118TH CONGRESS
2D SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to expand drug shortage notification practices to include surges in demand for a drug, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. KAINE (for himself and Mr. COTTON) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to expand drug shortage notification practices to include surges in demand for a drug, and for other purposes.

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 ''End Drug Shortages Act''.

SEC. 2. DRUG SHORTAGE NOTIFICATION PRACTICES.

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

(1) in the section heading, by inserting ''**OR SURGE IN DEMAND FOR**'' after ''**PRODUCTION OF**'';

(2) in subsection (a), in the matter following paragraph (2)—

(A) by striking ''or an interruption of the manufacture of the drug'' and inserting '', an interruption of the manufacture of the drug, or a surge in demand for the drug'';

(B) by striking ''such discontinuance or interruption'' and inserting ''such discontinuance, interruption, or surge in demand'';

(C) by striking ''the discontinuation or interruption'' and inserting ''the discontinuation, interruption, or surge in demand''; and

(D) by striking ''such discontinuation or interruption; the expected duration of the interruption;'' and inserting ''such discontinuation, interruption, or surge in demand; the expected duration of the interruption or surge in demand'';

(3) in subsection (b), by striking paragraphs (1) and (2) and inserting the following:

''(1) in the case of a notice of a discontinuance or interruption in the manufacture of a drug—

''(A) at least 6 months prior to the date of the discontinuance or interruption; or

''(B) if compliance with subparagraph (A) is not possible, as soon as practicable; or

''(2) in the case of a notice of a surge in demand for a drug, as soon as practicable.'';

(4) in subsection (c)—

(A) by striking ''discontinuance or interruption'' and inserting ''discontinuance, interruption, or surge in demand''; and

(B) by inserting ''and outsourcing facilities (as defined in section 503B(d))'' after ''patient organizations''; and

(5) in subsection (h)—

(A) in paragraph (1), by striking ''and that is subject to section 503(b)(1)'' and inserting ''or the active pharmaceutical ingredient of such a drug'';

(B) by amending paragraph (2), to read as follows:

''(2) the term 'drug shortage' or 'shortage', with respect to a drug, means a period of time with the demand or projected demand for the drug within the United States exceeds the supply of the drug, taking into consideration—

"(A) how the drug is prepared or dispensed, including the route of administration and dosage form; and

"(B) information reported by manufacturers, health care professionals, and patients;";

(C) in paragraph (3)(B), by striking the period and inserting "; and"; and

(D) by adding at the end the following:

"(4) the term 'surge' means an increase in demand or projected demand for a drug that the manufacturer likely will be unable to meet without meaningful shortfall or delay.".

SEC. 3. OUTSOURCING FACILITY COMPOUNDING.

Section 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353b) is amended—

(1) by redesignating the 2 subsections (d) (relating to definitions and relating to obligation to pay fees) as subsections (e) and (f), respectively; and

(2) by inserting after subsection (c) the following:

"(d) LIST OF IDENTIFIED BULK DRUG SUBSTANCES.—The Secretary shall make publicly available annual updates on the evaluation of bulk drug substances for purposes of the list maintained under subsection (a)(2)(A)(i).".

SEC. 4. HOSPITAL AND HEALTH SYSTEM COMPOUNDING.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall finalize the draft guidance entitled ''Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry'' issued in October 2021, and ensure that such guidance is consistent with the most current research and best clinical practices for pharmacy compounding relating to implementing section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a).