

**AMENDMENT TO THE RULES COMMITTEE PRINT
FOR H.R. 6
OFFERED BY MR. FITZPATRICK OF
PENNSYLVANIA**

Page 211, after line 2, insert the following new section:

1 **SEC. 2229. PREDICATE DEVICES THAT HAVE BEEN RE-**
2 **CALLED, CORRECTED, OR REMOVED FROM**
3 **THE MARKET.**

4 (a) SUBMISSION OF INFORMATION BY PERSONS
5 SEEKING SUBSTANTIAL EQUIVALENCE DETERMINA-
6 TION.—Section 513(i) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 360c(i)) is amended—

8 (1) by redesignating paragraph (3) as para-
9 graph (4); and

10 (2) by striking paragraph (2) and inserting the
11 following:

12 “(2)(A) Any person seeking a determination of sub-
13 stantial equivalence under subsection (f) or section 520(l)
14 for a device shall submit to the Secretary information (to
15 the extent such information is readily available) on the
16 market status of—

17 “(i) each predicate device; and

1 “(ii) each device in the full device lineage (as
2 defined in subparagraph (C)).

3 “(B) With respect to each device described in clause
4 (i) or (ii) of subparagraph (A), the information required
5 to be submitted under subparagraph (A) shall specify—

6 “(i) whether the device has been corrected or
7 removed from the market;

8 “(ii) if so, the basis for such correction or re-
9 moval, including whether such correction or removal
10 was because of an intrinsic flaw in technology or de-
11 sign that adversely affects safety; and

12 “(iii) why the device for which a substantial
13 equivalence determination is sought does not share
14 any such intrinsic flaw.

15 “(C) In this paragraph, the term ‘device in the full
16 device lineage’ means a device for which a substantial
17 equivalence determination was made leading to a substan-
18 tial equivalence determination for a predicate device re-
19 ferred to in subparagraph (A)(i).”.

20 (b) REJECTING CLAIMS OF SUBSTANTIAL EQUIVA-
21 LENCE.—Section 513(i) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 360c(i)), as amended, is further
23 amended by inserting after paragraph (2) the following:

24 “(3) The Secretary—

1 “(A) shall not find a device to be substantially
2 equivalent to a predicate device that has been—

3 “(i) removed from the market at the initia-
4 tive of the Secretary; or

5 “(ii) determined to be misbranded or adul-
6 terated by judicial order;

7 “(B) may reject a claim that a device is sub-
8 stantially equivalent to a predicate device if—

9 “(i) the predicate device, or any device in
10 a series of one or more devices for which a sub-
11 stantial equivalence determination was made
12 leading to a substantial equivalence determina-
13 tion for the predicate device, has been corrected
14 or removed from the market—

15 “(I) at the initiative of the sponsor; or

16 “(II) under any other circumstance
17 not covered by subparagraph (A); and

18 “(ii) the correction or removal is due, in
19 whole or in part, to an intrinsic flaw in tech-
20 nology or design that adversely affects safety;

21 “(C) may reject a claim that a device is sub-
22 stantially equivalent to a predicate device if—

23 “(i) the Secretary is in the process of re-
24 scinding the clearance granted under section
25 510(k), issuing or amending an order under

1 section 518(e) (relating to recall authority), or
2 taking any other regulatory action because of
3 an intrinsic flaw in technology or design that
4 adversely affects safety, with respect to—

5 “(I) the predicate device; or

6 “(II) any device in the full predicate
7 device lineage (meaning any device for
8 which a substantial equivalence determina-
9 tion was made leading to a substantial
10 equivalence determination for the predicate
11 device); or

12 “(ii) the manufacturer or importer of a de-
13 vice described in subclause (I) or (II) of clause
14 (i) is in the process of correcting or removing
15 the device from the market; and

16 “(D) may reject a claim that a device is sub-
17 stantially equivalent to a predicate device if the
18 predicate device has been corrected or removed from
19 the market and the manufacturer or importer of the
20 predicate failed to submit notice of such correction
21 or removal in accordance with section 519(g).”.

