AMENDMENT TO RULES COMMITTEE PRINT 115-10

OFFERED BY MR. FITZPATRICK OF PENNSYLVANIA

Page 7, line 19, strike ''A health care provider'' and insert the following: ''(a) IN GENERAL.—A health care provider''.

Page 7, insert after line 25 the following:

(b) EXCEPTION.—

(1) IN GENERAL.—This section does not apply in any health care lawsuit in which a health care provider does not report to the Food and Drug Administration about significant adverse experiences caused by medical devices in accordance with paragraph (2).

(2) REPORTING REQUIRED.—Beginning on the date that is 3 years after the date of enactment of this Act:

(A) Whenever a health care provider receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death

of a patient of the health care provider, the health care provider shall, as soon as practicable, but not later than 10 working days after becoming aware of the information, report the information to the Secretary of Health and Human Services and, if the identity of the manufacturer is known, to the manufacturer of the device.

(B) Whenever a health care provider receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to—

(i) the serious illness of, or serious injury to, a patient of the health care provider, or

(ii) other significant adverse experiences, as determined by the Secretary of Health and Human Services by rule to be necessary to be reported,

the health care provider shall, as soon as practicable, but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary of Health and Human

Services if the identity of the manufacturer is not known.

(3) DEFINITIONS.—In this subsection:

(A) The terms ''serious illness'' and ''serious injury'' mean illness or injury, respectively, that—

(i) is life threatening,

(ii) results in permanent impairment of a body function or permanent damage to a body structure, or

(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(B) The term ''device'' and ''medical device'' respectively, refer to—

(i) a class III device; or

(ii) a class II device that is permanently implantable, is life supporting, or is life sustaining.