AMENDMENT TO
RULES COMMITTEE PRINT 117–54
OFFERED BY MRS. DINGELL OF MICHIGAN

At the end of title LI of division E, insert the following new section:

SEC. 51___. GAO STUDY ON POST-MARKET SURVEILLANCE OF MEDICAL DEVICES BY DEPARTMENT OF VETERANS AFFAIRS.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the efforts of the Under Secretary of Veterans Affairs for Health relating to post-market surveillance of implantable medical devices.

(b) REPORT.—Not later than one year after the date of the enactment of this Act, the Comptroller General shall submit to the Committees on Veterans' Affairs of the House of Representatives and the Senate a report on the findings of the study under subsection (a). Such report shall include the following:

(1) A description of the process used by the Veterans Health Administration for documenting implantable medical devices issued to patients.

(2) An evaluation of the capability of the Veterans Health Administration to identify, in a timely

manner, adverse events and safety issues relating to implantable medical devices.

(3) An evaluation of the process for, and potential barriers to, the Under Secretary of Veterans Affairs for Health notifying patients of an implantable medical device recall.

(4) An evaluation of the accessibility of the adverse event reporting systems of the Veterans Health Administration for patients with disabilities.

(5) Recommendations to address gaps in such adverse event reporting systems, to better identify adverse events and safety issues from implantable medical devices.