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

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

SEC. 3061. LIABILITY UNDER STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES.

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

“(c) NO EFFECT ON LIABILITY UNDER STATE LAW.—Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.”.

(b) EFFECTIVE DATE; APPLICABILITY.—The amendment made by subsection (a) shall—

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

(2) apply to any civil action pending or filed on or after the date of enactment of this Act.
SEC. 3062. REPORTING BY PHYSICIANS AND PHYSICIAN’S OFFICES ON CERTAIN ADVERSE EVENTS INVOLVING MEDICAL DEVICES.

(a) Extending Requirements to Apply to Physicians and Physician’s Offices.—Subparagraph (A) of section 519(b)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(b)(6)) is amended to read as follows:

“(A) The term ‘covered device user’ means a hospital, ambulatory surgical facility, nursing home, outpatient treatment facility, physician, or physician’s office. The Secretary may by regulation include an outpatient diagnostic facility.”.

(b) Conforming Amendments.—Section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is amended—

(1) in subsection (b)—

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

(B) by striking “the facility” each place it appears and inserting “the user”, except in the phrase “the facility, individual, or physician” in the matter following subparagraph (C) in paragraph (3);
(C) in paragraph (1)(D), by striking “that facility” and inserting “that user”; (D) in paragraph (3)(B), by striking “such a facility” and inserting “such a user”; and (E) in paragraph (5)—

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

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

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

(2) in subsection (b)(3)—

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

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

(C) by striking subparagraph (C); and

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

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