

115TH CONGRESS
1ST SESSION

H. R. 4374

To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 13, 2017

Mr. WALDEN introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Armed Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, 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. ADDITIONAL EMERGENCY USES FOR MEDICAL**
2 **PRODUCTS TO REDUCE DEATHS AND SEVER-**
3 **ITY OF INJURIES CAUSED BY AGENTS OF**
4 **WAR.**

5 (a) FDA AUTHORIZATION FOR MEDICAL PRODUCTS
6 FOR USE IN EMERGENCIES.—Section 564 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is
8 amended—

9 (1) in subsection (b)—

10 (A) in paragraph (1), by amending sub-
11 paragraph (B) to read as follows:

12 “(B) a determination by the Secretary of
13 Defense that there is a military emergency, or
14 a significant potential for a military emergency,
15 involving a heightened risk to United States
16 military forces, including personnel operating
17 under the authority of title 10 or title 50,
18 United States Code, of attack with—

19 “(i) a biological, chemical, radio-
20 logical, or nuclear agent or agents; or

21 “(ii) an agent or agents that may
22 cause, or are otherwise associated with, an
23 imminently life-threatening and specific
24 risk to United States military forces;” and
25 (B) by adding at the end the following:

1 “(6) MILITARY EMERGENCIES.—In the case of
2 a determination described in paragraph (1)(B), the
3 Secretary shall determine, within 45 calendar days
4 of such determination, whether to make a declara-
5 tion under paragraph (1), and, if appropriate, shall
6 promptly make such a declaration.”; and

7 (2) in subsection (c)—

8 (A) in paragraph (3), by striking “; and”
9 and inserting “;”;

10 (B) by redesignating paragraph (4) as
11 paragraph (5); and

12 (C) by inserting after paragraph (3) the
13 following:

14 “(4) in the case of a determination described in
15 subsection (b)(1)(B)(ii), that the request for emer-
16 gency use is made by the Secretary of Defense;
17 and”.

18 (b) EMERGENCY USES FOR MEDICAL PRODUCTS.—

19 (1) IN GENERAL.—The Secretary of Defense
20 may request that the Secretary of Health and
21 Human Services, acting through the Commissioner
22 of Food and Drugs, take actions to expedite the de-
23 velopment of a medical product, review of investiga-
24 tional new drug applications under section 505(i) of
25 the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 355(i)), review of investigational device ex-
2 emptions under section 520(g) of such Act (21
3 U.S.C. 360j(g)), and review of applications for ap-
4 proval and clearance of medical products under sec-
5 tions 505, 510(k), and 515 of such Act (21 U.S.C.
6 355, 360(k), 360(e)) and section 351 of the Public
7 Health Service Act (42 U.S.C. 262), including appli-
8 cations for licensing of vaccines or blood as biologi-
9 cal products under such section 351, or applications
10 for review of regenerative medicine advanced therapy
11 products under section 506(g) of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 356(g)), if there
13 is a military emergency, or significant potential for
14 a military emergency, involving a specific and immi-
15 nently life-threatening risk to United States military
16 forces of attack with an agent or agents, and the
17 medical product that is the subject of such applica-
18 tion, submission, or notification would be reasonably
19 likely to diagnose, prevent, treat, or mitigate such
20 life-threatening risk.

21 (2) ACTIONS.—Upon a request by the Secretary
22 of Defense under paragraph (1), the Secretary of
23 Health and Human Services, acting through the
24 Commissioner of Food and Drugs, shall take action
25 to expedite the development and review of an appli-

1 cable application or notification with respect to a
2 medical product described in paragraph (1), which
3 may include, as appropriate—

4 (A) holding meetings with the sponsor and
5 the review team throughout the development of
6 the medical product;

7 (B) providing timely advice to, and inter-
8 active communication with, the sponsor regard-
9 ing the development of the medical product to
10 ensure that the development program to gather
11 the nonclinical and clinical data necessary for
12 approval or clearance is as efficient as prac-
13 ticable;

14 (C) involving senior managers and experi-
15 enced review staff, as appropriate, in a collabo-
16 rative, cross-disciplinary review;

17 (D) assigning a cross-disciplinary project
18 lead for the review team to facilitate an effi-
19 cient review of the development program and to
20 serve as a scientific liaison between the review
21 team and the sponsor;

22 (E) taking steps to ensure that the design
23 of the clinical trials is as efficient as prac-
24 ticable, when scientifically appropriate, such as

1 by minimizing the number of patients exposed
2 to a potentially less efficacious treatment;

3 (F) applying any applicable Food and
4 Drug Administration program intended to expedite the development and review of a medical
5 product; and
6

7 (G) in appropriate circumstances, permitting expanded access to the medical product
8 during the investigational phase, in accordance
9 with applicable requirements of the Food and
10 Drug Administration.
11

12 (3) ENHANCED COLLABORATION AND COMMUNICATION.—In order to facilitate enhanced collaboration and communication with respect to the most
13 current priorities of the Department of Defense—
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15 (A) the Food and Drug Administration
16 shall meet with the Department of Defense and
17 any other appropriate development partners,
18 such as the Biomedical Advanced Research and
19 Development Authority, on a semi-annual basis
20 for the purposes of conducting a full review of
21 the relevant products in the Department of Defense portfolio; and
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23 (B) the Director of the Center for
24 Biologics Evaluation and Research shall meet quar-
25

1 terly with the Department of Defense to discuss
2 the development status of regenerative medicine
3 advanced therapy, blood, and vaccine medical
4 products and projects that are the highest pri-
5 orities to the Department of Defense (which
6 may include freeze dried plasma products and
7 platelet alternatives),
8 unless the Secretary of Defense determines that any
9 such meetings are not necessary.

10 (4) MEDICAL PRODUCT.—In this subsection,
11 the term “medical product” means a drug (as de-
12 fined in section 201 of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 321)), a device (as defined
14 in such section 201), or a biological product (as de-
15 fined in section 351 of the Public Health Service Act
16 (42 U.S.C. 262)).

17 (c) REPEAL.—Effective as of the enactment of the
18 National Defense Authorization Act for Fiscal Year 2018,
19 subsection (d) of section 1107a of title 10, United States
20 Code, as added by section 716 of the National Defense
21 Authorization Act for Fiscal Year 2018, is repealed.

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