

118TH CONGRESS
1ST SESSION

S. 2586

To address prescription drug shortages and improve the quality of prescription drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 27, 2023

Mr. CARDIN (for himself, Ms. SMITH, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To address prescription drug shortages and improve the quality of prescription drugs, and for other purposes.

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 “Drug Shortages Pre-
5 vention and Quality Improvement Act”.

6 **SEC. 2. LENGTHEN EXPIRATION DATES TO MITIGATE CRIT-**
7 **ICAL DRUG SHORTAGES.**

8 (a) IN GENERAL.—The Federal Food, Drug, and
9 Cosmetic Act is amended by inserting after section 506C–
10 1 (21 U.S.C. 356c–1) the following:

1 **“SEC. 506C-2. EXTENDED EXPIRATION DATES FOR LIFE-**
2 **SAVING DRUGS.**

3 “(a) IN GENERAL.—A manufacturer of a life-saving
4 drug shall—

5 “(1) submit to the Secretary data and informa-
6 tion as required by subsection (b)(1);

7 “(2) conduct and submit the results, data, and
8 information of any studies required under subsection
9 (b)(2); and

10 “(3) make any labeling change described in
11 subsection (c) by the date specified by the Secretary
12 pursuant to such subsection.

13 “(b) NOTIFICATION.—

14 “(1) IN GENERAL.—The Secretary may issue
15 an order requiring the manufacturer of any life-sav-
16 ing drug to submit, in such manner as the Secretary
17 may prescribe, data and information from any stage
18 of development of the drug that are adequate to as-
19 sess the stability of the drug to determine the long-
20 est supported expiration date.

21 “(2) UNAVAILABLE OR INSUFFICIENT DATA
22 AND INFORMATION.—If the data and information re-
23 quired pursuant to an order issued under paragraph
24 (1) are not available or are insufficient, the Sec-
25 retary may require the manufacturer of the drug
26 to—

1 “(A) conduct studies adequate to provide
2 the data and information in accordance with
3 section 211.166 of title 21, Code of Federal
4 Regulations (or any successor regulations); and

5 “(B) submit to the Secretary the results,
6 data, and information generated by such studies
7 when available.

8 “(c) LABELING.—The Secretary may issue an order
9 requiring the manufacturer of a life-saving drug to, by a
10 specified date, make any labeling change regarding the ex-
11 piration date that the Secretary determines to be appro-
12 priate based on the data and information required to be
13 submitted under this section in accordance with labeling
14 requirements under subparts F and G of part 211 of title
15 21, Code of Federal Regulations (or any successor regula-
16 tions) or any other data and information available to the
17 Secretary.

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

24 “(e) DEFINITION.—In this section, the term ‘life-sav-
25 ing drug’ means a drug described in section 506C(a).”.

1 (b) CIVIL MONETARY PENALTY.—Section 303(b) of
 2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 3 333(b)) is amended by adding at the end the following:

4 “(9)(A) If a manufacturer fails to submit data and
 5 information as required under section 506C–2(b)(1), fails
 6 to conduct or submit the results, data, and information
 7 generated by studies as required under section 506C–
 8 2(b)(3), or fails to make a labeling change as required
 9 under section 506C–2(c), such manufacturer shall be lia-
 10 ble to the United States for a civil penalty in an amount
 11 not to exceed \$10,000 for each such violation.

12 “(B) If a violation described in subparagraph (A) is
 13 not corrected within the 30-day period following notifica-
 14 tion by the Secretary of a violation described in subpara-
 15 graph (A), the manufacturer shall, in addition to any pen-
 16 alty under subparagraph (A), be subject to a civil mone-
 17 tary penalty of not more than \$10,000 for each day of
 18 the violation after such period until the violation is cor-
 19 rected.”.

20 **SEC. 3. REPORTING ON INCREASES IN DEMAND FOR A**
 21 **DRUG.**

22 (a) IN GENERAL.—Section 506C of the Federal
 23 Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amend-
 24 ed—

1 (1) in the section heading, by inserting “**OR IN-**
 2 **CREASE IN DEMAND FOR**” after “**PRODUCTION**
 3 **OF**”;

4 (2) in subsection (a), in the matter following
 5 paragraph (2), by striking “drug, and the reasons
 6 for such discontinuance or interruption” and insert-
 7 ing “drug, or increase in the demand for such drug
 8 that is likely to lead to a shortage of the drug, and
 9 the reasons for such discontinuance, interruption, or
 10 increase in demand”;

11 (3) in subsection (b)—

12 (A) in paragraph (1), by striking “; or”
 13 and inserting a semicolon;

14 (B) by redesignating paragraph (2) as
 15 paragraph (3);

16 (C) by inserting after paragraph (1) the
 17 following:

18 “(2) in the case of an increase in the demand
 19 for a drug, not later than 30 days after the manu-
 20 facture has knowledge of such increase; or”; and

21 (D) in paragraph (3), as so redesignated,
 22 by striking “paragraph (1)” and inserting
 23 “paragraph (1) or (2)”; and

24 (4) in subsection (c), by inserting “, or increase
 25 in demand for,” after “the manufacture of”.

1 (b) PROHIBITED ACT.—

2 (1) IN GENERAL.—Section 301 of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is
4 amended by adding at the end the following:

5 “(jjj) The failure to notify the Secretary as required
6 under section 506C(a).”.

7 (2) ENFORCEMENT.—Section 303 of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C.
9 333(c)) is amended—

10 (A) in paragraph (c), by adding before the
11 period at the end the following: “; or (7) for
12 having violated section 301(jjj) if such person
13 acted in good faith and had a reasonable basis
14 for not notifying as required under section
15 506C”; and

16 (B) by adding at the end the following:

17 “(h) Notwithstanding subsection (a), any manufac-
18 turer who violates section 301(jjj) shall be subject to a
19 civil penalty in an amount not to exceed \$50,000 per viola-
20 tion.”.

1 **SEC. 4. SUPPORTING CONTINUOUS MANUFACTURING TO**
 2 **PREVENT SHORTAGES FOR SUSCEPTIBLE**
 3 **DRUGS.**

4 (a) IN GENERAL.—Subtitle B of title III of the 21st
 5 Century Cures Act is amended by inserting after section
 6 3016 (21 U.S.C. 399h) the following:

7 **“SEC. 3017. GRANTS FOR CONTINUOUS MANUFACTURING**
 8 **TO PREVENT DRUG SHORTAGES.**

9 “(a) IN GENERAL.—The Secretary of Health and
 10 Human Services shall solicit and, beginning not later than
 11 one year after the date of enactment of the Drug Short-
 12 ages Prevention and Quality Improvement Act, receive, re-
 13 quests for grants from institutions of higher education or
 14 nonprofit entities engaged in the manufacture of sterile
 15 injectable drugs for the purpose of upgrading drug estab-
 16 lishment to continuous manufacturing or other advanced
 17 manufacturing capabilities.

18 “(b) GRANT CRITERIA.—An institution of higher
 19 education or a nonprofit entity shall be eligible for a grant
 20 under this section if such institution or entity manufac-
 21 tures a drug that—

22 “(1) is categorized as an essential medicine
 23 under Executive Order 13944;

24 “(2) is a sterile injectable drug; and

1 “(3) is vulnerable to shortage, including as de-
 2 termined through notifications submitted to the Sec-
 3 retary under section 506C.

4 “(c) GRANT SELECTION.—As a condition for accept-
 5 ing a grant under this section, an institution of higher
 6 education and nonprofit entity shall agree to develop and
 7 carrying out a robust plan focused on sustainability of the
 8 continuous manufacturing or other advanced manufac-
 9 turing capabilities supported by the grant.

10 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
 11 carry out this section, in addition to amounts otherwise
 12 made available for such purposes, there is authorized to
 13 be appropriated \$1,000,000,000 for the period of fiscal
 14 years 2024 through 2029.

15 “(e) DEFINITIONS.—In this section:

16 “(1) ADVANCED MANUFACTURING.—The term
 17 ‘advanced manufacturing’ means an approach for
 18 the manufacturing of drugs that incorporates novel
 19 technology, or uses an established technique or tech-
 20 nology in a new or innovative that enhances drug
 21 quality or improves the manufacturing process.

22 “(2) CONTINUOUS MANUFACTURING.—The
 23 term ‘continuous manufacturing’—

24 “(A) means a process where the input ma-
 25 terials are continuously fed into and trans-

1 formed within the process, and the processed
2 output materials are continuously removed from
3 the system; and

4 “(B) consists of an integrated process that
5 consists of a series of 2 or more unit oper-
6 ations.

7 “(3) STERILE INJECTABLE DRUG.—The term
8 ‘sterile injectable drug’ means a drug approved
9 under section 505 of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 355), a biological product
11 licensed under section 351 of the Public Health
12 Service Act (42 U.S.C. 262), or a combination prod-
13 uct (as described in section 503(g) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 353(g))
15 whose primary mode of action is that of a drug or
16 biological product, that is intended for injection for
17 intravenous use of infusion and whose manufac-
18 turing, distribution, and administration processes re-
19 quire sterile conditions.”.

20 (b) GAO STUDY ON QUALITY MANAGEMENT PUR-
21 CHASING.—The Comptroller General of the United States
22 shall conduct a study on including quality management
23 maturity as a factor in prescription drug purchasing by
24 Federal health care programs (as defined in section
25 1128B(f) of the Social Security Act (42 U.S.C. 1320a–

1 7b(f))), and not later than 2 years after the date of enact-
 2 ment of this Act, shall submit a report on such study to
 3 Congress.

4 **SEC. 5. AUTHORITY TO USE ALTERNATIVE PAYMENT**
 5 **UNDER THE MEDICARE PROGRAM FOR**
 6 **DRUGS AND BIOLOGICALS TO PREVENT PO-**
 7 **TENTIAL DRUG SHORTAGES.**

8 (a) PAYMENT UNDER PART B.—Section 1847A(e) of
 9 the Social Security Act (42 U.S.C. 1395w–3a(e)) is
 10 amended—

11 (1) by striking “PAYMENT IN RESPONSE TO
 12 PUBLIC HEALTH EMERGENCY.—In the case” and
 13 inserting “PAYMENTS.—

14 “(1) IN RESPONSE TO PUBLIC HEALTH EMER-
 15 GENCY.—In the case”; and

16 (2) by adding at the end the following new
 17 paragraph:

18 “(2) PREVENTING POTENTIAL DRUG SHORT-
 19 AGES.—

20 “(A) IN GENERAL.—In the case of a drug
 21 or biological described in subparagraph (B), the
 22 Secretary may use the wholesale acquisition
 23 cost (or other reasonable measure of a drug or
 24 biological price) instead of the manufacturer’s
 25 average sales price for quarters beginning on or

1 after the date on which the Secretary deter-
2 mines the drug or biological is described in such
3 subparagraph and for subsequent quarters until
4 the end of the quarter in which such drug or
5 biological is removed from the drug shortage
6 list under section 506E of the Federal Food,
7 Drug, and Cosmetic Act, or in the case of a
8 drug or biological described in subparagraph
9 (B)(ii)(II), the date on which the Secretary de-
10 termines the manufacturing capacity or the
11 number of manufacturers of such drug or bio-
12 logical is sufficient to prevent a potential short-
13 age of the drug or biological.

14 “(B) DRUG OR BIOLOGICAL DESCRIBED.—
15 For purposes of subparagraph (A), a drug or
16 biological described in this subparagraph is a
17 drug or biological—

18 “(i) that is life-supporting, life-sus-
19 taining, or intended for use in the preven-
20 tion or treatment of a debilitating disease
21 or condition (as those terms are defined
22 for purposes of section 506C of the Fed-
23 eral Food, Drug, and Cosmetic Act and is
24 subject to the reporting requirements
25 under section 506C(b) of such Act), in-

cluding any such drug or biological that is
used in emergency medical care or during
surgery; and

“(ii)(I) that is listed on the drug and
biological shortage list maintained by the
Food and Drug Administration pursuant
to section 506E of the Federal Food,
Drug, and Cosmetic Act, and for which the
manufacturer of such drug or biological
notifies the Secretary of a permanent dis-
continuance or an interruption that is like-
ly to lead to a meaningful disruption in the
manufacturer’s supply of that drug or bio-
logical pursuant to section 506C(b)(1) of
such Act; or

“(II) that was listed on such drug and
biological shortage list within the preceding
5 years and for which the manufacturing
capacity of manufacturers with an ap-
proved application for such drug or biologi-
cal, or the number of manufacturers with
an approved application for such drug or
biological, declines during a 6-month pe-
riod, as determined by the Secretary.

1 “(C) PROVISION OF ADDITIONAL INFORMA-
2 TION.—For each quarter in which the amount
3 of payment for a drug or biological described in
4 subparagraph (B) pursuant to subparagraph
5 (A) exceeds the amount of payment for the
6 drug or biological otherwise applicable under
7 this section, the manufacturer of such drug or
8 biological shall provide to the Secretary infor-
9 mation related to the potential cause or causes
10 of the shortage and the expected length of the
11 shortage with respect to such drug.”.

12 (b) ADDITIONAL PAYMENT UNDER IPPS.—Section
13 1886(d)(5) of the Social Security Act (42 U.S.C.
14 1395ww(d)(5)) is amended by adding at the end the fol-
15 lowing new subparagraph:

16 “(N) The Secretary shall establish a modifier or other
17 mechanism for purposes of tracking utilization of drugs
18 on the shortage list pursuant to section 506E of the Fed-
19 eral Food, Drug, and Cosmetic Act, and update the modi-
20 fier to reflect the drugs on such list each calendar year.”.

21 (c) GAO STUDY ON DRUG SHORTAGES.—Not later
22 than 2 years after the date of enactment of this Act, the
23 Comptroller General of the United States shall—

24 (1) conduct a study on—

1 (A) drugs and biologicals for which pay-
2 ment is made under the inpatient prospective
3 payment system (IPPS) under section 1886 of
4 the Social Security Act (42 U.S.C. 1395ww)
5 and the hospital outpatient prospective payment
6 system (OPPS) under section 1833(t) of the
7 Social Security Act (42 U.S.C. 1395l(t)) that
8 have been on the shortage list under section
9 506E of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 356e(c)(2)) in the last 5 years;
11 and

12 (B) whether any changes to payment
13 under such payment systems would decrease—

14 (i) the number of drugs and
15 biologicals on such shortage list; or

16 (ii) the frequency with which the
17 drugs and biologicals appear on such
18 shortage list; and

19 (2) submit to Congress recommendations for
20 legislation and administrative actions with respect to
21 the matters described in subparagraphs (A) and (B)
22 of paragraph (1).

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