

117TH CONGRESS  
1ST SESSION

# H. R. 4511

To amend the Federal Food, Drug, and Cosmetic Act to authorize 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.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 19, 2021

Mr. BURGESS (for himself and Ms. CRAIG) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA Advancing Col-  
5 lection of Transformative Science Act” or the “FACTS  
6 Act”.

1 **SEC. 2. 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 Section 564(k) of the Federal Food, Drug, and Cos-  
7 metic Act (21 U.S.C. 360bbb-3(k)) is amended—

8 (1) by striking “If a product” and inserting the  
9 following:

10 “(1) IN GENERAL.—If a product”; and

11 (2) by adding at the end the following:

12 “(2) DATA RELATING TO A DRUG, BIOLOGICAL  
13 PRODUCT, OR DEVICE GENERATED DURING EMER-  
14 GENCY USE.—Emergency use-related data submitted  
15 by a sponsor in an application for, or submission re-  
16 lating to, the approval, licensure, or clearance of a  
17 drug, biological product, or device may constitute  
18 valid scientific evidence or otherwise satisfy the  
19 standard of evidence for approval, licensure, or  
20 clearance of such drug, biological product, or device,  
21 and shall be considered for purposes of—

22 “(A) reviewing submissions and approving,  
23 licensing, or clearing such drug, biological prod-  
24 uct, or device pursuant to, as applicable, sec-  
25 tions 505, 510(k), 513(f), and 515 of this Act

1           and section 351 of the Public Health Service  
2           Act; and

3                   “(B) otherwise meeting the requirements  
4           of this Act or section 351 of the Public Health  
5           Service Act.

6           “(3) APPLICABILITY OF CERTAIN CATEGORIZA-  
7           TIONS FOR PREMARKET DEVICE REVIEW.—In the  
8           case of a device receiving an authorization under  
9           this section for which the Secretary has determined,  
10          in accordance with subsection (m), that a laboratory  
11          examination or procedure associated with such de-  
12          vice is deemed to be in the category of examinations  
13          and procedures described in section 353(d)(3) of the  
14          Public Health Service Act, such determination shall  
15          apply with regard to a submission pursuant to sec-  
16          tion 510(k), 513(f), or 515 for such device, unless  
17          the Secretary (taking into account any applicable  
18          conditions specified pursuant to subsection (m)(2) of  
19          this section) identifies new information not included  
20          in the request for authorization that indicates that  
21          the criteria under section 353(d)(3) of the Public  
22          Health Service Act are not met.

23                   “(4) RULE OF CONSTRUCTION.—Nothing in  
24          this subsection shall be construed as altering the re-  
25          view standards or otherwise affecting the require-

1       ments under section 505, 510(k), 513(f), or 515 of  
2       this Act, or section 351 of the Public Health Service  
3       Act for the approval, licensure, or clearance of a  
4       drug, biological product, or device.

5               “(5) EMERGENCY USE-RELATED DATA DE-  
6       FINED.—

7               “(A) IN GENERAL.—In this subsection, the  
8       term ‘emergency use-related data’ means—

9               “(i) data that is used to support the  
10       issuance of an authorization under this  
11       section with respect to a drug, biological  
12       product, or device;

13              “(ii) data generated during the period  
14       under which such authorization is in effect,  
15       with respect to such drug, biological prod-  
16       uct, or device; and

17              “(iii) real world evidence relating to  
18       such drug, biological product, or device  
19       used pursuant to such authorization.

20              “(B) EXCLUSION.—Such term does not in-  
21       clude data previously reviewed and determined  
22       to be inadequate or insufficient to support such  
23       an authorization.”.

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