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:

SEC. 2229. PREDICATE DEVICES THAT HAVE BEEN RECALLED, CORRECTED, OR REMOVED FROM THE MARKET.

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

(1) by redesignating paragraph (3) as paragraph (4); and

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

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

“(i) each predicate device; and

“(ii) each predicate device that has been recalled, corrected, or removed from the market.”
“(ii) each device in the full device lineage (as defined in subparagraph (C)).

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

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

“(ii) if so, the basis for such correction or removal, including whether such correction or removal was because of an intrinsic flaw in technology or design that adversely affects safety; and

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

“(C) In this paragraph, the term ‘device in the full device lineage’ means a device for which a substantial equivalence determination was made leading to a substantial equivalence determination for a predicate device referred to in subparagraph (A)(i).”.

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

“(3) The Secretary—
“(A) shall not find a device to be substantially equivalent to a predicate device that has been—

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

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

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

“(i) the predicate device, or any device in a series of one or more devices for which a substantial equivalence determination was made leading to a substantial equivalence determination for the predicate device, has been corrected or removed from the market—

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

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

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

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

“(i) the Secretary is in the process of rescinding the clearance granted under section 510(k), issuing or amending an order under
section 518(e) (relating to recall authority), or
taking any other regulatory action because of
an intrinsic flaw in technology or design that
adversely affects safety, with respect to—

“(I) the predicate device; or

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

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

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