117TH CONGRESS
1ST SESSION

S. 1508

To provide for the use of emergency use authorization data and real world evidence gathered during an emergency to support premarket applications for drugs, biological products, and devices, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 29, 2021

Mr. MARSHALL (for himself, Ms. SMITH, and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide for the use of emergency use authorization data and real world evidence gathered during an emergency to support premarket applications for drugs, biological products, and devices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. USING EMERGENCY USE AUTHORIZATION DATA AND REAL WORLD EVIDENCE GATHERED DURING AN EMERGENCY TO SUPPORT PREMARKET APPLICATIONS FOR DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

(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 drug, biological product, or device, and real world evidence relating to such drug, biological product, or device used pursuant to such authorization, may constitute valid scientific evidence, and shall be considered for purposes of—

(1) reviewing submissions pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and section 351 of the Public Health Service Act (42 U.S.C. 262);

(2) 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

(3) otherwise meeting the requirements of such Act and such section 351 of the Public Health Service Act.

(b) APPLICABILITY OF CERTAIN CATEGORIZATIONS FOR PREMARKET DEVICE REVIEW.—In the case of a de-

vice 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 505, 510(k), 513(f), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 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.

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