

110TH CONGRESS  
2D SESSION

# S. 3020

To amend the Federal Food, Drug, and Cosmetic Act with respect to the postmarket surveillance of devices.

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IN THE SENATE OF THE UNITED STATES

MAY 15, 2008

Mrs. BOXER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the postmarket surveillance of devices.

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.**

4 This Act may be cited as the “Food and Drug Ad-  
5 ministration Accountability and Transparency Act”.

6 **SEC. 2. POSTMARKET SURVEILLANCE OF DEVICES.**

7 (a) AVAILABILITY OF POSTMARKET SURVEILLANCE  
8 PLANS.—Section 522 of the Federal Food, Drug, and  
9 Cosmetic Act (21 U.S.C. 360l) is amended by adding at  
10 the end the following:

1 “(c) AVAILABILITY OF PLANS.—

2 “(1) IN GENERAL.—Subject to paragraph (2),  
3 the Secretary shall publish in the Federal Register,  
4 and make available to interested persons upon re-  
5 quest, a plan (and any amendments to such plan)  
6 submitted to the Secretary under subsection (b).

7 “(2) LIMITATION.—The Secretary shall not dis-  
8 close information under paragraph (1) that is ex-  
9 empted from disclosure under section 552 of title 5,  
10 United States Code (popularly known as the Free-  
11 dom of Information Act).”.

12 (b) INCREASED CIVIL PENALTIES FOR FAILURE TO  
13 COMPLY WITH POSTMARKET SURVEILLANCE PLAN.—

14 (1) IN GENERAL.—Section 303(f) of the Fed-  
15 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
16 333(f)) is amended—

17 (A) by redesignating paragraphs (5), (6),  
18 and (7) as paragraphs (6), (7), and (8), respec-  
19 tively; and

20 (B) by inserting after paragraph (4) the  
21 following:

22 “(5)(A) Any manufacturer that fails to comply with  
23 a requirement of section 522, including a requirement of  
24 a required surveillance plan under such section, shall be  
25 subject to a civil monetary penalty of—

1           “(i) not more than \$250,000 per violation, and  
2           not to exceed \$1,000,000 for all such violations ad-  
3           judicated in a single proceeding; or

4           “(ii) in the case of a violation that continues  
5           after the Secretary provides written notice to the  
6           manufacturer, the manufacturer shall be subject to  
7           a civil monetary penalty of \$250,000 for the first  
8           30-day period (or any portion thereof) that the man-  
9           ufacturer continues to be in violation, and such  
10          amount shall double for every 30-day period there-  
11          after that the violation continues, not to exceed  
12          \$1,000,000 for any 30-day period, and not to exceed  
13          \$10,000,000 for all such violations adjudicated in a  
14          single proceeding.

15          “(B) In determining the amount of a civil penalty  
16          under subparagraph (A)(ii), the Secretary shall take into  
17          consideration whether the manufacturer is making efforts  
18          toward correcting the violation of the requirement for  
19          which the manufacturer is subject to such civil penalty.”.

20                 (2)     CONFORMING     AMENDMENTS.—Section  
21                 303(f) of the Federal Food, Drug, and Cosmetic Act  
22                 (21 U.S.C. 333(f)) is amended—

23                         (A) in paragraph (6), as so redesignated,  
24                         by striking “, or (4)” each place it appears and  
25                         inserting “(4), or (5)”;

1 (B) in paragraph (7), as so redesignated,  
2 by striking “(5)(A)” and inserting “(6)(A)”;  
3 and

4 (C) in paragraph (8), as so redesignated,  
5 by striking “paragraph (6)” each place it ap-  
6 pears and inserting “paragraph (7)”.

7 **SEC. 3. NOTIFICATIONS.**

8 Section 518(a)(1) of the Federal Food, Drug, and  
9 Cosmetic Act (21 U.S.C. 360h(a)(1)) is amended by in-  
10 sserting “or that a violation of section 522 by the manufac-  
11 turer of a device presents an unreasonable risk of substan-  
12 tial harm to the public health” after “public health”.

13 **SEC. 4. EFFECTIVE DATE; APPLICABILITY.**

14 The amendments made by this Act—

15 (1) shall take effect 180 days after the date of  
16 enactment of this Act; and

17 (2) shall apply to a class II or class III device  
18 approved or cleared by the Secretary of Health and  
19 Human Services under chapter V of the Federal  
20 Food, Drug, and Cosmetic Act (21 U.S.C. 351 et  
21 seq.) before, on, or after the date of enactment of  
22 this Act.

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