TAM22472 R4W S.L.C.

AMENDMENT NO. 6 Calendar No._____

Purpose: To make improvements to the bill with respect to the use of real world evidence.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 3799

To prepare for, and respond to, existing viruses, emerging new threats, and pandemics.

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 Mr. MARSHALL + Ms. Smith

Viz:

Strike paragraph (2) of section 505 and insert the following:

(2) In the case of a device receiving an authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) for which the Secretary has determined, in accordance with subsection (m) of such section, that a laboratory examination or procedure associated with such device is deemed to be in the category of examinations and procedures described in section 353(d)(3) of the Public Health Service Act (42 U.S.C. 263a), such determination shall apply with regard to a sub-

mission pursuant to section 510(k), 513(f), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c(f), or 360e) for such device, unless the Secretary (taking into account any applicable conditions specified pursuant to subsection (m)(2) of section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3)) identifies new information not included in the request for authorization that indicates that the criteria under section 353(d)(3) of the Public Health Service Act (42 U.S.C. 263a(d)(3)) are not met.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as altering the review standards or otherwise affecting the requirements under section 505, 510(k), 513(f), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360c(f), or 360e) or under section 351 of the Public Health Service Act (42 U.S.C. 262) for the clearance or approval of a device, approval of a drug, or licensure of a biological product.