

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. USING EMERGENCY USE AUTHORIZATION DATA**
2 **AND REAL WORLD EVIDENCE GATHERED**
3 **DURING AN EMERGENCY TO SUPPORT PRE-**
4 **MARKET APPLICATIONS FOR DRUGS, BIO-**
5 **LOGICAL PRODUCTS, AND DEVICES.**

6 (a) IN GENERAL.—Data generated to support an au-
7 thorization under section 564 of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 360bbb–3) with respect to
9 a drug, biological product, or device, and real world evi-
10 dence relating to such drug, biological product, or device
11 used pursuant to such authorization, may constitute valid
12 scientific evidence, and shall be considered for purposes
13 of—

14 (1) reviewing submissions pursuant to section
15 505 of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 355) and section 351 of the Public
17 Health Service Act (42 U.S.C. 262);

18 (2) reviewing submissions pursuant to sections
19 510(k), 513(f), and 515 of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 21 U.S.C. 360(k),
21 360c(f), or 360e); and

22 (3) otherwise meeting the requirements of such
23 Act and such section 351 of the Public Health Serv-
24 ice Act.

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

1 vice receiving an authorization under section 564 of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 360bbb–3) for which the Secretary has determined, in ac-
4 cordance with subsection (m) of such section, that a lab-
5 oratory examination or procedure associated with such de-
6 vice is deemed to be in the category of examinations and
7 procedures described in section 353(d)(3) of the Public
8 Health Service Act (42 U.S.C. 262), such determination
9 shall apply with regard to a submission pursuant to sec-
10 tion 510(k), 513(f), or 515 of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 21 U.S.C. 360(k), 360c(f),
12 or 360e) for such device, unless the Secretary (taking into
13 account any applicable conditions specified pursuant to
14 subsection (m)(2) of section 564 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3)) identifies
16 new information not included in the request for authoriza-
17 tion that indicates that the criteria under section
18 353(d)(3) of the Public Health Service Act (42 U.S.C.
19 262) are not met.

20 (c) RULE OF CONSTRUCTION.—Nothing in this sec-
21 tion shall be construed as altering the review standards
22 or otherwise affecting the requirements under section 505,
23 510(k), 513(f), or 515 of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 21 U.S.C. 355, 360(k), 360c(f),
25 or 360e) or under section 351 of the Public Health Service

1 Act (42 U.S.C. 262) for the clearance or approval of a
2 device, approval of a drug, or licensure of a biological
3 product.

