116TH CONGRESS
2D SESSION

S. 3781

To increase reporting of, help mitigate potential shortages related to, and promote, accountability and transparency for pharmaceuticals and medical devices.

IN THE SENATE OF THE UNITED STATES

MAY 20, 2020

Mr. PETERS introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To increase reporting of, help mitigate potential shortages related to, and promote, accountability and transparency for pharmaceuticals and medical devices.

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 ''Pharmaceutical Accountability, Responsibility, and Transparency Act'' or the ''PART Act''.

SEC. 2. FDA INCREASED DEMAND REPORTING WITH RESPECT TO DRUGS.

Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c), as amended by the CARES Act (Public Law 116–136), is further amended—

(1) in subsections (c), (e), (f), (g), and (j), by inserting ''or (k)'' after ''subsection (a)'' each place such term appears; and

(2) by adding at the end the following:

''(k) INCREASED DEMAND REPORTING.—

''(1) IN GENERAL.—The manufacturer of a drug described in subsection (a) or a biological product subject to subsection (i)(3) shall notify the Secretary, in accordance with paragraph (2), of any—

''(A) increase in demand for the drug that the manufacturer likely will be unable to meet; or

''(B) export restrictions or other limitations imposed, on or after the date of enactment of the PART Act, on manufacturing or shipment of the drug or any of its active pharmaceutical ingredients by the country in which such drug or any such ingredient is manufactured.

''(2) TIMING.—A notice required under paragraph (1) shall be submitted to the Secretary as

soon as practicable but not later than 5 calendar days after the manufacturer becomes aware of the issue requiring notification under such paragraph.

''(3) NOTIFICATION OF RESOLUTION OF ISSUE.—A manufacturer of a drug who submits a notification to the Secretary under paragraph (1) shall notify the Secretary after the issue giving rise to such notification has been resolved or when the manufacturer is able to meet demand.''.

SEC. 3. FDA INCREASED DEMAND REPORTING WITH RESPECT TO DEVICES.

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

(1) in subsections (c), (e), and (f), by inserting ''or (j)'' after ''subsection (a)'' each place such term appears; and

(2) by adding at the end the following:

''(j) INCREASED DEMAND REPORTING.—

''(1) IN GENERAL.—The manufacturer of a device described in subsection (a) shall notify the Secretary, in accordance with paragraph (2), of any—

''(A) increase in demand for the device that the manufacturer likely will be unable to meet; or

''(B) export restrictions or other limitations imposed, on or after the date of enactment of the PART Act, on manufacturing or export of the device by the country in which such device or any component of the device is manufactured.

''(2) TIMING.—A notice required under paragraph (1) shall be submitted to the Secretary as soon as practicable but not later than 5 calendar days after the manufacturer becomes aware of the issue requiring notification under such paragraph.

''(3) NOTIFICATION OF RESOLUTION OF ISSUE.—A manufacturer of a device who submits a notification to the Secretary under paragraph (1) shall notify the Secretary after the issue giving rise to such notification has been resolved or when the manufacturer is able to meet demand.''.

SEC. 4. QUARTERLY MANUFACTURER REPORTING WITH RESPECT TO DRUGS AND DEVICES.

(a) REGISTRATION OF CERTAIN FOREIGN ESTABLISHMENTS.—Section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) is amended by inserting at the end the following new paragraph:

''(5) The requirements of paragraphs (1) and (2) shall apply to establishments within a foreign country en-

gaged in the manufacture, preparation, propagation, compounding, or processing of any drug, including the active pharmaceutical ingredient, or device that is required to be listed pursuant to subsection (j). Such requirements shall apply regardless of whether the drug, active pharmaceutical ingredient, or device undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment or establishments outside the United States prior to being imported or offered for import into the United States.''.

(b) LISTING OF DRUGS.—Section 510(j)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)(1)) is amended—

(1) in subparagraph (D), by striking ''and'' at the end;

(2) in subparagraph (E), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(F) in the case of a drug contained in the applicable list, a certification that the registrant has—

''(i) identified every other establishment where manufacturing is performed for the drug; and

''(ii) notified each known foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of the drug, including the active pharmaceutical ingredient, of the inclusion of the drug in the list and the obligation to register under subsection (i)(5).''.

(c) QUARTERLY REPORTING.—Paragraph (3) of section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)), as amended by the CARES Act (Public Law 116–136), is amended to read as follows:

''(3)(A) Subject to subparagraph (C) each person who registers with the Secretary under this section shall submit to the Secretary quarterly reports, in such electronic data format as the Secretary requires, containing the following information, as applicable, with respect to all drugs, drug substances, and devices manufactured, prepared, propagated, compounded, or processed at the establishment, whether for import into the United States or distribution in another country:

''(i) With respect to a finished drug product—

''(I) the number of dosage units manufactured at each establishment since the last report, broken down by—

''(aa) the number of dosage units manufactured at each establishment at which final manufacturing occurred, and the unique facility identifier of each such establishment;

''(bb) the number of dosage units from each such establishment that were distributed (or are intended to be distributed) for use in the United States and the number of dosage units that were distributed (or are intended to be distributed) for use outside of the United States; and

''(II) the sources of drug substances used in the manufacturing of the finished drug product, and, for each such source—

''(aa) the unique facility identifier of each source of drug substance; and

''(bb) the number of dosage units of the finished drug product manufactured using that drug substance from each source of drug substance; and

''(III) the National Drug Code number.

''(ii) With respect to a drug substance—

''(I) the amount of drug substance manufactured at each establishment since the last re-

port and the unique facility identifier of each such establishment;

''(II) the amount of the drug substance manufactured at each such establishment that was distributed (or are intended to be distributed) for use in the United States and the amount that was distributed (or are intended to be distributed) for use outside of the United States; and

''(III) the National Drug Code number.

''(iii) With respect to a device, the number of units manufactured at each establishment since the last report, broken down by—

''(I) the number of units manufactured at each establishment at which final manufacturing occurred, and the establishment identification number of each such establishment; and

''(II) the number of units from each such establishment that were distributed (or are intended to be distributed) for use in the United States and the number of units that were distributed (or are intended to be distributed) for use outside of the United States.

''(B) By order of the Secretary, certain biological products or categories of biological products may be exempt from some or all of the reporting requirements under subparagraph (A), if the Secretary determines, at the Secretary's sole discretion, that applying such reporting requirements to such biological products or categories is not necessary to protect the public health.

''(C) The determination of the appropriate structured electronic data format by the Secretary under subparagraph (A), whether to exempt certain biological products or categories of biological products under subparagraph (B), and the date on which reporting begins under this section shall be exempt from the requirements of section 553 of title 5, United States Code.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on September 23, 2020.

(e) CONFIDENTIALITY.—Nothing in the amendments made by this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 5. REQUIRING FDA TO SHARE MANUFACTURING INFORMATION WITH ASPR AND THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS.

(a) IN GENERAL.—Beginning as soon as practicable, but not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall provide to the Assistant Secretary for Preparedness and Response and the Assistant Secretary of Defense for Health Affairs all drug and device manufacturing data described in subsection (b), as appropriate and applicable, for any of the following purposes:

(1) Maintaining the strategic national stockpile under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b).

(2) Evaluating health infrastructure under the Division of Critical Infrastructure Protection of the Office of the Assistant Secretary for Preparedness and Response.

(3) Preparing for and responding to public health emergencies and national security concerns.

(4) Mitigating potential drug shortages.

(b) REPORTING PROVISIONS.—The drug and device manufacturing data required to be provided as described in subsection (a) includes—

(1) information reported by any manufacturer under subsection (a) or (k) of section 506C(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) or subsection (a) or (j) of section 506J of such Act (21 U.S.C. 356j);

(2) any risk management plan under section 506C(j) of such Act (21 U.S.C. 356c(j)) that is made available to the Secretary pursuant to such section;

(3) records or other information provided under section 704(a)(4) of such Act (21 U.S.C. 374(a)(4)); and

(4) to the extent not already provided, the locations where each drug that is a subject of a report or plan under paragraph (1), (2), or (3) is manufactured.

(c) MEMORANDA OF UNDERSTANDING.—The Commissioner of Food and Drugs and the Assistant Secretary for Preparedness and Response, and the Commissioner of Food and Drugs and the Assistant Secretary of Defense for Health Affairs, shall enter into memoranda of understanding to set forth the manner in which data will be shared under this section and the procedures for protecting any nonpublic data from further disclosure.

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