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(Original Signature of Member)

116TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide enhanced security for the medical supply chain.

IN THE HOUSE OF REPRESENTATIVES

Mr. GALLAGHER introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide enhanced security for the medical supply chain.

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 ''Medical Supply Chain Security Act''.

SEC. 2. MEDICAL SUPPLY CHAIN SECURITY.

(a) ADDITIONAL MANUFACTURER REPORTING FOR ESSENTIAL MEDICAL DEVICES.—Section 506C of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by inserting ''or device'' after ''a drug''; and

(B) in the flush matter by inserting ''or device'' after ''drug'' each place such term appears;

(2) in subsection (c), by inserting ''and devices'' after ''drugs'';

(3) in subsection (g)—

(A) in the matter preceding paragraph (1), by striking ''drug shortage of a drug'' and inserting ''shortage of a drug or device'';

(B) in paragraph (1), by striking ''; or'' and inserting a semicolon;

(C) by redesignating paragraph (2) as paragraph (3);

(D) by inserting after paragraph (1) the following:

''(2) expedite the review of a device subject to premarket approval under section 515 that could help mitigate or prevent such shortage; or''; and

(E) in paragraph (3), as so redesignated, by striking ''drug shortage'' and inserting ''shortage'';

(4) in subsection (h)—

(A) by amending paragraph (2) to read as follows:

''(2) the term 'shortage', with respect to a drug or device, means a period of time when the demand or projected demand for the drug or device within the United States exceeds the supply of the drug or device; and''; and

(B) in paragraph (3)(A), by inserting ''or device'' after ''drug''; and

(5) by adding at the end the following:

''(j) ADDITIONAL MANUFACTURER REPORTING FOR ESSENTIAL DRUGS AND DEVICES.—Each manufacturer of a drug or device described in subsection (a) shall provide to the Food and Drug Administration, on an annual basis, or more frequently at the request of the Secretary, information related to the manufacturing capacity of such drug or device. Such information shall include—

''(1) details about—

''(A) all locations of production;

''(B) the sourcing of all component parts;

''(C) the sourcing of any active pharmaceutical ingredients; and

''(D) the use of any scarce raw materials; and

''(2) any other information determined by the Secretary to be relevant to the security of the supply chain of the drug or device.''.

(b) PROVISION OF ADDITIONAL INFORMATION.—Section 506C–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c–1) is amended—

(1) in the heading, by striking ''**DRUG SHORTAGES**'' and inserting ''**DRUG OR DEVICE SHORTAGES**'';

(2) by striking ''drug shortages'' each place it appears and inserting ''drug or device shortages'';

(3) in subsection (a)—

(A) in paragraph (3)(B)—

(i) in clause (i), by striking ''section 506C(g)(1)'' and inserting ''paragraph (1) or (2) of section 506C(g)''; and

(ii) in clause (ii), by striking ''section 506C(g)(2)'' and inserting ''section 506C(g)(3)''; and

(B) in paragraph (5), by striking ''drug shortage'' and inserting ''drug or device shortage''; and

(4) in subsection (c), by striking '' 'drug shortage' or''.