Purpose: To protect the warfighter by improving communication between the Food and Drug Administration and the Department of Defense, through timely development and review of medical products, and by strengthening the emergency use authority of the Food and Drug Administration.

H. R. 2810

To authorize appropriations for fiscal year 2018 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT INTENDED TO BE PROPOSED BY _____

Viz:

Strike section 732 and insert the following:

SEC. 732. ADDITIONAL EMERGENCY USES FOR MEDICAL PRODUCTS TO REDUCE DEATHS AND SEVERITY OF INJURIES CAUSED BY AGENTS OF WAR.

(a) Emergency Uses for Medical Products.—

(1) IN GENERAL.—The Secretary of Defense may request that the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, take actions to expedite the development of a medical product, review of investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)), review of investigational device exemptions under section 520(g) of such Act (21 U.S.C. 360j(g)), and review of applications for approval and clearance of medical products under sections 505, 510(k), and 515 of such Act (21 U.S.C. 355, 360(k), 360(e)) and section 351 of the Public Health Service Act (42 U.S.C. 262), including applications for licensing of vaccines or blood as biological products under such section 351, or applications for review of regenerative medicine advanced therapy products under section 506(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(g)), if there is a military emergency,

or significant potential for a military emergency, involving a specific and imminently life-threatening risk to United States military forces of attack with an agent or agents, and the medical product that is the subject of such application, submission, or notification would be reasonably likely to diagnose, prevent, treat, or mitigate such life-threatening risk.

(2) ACTIONS.—Upon a request by the Secretary of Defense under paragraph (1), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall take action to expedite the development and review of an applicable application or notification with respect to a medical product described in paragraph (1), which may include, as appropriate—

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

(B) providing timely advice to, and interactive communication with, the sponsor regarding the development of the medical product to ensure that the development program to gather the nonclinical and clinical data necessary for approval or clearance is as efficient as practicable;

(C) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(D) assigning a cross-disciplinary project lead for the review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor;

(E) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment;

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

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

(3) ENHANCED COLLABORATION AND COMMUNICATION.—In order to facilitate enhanced collaboration and communication with respect to the most current priorities of the Department of Defense—

(A) the Food and Drug Administration shall meet with the Department of Defense and any other appropriate development partners, such as the Biomedical Advanced Research and Development Authority, on a semi-annual basis for the purposes of conducting a full review of the relevant products in the Department of Defense portfolio; and

(B) the Director of the Center for Biologics Evaluation and Research shall meet quarterly with the Department of Defense to discuss the development status of regenerative medicine advanced therapy, blood, and vaccine medical products and projects that are the highest priorities to the Department of Defense (which may include freeze dried plasma products and platelet alternatives),

unless the Secretary of Defense determines that any such meetings are not necessary.

(4) MEDICAL PRODUCT.—In this subsection, the term "medical product" means a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)), a device (as defined in such section 201), or a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262)).

(b) FDA Authorization for Medical Products for Use in Emergencies.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended—

(1) in subsection (b)(1)(B), by amending subparagraph (B) to read as follows:

"(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with—

"(i) a biological, chemical, radiological, or nuclear agent or agents; or

"(ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;"; and

(2) in subsection (c)—

(A) in paragraph (3), by striking "; and" and inserting ";";

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

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

"(4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and".