

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.

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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

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## 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.

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 AND REFERENCE.**

4       (a) **SHORT TITLE.**—This Act may be cited as the  
5       “Medical Technology, Public Health, and Innovation Act  
6       of 1997”.

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

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

5 **SEC. 2. FINDINGS; MISSIONS STATEMENT.**

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

7 (1) While the United States appropriately puts  
8 a top priority on the regulation of medical tech-  
9 nologies to ensure the safety and efficacy of medical  
10 technologies that are introduced into the market-  
11 place, the administration of such regulatory effort is  
12 causing the United States to lose its leadership role  
13 in producing innovative, top-quality medical devices.

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

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

24 (4) Delayed patient access to new medical tech-  
25 nology results in lost opportunities to save lives, to

1 reduce hospitalization and recovery time, and to im-  
2 prove the quality of life of patients.

3 (5) The economic benefits that the United  
4 States medical device industry, which is composed  
5 principally of smaller companies, has provided  
6 through growth in jobs and global trade are threat-  
7 ened by the slow and unpredictable regulatory proc-  
8 ess at the Food and Drug Administration.

9 (6) The pace and predictability of the medical  
10 device regulatory process are in part responsible for  
11 the increasing tendency of United States medical de-  
12 vice companies to shift research, product develop-  
13 ment, and manufacturing offshore, at the expense of  
14 American jobs, patients, and leading edge clinical re-  
15 search.

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

20 (1) providing for the use of nationally and  
21 internationally recognized performance standards to  
22 assist the Food and Drug Administration in deter-  
23 mining the safety and effectiveness of medical de-  
24 vices;

1           (2) facilitating communication between medical  
2 device companies and the Food and Drug Adminis-  
3 tration;

4           (3) targeting the use of Food and Drug Admin-  
5 istration resources on medical devices that are likely  
6 to have serious adverse health consequences; and

7           (4) requiring the Food and Drug Administra-  
8 tion to determine the least costly, most efficient ap-  
9 proach to reasonably assuring the safety and effec-  
10 tiveness of devices.

11 **SEC. 3. DEVICE PERFORMANCE STANDARDS.**

12       (a) ALTERNATIVE PROCEDURE.—Section 514 (21  
13 U.S.C. 360d) is amended by adding at the end the follow-  
14 ing:

15       “RECOGNITION OF A PERFORMANCE STANDARD

16       “(c)(1)(A) The Secretary may, through publication in  
17 the Federal Register, issue notices identifying and listing  
18 nationally and internationally recognized performance  
19 standards for which persons may provide a certification  
20 of a device’s conformity under paragraph (3) in order to  
21 meet the premarket submission requirements or other re-  
22 quirements under the Act to which the standards are ap-  
23 plicable.

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

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

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

7 “(3)(A) A person may provide a certification that a  
8 device conforms to an applicable standard listed under  
9 paragraph (1) to meet the requirements described in para-  
10 graph (1) and the Secretary shall accept such certification.

11 “(B) The Secretary may, at any time, request a per-  
12 son who submits a certification described in subparagraph  
13 (A) to submit the data or information that the person re-  
14 lied on in making the certification.

15 “(C) A person who submits a certification described  
16 in subparagraph (A) shall maintain the data and informa-  
17 tion upon which the certification was made for a period  
18 of 2 years after the submission of the certification or a  
19 time equal to the expected design life of a device, which-  
20 ever is longer.”.

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

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

1 data or information requested by the Secretary under such  
2 section.”.

3 (c) SECTION 501.—Section 501(e) (21 U.S.C.  
4 351(e)) is amended by striking “established” and insert-  
5 ing “established or listed”.

6 **SEC. 4. PREMARKET APPROVAL.**

7 (a) APPLICATION.—Section 515(c) (21 U.S.C.  
8 360e(c)) is amended—

9 (1) in paragraph (1)—

10 (A) in subparagraph (F), by striking “;  
11 and” and inserting a semicolon;

12 (B) in subparagraph (G), by striking “re-  
13 quire.” and inserting “require; and”; and

14 (C) by adding at the end the following:

15 “(H) an identifying reference to any perform-  
16 ance standard listed under section 514(c) that is ap-  
17 plicable to such device.”.

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

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

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

4               “(A) are necessary;

5               “(B) are scientifically and ethically feasible; and

6               “(C) other less burdensome and controls, such  
7 as historical controls, are not available to permit a  
8 determination of a reasonable assurance of safety  
9 and effectiveness.”.

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

12               (1) in paragraph (1)(A)—

13                       (A) by striking “paragraph (2) of this sub-  
14 section” each place it appears and inserting  
15 “paragraph (8)”; and

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

18 “In making a determination to approve or deny an appli-  
19 cation, the Secretary shall rely on the conditions of use  
20 proposed in the labeling of device as the basis for deter-  
21 mining whether or not there is a reasonable assurance of  
22 safety and effectiveness. If, based on a fair evaluation of  
23 all material facts, the proposed labeling of the device is  
24 neither false nor misleading in any particular, the Sec-

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

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

5 (3) by inserting after paragraph (1) the follow-  
6 ing:

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

12 “(3)(A) Not later than 100 days after the receipt of  
13 an application that has been filed by the Secretary because  
14 the application satisfies the content requirements of sub-  
15 section (c)(1), the Secretary shall meet with the applicant  
16 and disclose each deficiency relating to the application  
17 that would preclude approval of the application under  
18 paragraph (1).

19 “(B) The applicant shall have the right to be in-  
20 formed in writing with respect to the information commu-  
21 nicated to the applicant during the meeting.

22 “(4) To permit better treatment or better diagnoses  
23 of life-threatening or irreversibly debilitating diseases or  
24 conditions, the Secretary shall expedite the review for de-  
25 vices—

1           “(A) representing breakthrough technologies;

2           “(B) offering significant advantages over exist-  
3           ing approved alternatives; or

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

6           “(5) The Secretary shall complete the review of all  
7           supplemental applicants to an application approved under  
8           paragraph (1) that do not contain clinical data within 90  
9           days after the receipt of a supplemental that has been ac-  
10          cepted for filing.”

11          “(6)(A) A supplemental application shall be required  
12          for any change to a device subject to an approved applica-  
13          tion under this subsection if the change affects safety or  
14          effectiveness, unless the change is a modification in a  
15          manufacturing procedures or method of manufacturing  
16          and the holder of an approved application submits a notice  
17          to the Secretary that describes the change and informs  
18          the Secretary that the change has been made under the  
19          requirements of section 520(f).

20          “(B)(i) In reviewing a supplement to an approved ap-  
21          plication for an incremental change to the design of a de-  
22          vice that affects safety or effectiveness, the Secretary shall  
23          approve the supplement if—

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

4           “(II) clinical data from the approved applica-  
5           tion and any supplements to the approved applica-  
6           tion provide a reasonable assurance of safety and ef-  
7           fectiveness.

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

12          “(7) Any representation in promotional materials for  
13          a device subject to an approved application under this sub-  
14          section shall not be subject to premarket approval under  
15          this section, unless such representations establish new  
16          conditions of use. Any representations made in pro-  
17          motional materials for devices subject to an approved ap-  
18          plication shall be supported by appropriate data or infor-  
19          mation that can substantiate the representations at the  
20          time such representations are made.”.

21          (c) WITHDRAWAL OR TEMPORARY SUSPENSION OF  
22          APPROVAL OF APPLICATION.—Section 5155(e)(1) (21  
23          U.S.C. 360e(1)) is amended in subparagraph (G) by in-  
24          serting after the word “effect” the words “or listed.”

1 **SEC. 5. PREMARKET NOTIFICATION.**

2 (a) EXEMPTION OF CERTAIN DEVICES.—Section 510  
3 (21 U.S.C. 360) is amended—

4 (1) in subsection (k), by striking “intended for  
5 human use” and inserting “intended for human use  
6 (except a device that is classified into class I under  
7 section 513 or 520 or a device that is classified into  
8 class II under section 513 or 520, and is exempt  
9 from the requirements of this subsection under sub-  
10 section (l))”;

11 (2) by adding at the end of subsection (k) (as  
12 amended by paragraph (1)) the following flush sen-  
13 tence:

14 “The Secretary shall review the notification required by  
15 this subsection and make a determination under section  
16 513(f)(1)(A) within 90 days after receiving the notifica-  
17 tion.”; and

18 (3) by adding at the end the following:

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

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

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

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

16 **SEC. 6. INVESTIGATIONAL DEVICE EXEMPTION.**

17 (a) REGULATIONS.—Section 520(g) (21 U.S.C.  
18 360j(g)) is amended—

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

21 (2) by inserting after paragraph (3) the follow-  
22 ing:

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

1 of Federal Regulations, amend the procedures with re-  
2 spect to the approval of clinical studies under this sub-  
3 section as follows:

4           “(A) The Secretary shall permit the sponsor of  
5 an investigation to meet with the Secretary prior to  
6 the submission of an application to develop a proto-  
7 col for a clinical study subject to the regulation and  
8 require that the protocol be agreed upon in writing  
9 by the sponsor and the Secretary.

10           “(B)(i) The Secretary shall permit developmen-  
11 tal changes to devices in response to information  
12 gathered during the course of an investigation with-  
13 out requiring an additional approval of an applica-  
14 tion for an investigational device exemption, or the  
15 approval of a supplement to the application, if the  
16 changes meet the following requirements:

17           “(I) The changes do not constitute a sig-  
18 nificant change in the design of the product or  
19 a significant change in basic principles of oper-  
20 ation.

21           “(II) The changes do not adversely affect  
22 patient safety.

23           “(ii) The Secretary shall require that each such  
24 change shall be documented with information de-  
25 scribing the change and the basis of the sponsor of

1 application for concluding that the change does not  
2 constitute a significant change in design or operat-  
3 ing principles, and that the change does not ad-  
4 versely affect patient safety.”.

5 (b) CONFORMING AMENDMENTS.—Section 517(a)(7)  
6 (21 U.S.C. 360g(a)(7)) is amended—

7 (1) by striking “section 520(g)(4)” and insert-  
8 ing “section 520(g)(5)”; and

9 (2) by striking “section 520(g)(5)” and insert-  
10 ing “section 520(g)(6)”.

11 **SEC. 7 PRODUCT REVIEW.**

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

13 (1) in subsection (a)(3)(A)—

14 (A) by striking “including clinical inves-  
15 tigation where appropriate” and inserting “in-  
16 cluding 1 or more clinical investigations where  
17 appropriate”;

18 (B) by adding at the end the following:

19 “When evaluating the type and amount of data  
20 necessary to find a reasonable assurance of de-  
21 vice effectiveness for an approval under section  
22 515, the Secretary shall consider the extent to  
23 which reliance on postmarket controls may con-  
24 tribute to such assurance and expedite effective-  
25 ness determinations without increasing regu-

1 latory burdens on persons who submit applica-  
2 tions under section 515(c).”;

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

5 “(C)(i) The Secretary upon the request of any person  
6 intending to submit an application under section 515 shall  
7 meet with the person to determine the type of valid sci-  
8 entific evidence within the meaning of subparagraphs (A)  
9 and (B) that will be necessary to demonstrate the effec-  
10 tiveness of a device for the conditions of use proposed by  
11 such person to support an approval of an application.

12 “(ii) Within 30 days after such meeting, the Sec-  
13 retary shall specify in writing the type of valid scientific  
14 evidence that will provide a reasonable assurance that a  
15 device is effective under the conditions of use proposed by  
16 the person.

17 “(iii) Any clinical data, including 1 or more well-con-  
18 trolled investigations, specified by the Secretary for dem-  
19 onstrating a reasonable assurance of device effectiveness  
20 shall reflect the Secretary’s determination that such data  
21 are necessary to establish device effectiveness and that no  
22 other less burdensome means of evaluating device effec-  
23 tiveness are available which would have a reasonable likeli-  
24 hood of resulting in an approval.

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

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

8       “(C) To facilitate reviews of reports submitted to the  
9 Secretary under section 510(k), the Secretary shall con-  
10 sider the extent to which reliance on postmarket controls  
11 may expedite the classification of devices under subsection  
12 (f)(1).

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

21       “(E) Any determinations of substantial equivalence  
22 by the Secretary shall be based upon the intended uses  
23 proposed in labeling submitted in a report under section  
24 510(k).

1       “(F) Any representations made in promotional mate-  
2 rials for devices shall not require a report under section  
3 510(k), unless such representations establish new intended  
4 uses for a legally marketed device.”.

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