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118TH CONGRESS
1ST SESSION

H. R. 3793

To amend the Federal Food, Drug, and Cosmetic Act to require manufacturers of life-saving drugs to submit data and information to assess the stability of the drugs and determine their longest supported expiration date, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 5, 2023

Ms. SLOTKIN 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 require manufacturers of life-saving drugs to submit data and information to assess the stability of the drugs and determine their longest supported expiration date, 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 ''Ensuring Access to Lifesaving Drugs Act of 2023''.

SEC. 2. EXTENDED EXPIRATION DATES FOR LIFE-SAVING DRUGS.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended by inserting after section 506L of such Act (21 U.S.C. 356l) the following new section:

"SEC. 506M. EXTENDED EXPIRATION DATES FOR LIFE-SAVING DRUGS.

''(a) IN GENERAL.—A manufacturer of a life-saving drug shall—

''(1) submit to the Secretary data and information as required by subsection (b)(1);

''(2) conduct and submit the results, data, and information generated by any studies required under subsection (b)(2); and

''(3) make any labeling change described in subsection (c) by the date specified by the Secretary pursuant to such subsection.

''(b) DATA AND INFORMATION.—

''(1) IN GENERAL.—The Secretary may issue an order requiring the manufacturer of a life-saving drug to submit, in such manner as the Secretary may prescribe, data and information from any stage of development of the drug that are adequate to assess the stability of the drug to determine the longest supported expiration date.

''(2) LACK OF DATA AND INFORMATION.—If the data and information required pursuant to an order issued under paragraph (1) are not available or are insufficient, as determined by the Secretary, the Secretary may issue an order requiring the manufacturer of the drug—

''(A) to conduct studies, which may be a continuation of ongoing studies, to provide data and information adequate to assess the stability of the drug and to determine the longest supported expiration date; and

''(B) to submit such data and information to the Secretary in such manner as the Secretary may prescribe in the order.

''(c) LABELING.—The Secretary may issue an order requiring the manufacturer of a life-saving drug, by a date determined by the Secretary in consultation with the sponsor of the drug, to make any labeling change regarding the expiration date or storage and handling of the drug that the Secretary determines to be appropriate based on the data and information required to be submitted under this section or any other data and information available to the Secretary.

''(d) DEFINITIONS.—In this section:

''(1) LIFE-SAVING DRUG.—The term 'life-saving drug' means a drug, that is—

''(A)(i) a medical countermeasure; or

''(ii) on the drug shortage list under section 506E or determined by the Secretary to be at risk of shortage; and

''(B)(i) life-supporting;

''(ii) life-sustaining; or

''(iii) intended for use in the prevention or treatment of a debilitating disease or condition in humans or animals, including any such drug used in emergency medical care or during surgery or any such drug that is critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.

''(2) MEDICAL COUNTERMEASURE.—The term 'medical countermeasure' means a countermeasure as defined in section 565(a).

''(e) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.''.

(b) PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 3503(a)(1)(A) of division FF of Public Law 117–328, is amended by inserting at the end the following new subsection:

''(jjj) The failure to comply with any order issued under section 506M.''.

(c) PENALTIES.—Subsection (b) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by inserting at the end the following:

''(9) If a manufacturer of a life-saving drug fails to submit data and information as required under section 506M(b)(1), fails to conduct or submit the data and information generated by studies as required under section 506M(b)(2), or fails to make a labeling change as required under section 506M(c), such manufacturer shall be subject to a civil penalty of not more than $10,000 for the first day on which the violation occurs and not more than $10,000 for each subsequent day on which the violation is not corrected.''.

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