

Merkley / Amendment #1 

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To ensure that the Food and Drug Administration has the appropriate authority to ensure that a device that has been recalled voluntarily by the manufacturer for safety reasons may not be used as a predicate for a subsequent device unless the manufacturer of the subsequent device can show that it has corrected the flaw that was the basis of the recall.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

(no.) \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Referred to the Committee on \_\_\_\_\_ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by \_\_\_\_\_

Viz:

- 1 At the end of title VI, insert the following:
- 2 **SEC. 616. PREDICATE DEVICES THAT HAVE BEEN RE-**
- 3 **CALLED, CORRECTED, OR REMOVED FROM**
- 4 **THE MARKET.**
- 5 (a) SUBMISSION OF INFORMATION BY PERSONS
- 6 SEEKING SUBSTANTIAL EQUIVALENCE DETERMINA-
- 7 TION.—Section 513(i) (21 U.S.C. 360c(i)) is amended—

1 (1) by redesignating paragraph (3) as para-  
2 graph (5); and

3 (2) by striking paragraph (2) and inserting the  
4 following:

5 “(2)(A) Any person seeking a determination of  
6 substantial equivalence under subsection (f) or sec-  
7 tion 520(1) for a device shall submit to the Secretary  
8 information (to the extent such information is read-  
9 ily available) on the market status of—

10 “(i) each predicate device; and

11 “(ii) each device in the full device lineage,  
12 as defined in subparagraph (C).

13 “(B) With respect to a device described in sub-  
14 paragraph (A), the information required to be sub-  
15 mitted under subparagraph (A) shall specify—

16 “(i) whether the device has been corrected  
17 or removed from the market;

18 “(ii) if the device has been corrected or re-  
19 moved from the market, the basis for such cor-  
20 rection or removal, including whether such cor-  
21 rection or removal was because of an intrinsic  
22 flaw in technology or design that adversely ef-  
23 fects safety and that can be reasonably found,  
24 rather than a correctable manufacturing flaw or  
25 labeling problem; and

1           “(iii) why the device for which a substan-  
2           tial equivalence determination is sought does  
3           not share any such intrinsic flaw.

4           “(C) DEVICE IN THE FULL DEVICE LINEAGE.—

5           In this paragraph, the term ‘device in the full device  
6           lineage’ means a device for which a substantial  
7           equivalence determination was made leading to a  
8           substantial equivalence determination for a predicate  
9           device referred to in subparagraph (A)(i).

10          “(3) The Secretary—

11           “(A) shall not find a device to be substan-  
12           tially equivalent to a predicate device that has  
13           been—

14           “(i) removed from the market at the  
15           initiative of the Secretary; or

16           “(ii) determined to be misbranded or  
17           adulterated by judicial order;

18           “(B) may reject a claim that a device is  
19           substantially equivalent to a predicate device  
20           if—

21           “(i) the predicate device, or any device  
22           in a series of one or more devices for which  
23           a substantial equivalence determination  
24           was made leading to a substantial equiva-  
25           lence determination for the predicate de-

1 vice, has been corrected or removed from  
2 the market because of an intrinsic flaw in  
3 technology or design that adversely effects  
4 safety—

5 “(I) at the initiative of the spon-  
6 sor; or

7 “(II) under any other cir-  
8 cumstance not covered by subpara-  
9 graph (A); and

10 “(ii) the correction or removal is due,  
11 in whole or in part, to an intrinsic flaw in  
12 technology or design that adversely affects  
13 safety;

14 “(C) may reject a claim that a device is  
15 substantially equivalent to a predicate device  
16 if—

17 “(i) the Secretary is in the process of  
18 rescinding the clearance granted under sec-  
19 tion 510(k), issuing or amending an order  
20 under section 518(e) (relating to recall au-  
21 thority), or taking any other regulatory ac-  
22 tion because of an intrinsic flaw in tech-  
23 nology or design that adversely affects  
24 safety, with respect to—

25 “(I) the predicate device; or

1                   “(II) any device in the full predi-  
2                   cate device lineage (meaning any de-  
3                   vice for which a substantial equiva-  
4                   lence determination was made leading  
5                   to a substantial equivalence deter-  
6                   mination for the predicate device); or

7                   “(ii) the manufacturer or importer of  
8                   a device described in subclause (I) or (II)  
9                   of clause (i) is in the process of correcting  
10                  or removing the device from the market;  
11                  and

12                  “(D) may reject a claim that a device is  
13                  substantially equivalent to a predicate device if  
14                  the predicate device has been corrected or re-  
15                  moved from the market because of an intrinsic  
16                  flaw in technology or design that adversely af-  
17                  fects safety and the manufacturer or importer  
18                  of the predicate failed to submit notice of such  
19                  correction or removal in accordance with section  
20                  519(g).”