I

118TH CONGRESS
1ST SESSION

H. R. 3807

To amend the Federal Food, Drug, and Cosmetic Act with respect to device shortage notifications.

IN THE HOUSE OF REPRESENTATIVES

JUNE 5, 2023

Ms. CASTOR of Florida introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to device shortage notifications.

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 Device Shortage Reduction Act of 2023''.

SEC. 2. CLARIFYING DEVICE SHORTAGE NOTIFICATIONS.

Section 506J(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j(a)) is amended—

(1) in paragraph (2), by striking ''during, or in advance of, a public health emergency''; and

(2) in the matter following paragraph (2), by striking ", during, or in advance of, a public health emergency declared by the Secretary under section 319 of the Public Health Service Act,".

SEC. 3. SUPPLY CHAIN RISK MANAGEMENT.

(a) Section 506J of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j) is amended by striking subsection (h) and inserting the following:

"(h) RISK MANAGEMENT PLANS.—Each manufacturer of a device described in subsection (a) shall develop, maintain, and, as appropriate, implement a risk management plan that identifies and evaluates risks to the supply of the device, as applicable, for each establishment in which such device is manufactured. Such risk management plan—

"(1) may identify and evaluate risks to the supply of more than 1 device, or device category, manufactured at the same establishment; and

"(2) shall be subject to inspection and copying by the Secretary pursuant to section 704 or at the request of the Secretary.".

(b) CONFORMING AMENDMENT.—Section 506J(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j(f)) is amended by striking "or (h)" after "subsection (a)".

SEC. 4. CLARIFYING VOLUNTARY NOTIFICATIONS.

Section 506J(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356j(i)) is amended by adding at the end the following: ''Nothing in this section shall be construed to limit the authority of the Secretary to request that a manufacturer (or other person involved in the device supply chain) provide, on a voluntary basis, information to the Secretary or the authority of the Secretary to receive such information.''.

○