TAM17917 S.L.C. Patty Murray

AMENDMENT NO. 2 Calendar No._____

Purpose: To clarify the process for the review of device applications with respect to postmarket activities.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

At the end of section 202, add the following:

(5) by amending subparagraph (J) of paragraph (9) (as redesignated by paragraph (1)) to read as follows:

"(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act and supporting pilot projects under section 519(i).".