

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pharmaceutical Ac-
5 countability, Responsibility, and Transparency Act” or the
6 “PART Act”.

1 **SEC. 2. FDA INCREASED DEMAND REPORTING WITH RE-**
 2 **SPECT TO DRUGS.**

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

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

9 (2) by adding at the end the following:

10 “(k) INCREASED DEMAND REPORTING.—

11 “(1) IN GENERAL.—The manufacturer of a
 12 drug described in subsection (a) or a biological prod-
 13 uct subject to subsection (i)(3) shall notify the Sec-
 14 retary, in accordance with paragraph (2), of any—

15 “(A) increase in demand for the drug that
 16 the manufacturer likely will be unable to meet;
 17 or

18 “(B) export restrictions or other limita-
 19 tions imposed, on or after the date of enact-
 20 ment of the PART Act, on manufacturing or
 21 shipment of the drug or any of its active phar-
 22 maceutical ingredients by the country in which
 23 such drug or any such ingredient is manufac-
 24 tured.

25 “(2) TIMING.—A notice required under para-
 26 graph (1) shall be submitted to the Secretary as

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

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

10 **SEC. 3. FDA INCREASED DEMAND REPORTING WITH RE-**
 11 **SPECT TO DEVICES.**

12 Section 506J of the Federal Food, Drug, and Cos-
 13 metic Act (21 U.S.C. 356c) is amended—

14 (1) in subsections (c), (e), and (f), by inserting
 15 “or (j)” after “subsection (a)” each place such term
 16 appears; and

17 (2) by adding at the end the following:

18 “(j) INCREASED DEMAND REPORTING.—

19 “(1) IN GENERAL.—The manufacturer of a de-
 20 vice described in subsection (a) shall notify the Sec-
 21 retary, in accordance with paragraph (2), of any—

22 “(A) increase in demand for the device
 23 that the manufacturer likely will be unable to
 24 meet; or

1 “(B) export restrictions or other limita-
 2 tions imposed, on or after the date of enact-
 3 ment of the PART Act, on manufacturing or
 4 export of the device by the country in which
 5 such device or any component of the device is
 6 manufactured.

7 “(2) TIMING.—A notice required under para-
 8 graph (1) shall be submitted to the Secretary as
 9 soon as practicable but not later than 5 calendar
 10 days after the manufacturer becomes aware of the
 11 issue requiring notification under such paragraph.

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

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

20 (a) REGISTRATION OF CERTAIN FOREIGN ESTAB-
 21 LISHMENTS.—Section 510(i) of the Federal Food, Drug,
 22 and Cosmetic Act (21 U.S.C. 360(i)) is amended by in-
 23 serting at the end the following new paragraph:

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

1 gaged in the manufacture, preparation, propagation, com-
 2 pounding, or processing of any drug, including the active
 3 pharmaceutical ingredient, or device that is required to be
 4 listed pursuant to subsection (j). Such requirements shall
 5 apply regardless of whether the drug, active pharma-
 6 ceutical ingredient, or device undergoes further manufac-
 7 ture, preparation, propagation, compounding, or proc-
 8 essing at a separate establishment or establishments out-
 9 side the United States prior to being imported or offered
 10 for import into the United States.”.

11 (b) LISTING OF DRUGS.—Section 510(j)(1) of the
 12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 13 360(j)(1)) is amended—

14 (1) in subparagraph (D), by striking “and” at
 15 the end;

16 (2) in subparagraph (E), by striking the period
 17 at the end and inserting “; and”; and

18 (3) by adding at the end the following new sub-
 19 paragraph:

20 “(F) in the case of a drug contained in the ap-
 21 plicable list, a certification that the registrant has—

22 “(i) identified every other establishment
 23 where manufacturing is performed for the drug;
 24 and

1 “(ii) notified each known foreign establish-
 2 ment engaged in the manufacture, preparation,
 3 propagation, compounding, or processing of the
 4 drug, including the active pharmaceutical ingre-
 5 dient, of the inclusion of the drug in the list
 6 and the obligation to register under subsection
 7 (i)(5).”.

8 (c) QUARTERLY REPORTING.—Paragraph (3) of sec-
 9 tion 510(j) of the Federal Food, Drug, and Cosmetic Act
 10 (21 U.S.C. 360(j)), as amended by the CARES Act (Pub-
 11 lic Law 116–136), is amended to read as follows:

12 “(3)(A) Subject to subparagraph (C) each person
 13 who registers with the Secretary under this section shall
 14 submit to the Secretary quarterly reports, in such elec-
 15 tronic data format as the Secretary requires, containing
 16 the following information, as applicable, with respect to
 17 all drugs, drug substances, and devices manufactured, pre-
 18 pared, propagated, compounded, or processed at the estab-
 19 lishment, whether for import into the United States or dis-
 20 tribution in another country:

21 “(i) With respect to a finished drug product—

22 “(I) the number of dosage units manufac-
 23 tured at each establishment since the last re-
 24 port, broken down by—

1 “(aa) the number of dosage units
2 manufactured at each establishment at
3 which final manufacturing occurred, and
4 the unique facility identifier of each such
5 establishment;

6 “(bb) the number of dosage units
7 from each such establishment that were
8 distributed (or are intended to be distrib-
9 uted) for use in the United States and the
10 number of dosage units that were distrib-
11 uted (or are intended to be distributed) for
12 use outside of the United States; and

13 “(II) the sources of drug substances used
14 in the manufacturing of the finished drug prod-
15 uct, and, for each such source—

16 “(aa) the unique facility identifier of
17 each source of drug substance; and

18 “(bb) the number of dosage units of
19 the finished drug product manufactured
20 using that drug substance from each
21 source of drug substance; and

22 “(III) the National Drug Code number.

23 “(ii) With respect to a drug substance—

24 “(I) the amount of drug substance manu-
25 factured at each establishment since the last re-

1 port and the unique facility identifier of each
2 such establishment;

3 “(II) the amount of the drug substance
4 manufactured at each such establishment that
5 was distributed (or are intended to be distrib-
6 uted) for use in the United States and the
7 amount that was distributed (or are intended to
8 be distributed) for use outside of the United
9 States; and

10 “(III) the National Drug Code number.

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

14 “(I) the number of units manufactured at
15 each establishment at which final manufac-
16 turing occurred, and the establishment identi-
17 fication number of each such establishment;
18 and

19 “(II) the number of units from each such
20 establishment that were distributed (or are in-
21 tended to be distributed) for use in the United
22 States and the number of units that were dis-
23 tributed (or are intended to be distributed) for
24 use outside of the United States.

1 “(B) By order of the Secretary, certain biological
2 products or categories of biological products may be ex-
3 empt from some or all of the reporting requirements under
4 subparagraph (A), if the Secretary determines, at the Sec-
5 retary’s sole discretion, that applying such reporting re-
6 quirements to such biological products or categories is not
7 necessary to protect the public health.

8 “(C) The determination of the appropriate structured
9 electronic data format by the Secretary under subpara-
10 graph (A), whether to exempt certain biological products
11 or categories of biological products under subparagraph
12 (B), and the date on which reporting begins under this
13 section shall be exempt from the requirements of section
14 553 of title 5, United States Code.”.

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

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

1 **SEC. 5. REQUIRING FDA TO SHARE MANUFACTURING IN-**
2 **FORMATION WITH ASPR AND THE ASSISTANT**
3 **SECRETARY OF DEFENSE FOR HEALTH AF-**
4 **FAIRS.**

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

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

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

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

23 (4) Mitigating potential drug shortages.

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

1 (1) information reported by any manufacturer
2 under subsection (a) or (k) of section 506C(a) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 356c) or subsection (a) or (j) of section 506J of
5 such Act (21 U.S.C. 356j);

6 (2) any risk management plan under section
7 506C(j) of such Act (21 U.S.C. 356c(j)) that is
8 made available to the Secretary pursuant to such
9 section;

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

13 (4) to the extent not already provided, the loca-
14 tions where each drug that is a subject of a report
15 or plan under paragraph (1), (2), or (3) is manufac-
16 tured.

17 (c) MEMORANDA OF UNDERSTANDING.—The Com-
18 missioner of Food and Drugs and the Assistant Secretary
19 for Preparedness and Response, and the Commissioner of
20 Food and Drugs and the Assistant Secretary of Defense
21 for Health Affairs, shall enter into memoranda of under-
22 standing to set forth the manner in which data will be
23 shared under this section and the procedures for pro-
24 tecting any nonpublic data from further disclosure.

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