II

118TH CONGRESS
1ST SESSION

S. 1122

To improve the program to provide for priority review of human drug applications to encourage treatment for agents that present national security threats.

IN THE SENATE OF THE UNITED STATES

MARCH 30, 2023

Ms. ERNST 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 improve the program to provide for priority review of human drug applications to encourage treatment for agents that present national security threats.

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 ''Prioritizing Medical Countermeasures for National Security Act of 2023''.

SEC. 2. EXTENSION AND EXPANSION OF MEDICAL COUNTERMEASURE PRIORITY REVIEW VOUCHER PROGRAM.

(a) DEFINITION OF MEDICAL COUNTERMEASURE APPLICATION.—Subsection (a)(4) of section 565A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4a) is amended—

(1) in the paragraph heading, by striking ''**MATERIAL THREAT MEDICAL**'' and inserting ''**MEDICAL**'';

(2) in the matter preceding subparagraph (A), by striking ''material threat''; and

(3) by amending subparagraph (A) to read as follows:

''(A) is a human drug application for a drug that is—

''(i) labeled for an indication to prevent or treat a disease or condition specifically caused by a chemical, biological, radiological, or nuclear agent; and

''(ii) part of a class or category of drug on the list described in subsection (b) at the time of approval of the application.''.

(b) LIST OF MEDICAL COUNTERMEASURES FOR NATIONAL SECURITY THREATS.—Section 565A of the Fed-

eral Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4a) is amended—

(1) by redesignating subsections (b) through (g) as subsections (c) through (g) and (i), respectively; and

(2) by inserting after subsection (a), the following:

''(b) LIST OF MEDICAL COUNTERMEASURES FOR NATIONAL SECURITY THREATS.—

''(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary of Preparedness and Response, in consultation with the Public Health Emergency Medical Enterprise established under section 2801 of the Public Health Service Act, including the Secretary of Defense, shall establish and maintain a list of potentially eligible classes and categories of drugs that are identified as necessary to prevent or treat the diseases and conditions specifically caused by a chemical, biological, radiological, or nuclear agent that—

''(A) has the potential to lead to a public health emergency with significant potential to affect national security; or

''(B) may present a specific threat to the Armed Forces.

''(2) FACTORS.—In establishing and revising the list under paragraph (1), the Secretary may consider—

''(A) whether an eligible class or category of drugs that is identified is—

''(i) needed to protect the public health, using the same standard that applies with respect to determinations of material threats under section 319F–2(c)(2)(B)(ii) of the Public Health Service Act; and

''(ii) determined to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002);

''(B) for any class or category of drugs under consideration to address specific threats to the Armed Forces, information provided by the Secretary of Defense to help evaluate whether a priority review voucher is necessary and beneficial to incentivize product development for the Department of Defense use and fielding;

''(C) whether the class or category of drug requires incentivization in the form a priority review voucher based upon economic factors,

such as whether there is a sufficient market to support the development of the potential medical countermeasures and the maturity of the medical countermeasure pipeline;

''(D) the potential effect of an addition of a class or category of drug on the potential sale value of priority review vouchers; and

''(E) such other factors as the Secretary determines appropriate.

''(3) DUTIES.—The Secretary, acting through the Assistant Secretary of Preparedness and Response, shall—

''(A) in coordination with the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Program, disclose to interested priority review applicants the list developed under paragraph (1);

''(B) periodically review the list developed under paragraph (1) for continued necessity and appropriateness, and add, amend, or remove any classes or categories of drugs if no longer necessary or appropriate; and

''(C) maintain a publicly available archive of the list over time.

''(4) TRANSITION PERIOD.—Before the date of the initial publication of the list developed under paragraph (1), the most recent priority list developed under this section before the date of enactment of the Prioritizing Medical Countermeasures for National Security Act of 2023 shall remain in effect.''.

(c) GAO REPORT.—Section 565A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4a) is amended by inserting after subsection (g), as redesignated by subsection (b)(1), the following:

''(h) GAO REPORT.—

''(1) IN GENERAL.—Not later than September 30, 2027, the Comptroller General of the United States shall transmit to Congress a report on the effectiveness of this section in encouraging the development of the medical countermeasures needed to protect and prepare for emerging threats to public health and national security.

''(2) CONTENTS.—The report shall include—

''(A) input from the Secretary of Defense and the Secretary of Health and Human Services; and

''(B) recommendations of the Comptroller General of the United States, if any, on necessary modifications to this section.''.

(d) SUNSET.—Subsection (i) of such section, as redesignated by subsection (b)(1) of this section, is amended—

(1) by striking ''subsection (b)'' and inserting ''subsection (c)''; and

(2) by striking ''October 1, 2023'' and inserting ''October 1, 2029''.

(e) CONFORMING AMENDMENTS TO REMOVE REFERENCES TO MATERIAL THREATS.—Section 565A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4a) is amended by striking ''material threat'' each place it appears in—

(1) subsection (a)(3);

(2) paragraphs (1) and (2) of subsection (c), as redesignated by subsection (b)(1); and

(3) subsection (f), as so redesignated.

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