

117TH CONGRESS
1ST SESSION

S. 2595

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

IN THE SENATE OF THE UNITED STATES

AUGUST 4, 2021

Mr. CARDIN (for himself and Ms. SMITH) 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 SHELF LIFE DATES FOR ESSEN-**
2 **TIAL DRUGS.**

3 “(a) IN GENERAL.—A manufacturer of a drug sub-
4 ject to notification requirements under section 506C(a)
5 (referred to in this section as an ‘essential drug’) shall—

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

8 “(2) conduct and submit the results of any
9 studies required under subsection (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 essential
16 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 shelf life stability of the drug to determine
20 the longest 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 an essential drug to, by a
10 specified date, make any labeling change regarding the ex-
11 piration period that the Secretary determines to be appro-
12 priate based on the data and information required to be
13 submitted under this section or any other data and infor-
14 mation available to the Secretary in accordance with label-
15 ing requirements under subpart G of part 211 of title 21,
16 Code of Federal Regulations (or any successor regula-
17 tions).

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.”.

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) If a drug manufacturer fails to submit data and
5 information as required under section 506C–2(b)(1), fails
6 to conduct or submit the results of studies as required
7 under section 506C–2(b)(3), or fails to make a labeling
8 change as required under section 506C–2(c), such manu-
9 facturer shall be liable to the United States for a civil pen-
10 alty in an amount not to exceed \$10,000 for each such
11 violation.”.

12 (c) GAO STUDY OF SHELF LIFE DATA.—Not later
13 than 2 years after the date of enactment of this Act, the
14 Comptroller General of the United States shall conduct
15 a study examining the process by which prescription drug
16 manufacturers submit data on shelf life to the Food and
17 Drug Administration. In carrying out this study, the
18 Comptroller General shall consider whether manufacturers
19 adequately test the shelf life stability of their drug prod-
20 ucts subject to section 211.166 of title 21, Code of Federal
21 Regulations (or any successor regulations).

22 (d) SHELF LIFE STABILITY GUIDANCE.—Not later
23 than 6 months after the date of enactment of this Act,
24 the Secretary shall publish for notice and comment in the
25 Federal Register updates to stability testing under section

1 211.166 of title 21, Code of Federal Regulations (or any
2 successor regulations).

3 **SEC. 3. QUALITY MANAGEMENT MATURITY STERILE**
4 **INJECTABLE DRUG PILOT PROGRAM.**

5 (a) QUALITY MANAGEMENT MATURITY STERILE
6 INJECTABLE DRUG PILOT PROGRAM.—

7 (1) IN GENERAL.—Not later than 6 months
8 after the date of enactment of this Act, the Sec-
9 retary of Health and Human Services (referred to in
10 this section as the “Secretary”), acting through the
11 Commissioner of Food and Drugs, shall commence
12 the Quality Management Maturity (QMM) Sterile
13 Injectable Drug Pilot Program (referred to in this
14 section as the “pilot program”) under this section.
15 Under such program, the Secretary shall—

16 (A) select eligible drug manufacturers to
17 participate in the program in accordance with
18 paragraph (2); and

19 (B) contract with a third-party contractor
20 to develop a QMM assessment tool and conduct
21 assessments, in cooperation with staff of the
22 Food and Drug Administration, of each partici-
23 pant’s quality management system.

1 (2) ELIGIBILITY.—To be eligible to participate
2 in the pilot program under this section, a manufac-
3 turer shall—

4 (A) be a for-profit or nonprofit entity;

5 (B) manufacture a prescription drug that
6 is a sterile injectable drug;

7 (C) manufacture a drug that is deemed an
8 essential medicine under Executive Order
9 13944 (85 Fed. Reg. 49929);

10 (D) have received a final classification of
11 “No Action Indicated” or “Voluntary Action
12 Indicated” with respect to all inspections of all
13 manufacturing facilities of the entity conducted
14 by the Food and Drug Administration within
15 the 5-year period immediately preceding the
16 date of enactment of this Act;

17 (E) be a person who has registered one or
18 more establishments under subsection (b)(1) or
19 (i)(1) of section 510 of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 360), with respect
21 to the manufacture of a prescription drug de-
22 scribed in subparagraph (B); and

23 (F) agree to—

24 (i) permit a third-party contractor to
25 conduct regular assessments under the

1 QMM pilot program, as described in para-
2 graph (3), either on-site or remotely;

3 (ii) collect and submit metrics data to
4 the Food and Drug Administration and the
5 contractor by an agreed upon date, prior to
6 each assessment described in clause (i);
7 and

8 (iii) be available for consultations with
9 the third-party contractor and the Food
10 and Drug Administration prior to and
11 after each assessment described in clause
12 (i), including discussions regarding the
13 participant's established QMM-related ac-
14 tivities and the contractor's post-assess-
15 ment recommendations regarding these ac-
16 tivities.

17 (3) ASSESSMENTS.—Assessments that are con-
18 ducted jointly by a third-party contractor, in co-
19 operation with staff of the Food and Drug Adminis-
20 tration, will regularly conduct manufacturer facility
21 assessments to determine the manufacturer's quality
22 management maturity progress or status. Pilot pro-
23 gram assessments will cover multiple topics and
24 shall include—

25 (A) supply chain management;

1 (B) manufacturing strategy and oper-
2 ations;

3 (C) safety, environmental, and regulatory
4 compliance;

5 (D) inventory management;

6 (E) performance management and con-
7 tinual improvement;

8 (F) risk management;

9 (G) management review and responsibility;

10 (H) planning;

11 (I) workforce management;

12 (J) quality culture; and

13 (K) customer experience.

14 (4) PROGRAM DURATION.—Not later than 6
15 months after the date of enactment of this Act, the
16 Secretary shall publish instructions for applicants in
17 the Federal Register. Such instructions shall include
18 a timeline for the application period for such pro-
19 gram, and a 1-year timeline for the pilot program
20 following such application period.

21 (b) REPORT TO CONGRESS.—Not later than 6
22 months after the completion of the pilot program, the Sec-
23 retary shall submit a report to Congress on such pilot pro-
24 gram. Such report shall include—

1 (1) a summary of third-party assessments of
2 each participating manufacturer’s quality manage-
3 ment system;

4 (2) recommendations on next steps towards de-
5 veloping a publicly available Food and Drug Admin-
6 istration rating system for quality management ma-
7 turity systems of sterile injectable drug manufac-
8 turing facilities, including specific drugs manufac-
9 tured at each facility;

10 (3) considerations the Food and Drug Adminis-
11 tration may take in updating guidance of current
12 good manufacturing practice of sterile injectable
13 drug products; and

14 (4) recommendations on incorporating pilot pro-
15 grams (or related work) described in the guidances
16 entitled, “Quality Management Maturity for Fin-
17 ished Dosage Forms Pilot Program for Domestic
18 Drug Product Manufacturers; Program Announce-
19 ment”, issued by the Food and Drug Administration
20 on October 16, 2020 (85 Fed. Reg. 65824), and
21 “Quality Management Maturity for Active Pharma-
22 ceutical Ingredients Pilot Program for Foreign Fa-
23 cilities; Program Announcement”, issued by the
24 Food and Drug Administration on October 16, 2020
25 (85 Fed. Reg. 65828), into publicly available Food

1 and Drug Administration rating systems for overall
 2 quality management maturity systems.

3 (c) DEFINITION.—In this section, the term “sterile
 4 injectable drug” means a drug approved under section 505
 5 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 6 355), a biological product licensed under section 351 of
 7 the Public Health Service Act (42 U.S.C. 262), or a com-
 8 bination product (as described in section 503(g) of the
 9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g))
 10 whose primary mode of action is that of a drug or biologi-
 11 cal product, whose manufacturing, distribution, and ad-
 12 ministration processes require sterile conditions.

13 **SEC. 4. IMPROVED DATA SHARING: ENSURING TIMELY AND**
 14 **INFORMATIVE NOTIFICATION.**

15 (a) IN GENERAL.—Section 301 of the Federal Food,
 16 Drug, and Cosmetic Act (21 U.S.C. 331) is amended by
 17 adding at the end the following:

18 “(fff) FAILURE TO PROVIDE TIMELY AND INFORM-
 19 ATIVE NOTIFICATION.—Any manufacturer who violates a
 20 requirement of this Act that relates to critical drugs by
 21 failing to provide timely, adequate information related to
 22 drug shortages pursuant to section 506C(a) shall be sub-
 23 ject to a civil penalty in an amount not to exceed \$50,000
 24 per violation.”.

1 (b) REGULATIONS.—Not later than 1 year after the
 2 date of the enactment of this Act, the Secretary shall pro-
 3 mulgate final regulations to carry out section 301(fff) of
 4 the Federal Food, Drug, and Cosmetic Act, as added by
 5 subsection (a).

6 **SEC. 5. SUPPORTING CONTINUOUS MANUFACTURING TO**
 7 **PREVENT SHORTAGES FOR SUSCEPTIBLE**
 8 **DRUGS.**

9 Subtitle B of title III of the 21st Century Cures Act
 10 is amended by inserting after section 3016 (21 U.S.C.
 11 399h) the following:

12 **“SEC. 3017. GRANTS FOR CONTINUOUS MANUFACTURING**
 13 **TO PREVENT DRUG SHORTAGES.**

14 “(a) IN GENERAL.—The Secretary of Health and
 15 Human Services, acting through the Commissioner of
 16 Food and Drugs, shall solicit and, beginning not later than
 17 one year after the date of enactment of the Drug Short-
 18 ages Prevention and Quality Improvement Act, receive, re-
 19 quests from institutions of higher education and nonprofit
 20 entities engaged in the manufacture of sterile injectable
 21 drugs for the purpose of upgrading drug establishment to
 22 continuous manufacturing or other advanced manufac-
 23 turing capabilities.

24 “(b) GRANT CRITERIA.—An institution of higher
 25 education or a nonprofit entity shall be eligible for a grant

1 under this section if such institution or entity manufac-
2 tures a drug that—

3 “(1) is categorized as an essential medicine
4 under Executive Order 13944;

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

6 “(3) is vulnerable to shortage.

7 “(c) GRANT SELECTION.—As a condition for accept-
8 ing a grant under this section, an institution of higher
9 education and nonprofit entity shall agree to participate
10 in the Quality Management Maturity Sterile Injectable
11 Drug Pilot Program established under section 3 of the
12 Drug Shortages Prevention and Quality Improvement Act.

13 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
14 carry out this section, there is authorized to be appro-
15 priated \$1,000,000,000 for the period of fiscal years 2022
16 through 2027.

17 “(e) DEFINITIONS.—In this section:

18 “(1) ADVANCED MANUFACTURING.—The term
19 ‘advanced manufacturing’ means an approach for
20 the manufacturing of drugs that incorporates novel
21 technology, or uses an established technique or tech-
22 nology in a new or innovative way (such as contin-
23 uous manufacturing where the input materials are
24 continuously transformed within the process by 2 or

1 more unit operations) that enhances drug quality or
2 improves the manufacturing process.

3 “(2) CONTINUOUS MANUFACTURING.—The
4 term ‘continuous manufacturing’—

5 “(A) means a process where the input ma-
6 terials are continuously fed into and trans-
7 formed within the process, and the processed
8 output materials are continuously removed from
9 the system; and

10 “(B) consists of an integrated process that
11 consists of a series of 2 or more unit oper-
12 ations.

13 “(3) STERILE INJECTABLE DRUG.—The term
14 ‘sterile injectable drug’ means a drug approved
15 under section 505 of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 355), a biological product
17 licensed under section 351 of the Public Health
18 Service Act (42 U.S.C. 262), or a combination prod-
19 uct (as described in section 503(g) of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 353(g))
21 whose primary mode of action is that of a drug or
22 biological product, whose manufacturing, distribu-
23 tion, and administration processes require sterile
24 conditions.”.

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