AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO THE COMMITTEE PRINT RELATING TO PUBLIC HEALTH

OFFERED BY M__. _____

Page 36, after line 22, add the following:

CHAPTER 8—FOOD AND DRUG ADMINISTRATION

SEC. 3071. USING EMERGENCY USE AUTHORIZATION DATA AND REAL WORLD EVIDENCE GATHERED DURING AN EMERGENCY TO SUPPORT PREMARKET DEVICE APPLICATIONS.

(a) IN GENERAL.—Data generated to support an authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) with respect to a device, and real world evidence relating to a device used pursuant to such authorization, may constitute valid scientific evidence, and shall be considered for purposes of—

(1) reviewing submissions pursuant to sections 510(k), 513(f), and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 21 U.S.C. 360(k), 360c(f), or 360e); and

(2) otherwise meeting the requirements of such Act.

(b) APPLICABILITY OF CERTAIN CATEGORIZATIONS FOR PREMARKET DEVICE REVIEW.—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. 262), such determination shall apply with regard to a submission pursuant to section 510(k), 513(f), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 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. 262) are not met.

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as altering the review standards or otherwise affecting the requirements under section 510(k), 513(f), or 515 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 21 U.S.C. 360(k), 360c(f), or 360e) for the clearance or approval of a device.

☒