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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.

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.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''FDA Advancing Collection of Transformative Science Act'' or the ''FACTS Act''.

SEC. 2. USING EMERGENCY USE AUTHORIZATION DATA AND REAL WORLD EVIDENCE GATHERED DURING AN EMERGENCY TO SUPPORT PREMARKET APPLICATIONS FOR DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.

Section 564(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3(k)) is amended—

(1) by striking ''If a product'' and inserting the following:

''(1) IN GENERAL.—If a product''; and

(2) by adding at the end the following:

''(2) DATA RELATING TO A DRUG, BIOLOGICAL PRODUCT, OR DEVICE GENERATED DURING EMERGENCY USE.—Emergency use-related data submitted by a sponsor in an application for, or submission relating to, the approval, licensure, or clearance of a drug, biological product, or device may constitute valid scientific evidence or otherwise satisfy the standard of evidence for approval, licensure, or clearance of such drug, biological product, or device, and shall be considered for purposes of—

''(A) reviewing submissions and approving, licensing, or clearing such drug, biological product, or device pursuant to, as applicable, sections 505, 510(k), 513(f), and 515 of this Act

and section 351 of the Public Health Service Act; and

"(B) otherwise meeting the requirements of this Act or section 351 of the Public Health Service Act.

"(3) APPLICABILITY OF CERTAIN CATEGORIZATIONS FOR PREMARKET DEVICE REVIEW.—In the case of a device receiving an authorization under this section for which the Secretary has determined, in accordance with subsection (m), 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, such determination shall apply with regard to a submission pursuant to section 510(k), 513(f), or 515 for such device, unless the Secretary (taking into account any applicable conditions specified pursuant to subsection (m)(2) of this section) 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 are not met.

"(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as altering the review standards or otherwise affecting the require-

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

''(5) EMERGENCY USE-RELATED DATA DEFINED.—

''(A) IN GENERAL.—In this subsection, the term 'emergency use-related data' means—

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

''(ii) data generated during the period under which such authorization is in effect, with respect to such drug, biological product, or device; and

''(iii) real world evidence relating to such drug, biological product, or device used pursuant to such authorization.

''(B) EXCLUSION.—Such term does not include data previously reviewed and determined to be inadequate or insufficient to support such an authorization.''.

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