meet with the person to determine the type of valid scientific evidence within the meaning of subparagraphs (A) and (B) that will be necessary to demonstrate the effectiveness of a device for the conditions of use proposed by such person to support an approval of an application.

''(ii) Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by the person.

''(iii) Any clinical data, including 1 or more well-controlled investigations, specified by the Secretary for demonstrating a reasonable assurance of device effectiveness shall reflect the Secretary's determination that such data are necessary to establish device effectiveness and that no other less burdensome means of evaluating device effectiveness are available which would have a reasonable likelihood of resulting in an approval.

''(2) The determination of the Secretary with respect to the specification of the valid scientific evidence under clause (ii) shall be binding upon the Secretary, unless such determination by the Secretary would be contrary to the public health''; and

(3) in subsection (i), by adding at the end the following:

''(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1).

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

''(E) Any determinations of substantial equivalence by the Secretary shall be based upon the intended uses proposed in labeling submitted in a report under section 510(k).

''(F) Any representations made in promotional materials for devices shall not require a report under section 510(k), unless such representations establish new intended uses for a legally marketed device.''.

○