

**AMENDMENT TO  
RULES COMMITTEE PRINT 114-67  
OFFERED BY MR. FITZPATRICK OF  
PENNSYLVANIA**

Page 264, after line 23, insert the following sections:

1 **SEC. 3061. LIABILITY UNDER STATE AND LOCAL REQUIRE-**  
2 **MENTS RESPECTING DEVICES.**

3 (a) AMENDMENT.—Section 521 of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 360k) is amended by  
5 adding at the end the following:

6 “(c) NO EFFECT ON LIABILITY UNDER STATE  
7 LAW.—Nothing in this section shall be construed to mod-  
8 ify or otherwise affect any action for damages or the liabil-  
9 ity of any person under the law of any State.”.

10 (b) EFFECTIVE DATE; APPLICABILITY.—The amend-  
11 ment made by subsection (a) shall—

12 (1) take effect as if included in the enactment  
13 of the Medical Device Amendments of 1976 (Public  
14 Law 94–295); and

15 (2) apply to any civil action pending or filed on  
16 or after the date of enactment of this Act.

1 **SEC. 3062. REPORTING BY PHYSICIANS AND PHYSICIAN'S**  
2 **OFFICES ON CERTAIN ADVERSE EVENTS IN-**  
3 **VOLVING MEDICAL DEVICES.**

4 (a) **EXTENDING REQUIREMENTS TO APPLY TO PHY-**  
5 **SICIANS AND PHYSICIAN'S OFFICES.**—Subparagraph (A)  
6 of section 519(b)(6) of the Federal Food, Drug, and Cos-  
7 metic Act (21 U.S.C. 360i(b)(6)) is amended to read as  
8 follows:

9 “(A) The term ‘covered device user’ means  
10 a hospital, ambulatory surgical facility, nursing  
11 home, outpatient treatment facility, physician,  
12 or physician’s office. The Secretary may by reg-  
13 ulation include an outpatient diagnostic facil-  
14 ity.”.

15 (b) **CONFORMING AMENDMENTS.**—Section 519 of the  
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i)  
17 is amended—

18 (1) in subsection (b)—

19 (A) by striking “device user facility” each  
20 place it appears and inserting “covered device  
21 user”;

22 (B) by striking “the facility” each place it  
23 appears and inserting “the user”, except in the  
24 phrase “the facility, individual, or physician” in  
25 the matter following subparagraph (C) in para-  
26 graph (3);

1 (C) in paragraph (1)(D), by striking “that  
2 facility” and inserting “that user”;

3 (D) in paragraph (3)(B), by striking “such  
4 a facility” and inserting “such a user”; and

5 (E) in paragraph (5)—

6 (i) by striking “device user facilities”  
7 and inserting “covered device user”;

8 (ii) by striking “of user facilities” and  
9 inserting “of users”;

10 (iii) by striking “a user facility” and  
11 inserting “a user”; and

12 (2) in subsection (b)(3)—

13 (A) in subparagraph (A), by adding “or”  
14 at the end;

15 (B) in subparagraph (B), by striking “or”  
16 at the end;

17 (C) by striking subparagraph (C); and

18 (3) in subsection (e)(B)(ii), by striking “outside  
19 a device user facility” and inserting “by a person  
20 other than a covered device user (as defined in sub-  
21 section (b))”.

22 (c) APPLICABILITY.—The amendments made by this  
23 section apply beginning on the date that is 3 years after  
24 the date of enactment of this Act.

