117TH CONGRESS
1ST SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

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

A BILL

To address prescription drug shortages and improve the quality of prescription drugs, 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 "Drug Shortages Prevention and Quality Improvement Act".

SEC. 2. LENGTHEN EXPIRATION DATES TO MITIGATE CRITICAL DRUG SHORTAGES.

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

"SEC. 506C–2. EXTENDED SHELF LIFE DATES FOR ESSENTIAL DRUGS.

"(a) IN GENERAL.—A manufacturer of a drug subject to notification requirements under section 506C(a) (referred to in this section as an 'essential drug') shall—

"(1) submit to the Secretary data and information as required by subsection (b)(1);

"(2) conduct and submit the results of any studies required under subsection (b)(2); and

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

"(b) NOTIFICATION.—

"(1) IN GENERAL.—The Secretary may issue an order requiring the manufacturer of any essential drug to submit, in such manner as the Secretary may prescribe, data and information from any stage of development of the drug that are adequate to assess the shelf life stability of the drug to determine the longest supported expiration date.

"(2) UNAVAILABLE OR INSUFFICIENT DATA AND INFORMATION.—If the data and information required pursuant to an order issued under paragraph (1) are not available or are insufficient, the Secretary may require the manufacturer of the drug to—

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

"(B) submit to the Secretary the results, data, and information generated by such studies when available.

"(c) LABELING.—The Secretary may issue an order requiring the manufacturer of an essential drug to, by a specified date, make any labeling change regarding the expiration period that the Secretary determines to be appropriate based on the data and information required to be submitted under this section or any other data and information available to the Secretary in accordance with labeling requirements under subpart G of part 211 of title 21, Code of Federal Regulations (or any successor regulations).

"(d) CONFIDENTIALITY.—Nothing in 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.".

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

"(9) If a drug manufacturer fails to submit data and information as required under section 506C–2(b)(1), fails to conduct or submit the results of studies as required under section 506C–2(b)(3), or fails to make a labeling change as required under section 506C–2(c), such manufacturer shall be liable to the United States for a civil penalty in an amount not to exceed $10,000 for each such violation.".

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

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

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

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

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

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall commence the Quality Management Maturity (QMM) Sterile Injectable Drug Pilot Program (referred to in this section as the "pilot program") under this section. Under such program, the Secretary shall—

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

(B) contract with a third-party contractor to develop a QMM assessment tool and conduct assessments, in cooperation with staff of the Food and Drug Administration, of each participant's quality management system.

(2) ELIGIBILITY.—To be eligible to participate in the pilot program under this section, a manufacturer shall—

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

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

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

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

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

(F) agree to—

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

QMM pilot program, as described in paragraph (3), either on-site or remotely;

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

(iii) be available for consultations with the third-party contractor and the Food and Drug Administration prior to and after each assessment described in clause (i), including discussions regarding the participant's established QMM-related activities and the contractor's post-assessment recommendations regarding these activities.

(3) ASSESSMENTS.—Assessments that are conducted jointly by a third-party contractor, in cooperation with staff of the Food and Drug Administration, will regularly conduct manufacturer facility assessments to determine the manufacturer's quality management maturity progress or status. Pilot program assessments will cover multiple topics and shall include—

(A) supply chain management;

(B) manufacturing strategy and operations;

(C) safety, environmental, and regulatory compliance;

(D) inventory management;

(E) performance management and continual improvement;

(F) risk management;

(G) management review and responsibility;

(H) planning;

(I) workforce management;

(J) quality culture; and

(K) customer experience.

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

(b) REPORT TO CONGRESS.—Not later than 6 months after the completion of the pilot program, the Secretary shall submit a report to Congress on such pilot program. Such report shall include—

(1) a summary of third-party assessments of each participating manufacturer's quality management system;

(2) recommendations on next steps towards developing a publicly available Food and Drug Administration rating system for quality management maturity systems of sterile injectable drug manufacturing facilities, including specific drugs manufactured at each facility;

(3) considerations the Food and Drug Administration may take in updating guidance of current good manufacturing practice of sterile injectable drug products; and

(4) recommendations on incorporating pilot programs (or related work) described in the guidances entitled, "Quality Management Maturity for Finished Dosage Forms Pilot Program for Domestic Drug Product Manufacturers; Program Announcement", issued by the Food and Drug Administration on October 16, 2020 (85 Fed. Reg. 65824), and "Quality Management Maturity for Active Pharmaceutical Ingredients Pilot Program for Foreign Facilities; Program Announcement", issued by the Food and Drug Administration on October 16, 2020 (85 Fed. Reg. 65828), into publicly available Food

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

(c) DEFINITION.—In this section, the term "sterile injectable drug" means a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a combination product (as described in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) whose primary mode of action is that of a drug or biological product, whose manufacturing, distribution, and administration processes require sterile conditions.

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

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

"(fff) FAILURE TO PROVIDE TIMELY AND INFORMATIVE NOTIFICATION.—Any manufacturer who violates a requirement of this Act that relates to critical drugs by failing to provide timely, adequate information related to drug shortages pursuant to section 506C(a) shall be subject to a civil penalty in an amount not to exceed $50,000 per violation.".

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

SEC. 5. SUPPORTING CONTINUOUS MANUFACTURING TO PREVENT SHORTAGES FOR SUSCEPTIBLE DRUGS.

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

"SEC. 3017. GRANTS FOR CONTINUOUS MANUFACTURING TO PREVENT DRUG SHORTAGES.

"(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall solicit and, beginning not later than one year after the date of enactment of the Drug Shortages Prevention and Quality Improvement Act, receive, requests from institutions of higher education and nonprofit entities engaged in the manufacture of sterile injectable drugs for the purpose of upgrading drug establishment to continuous manufacturing or other advanced manufacturing capabilities.

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

under this section if such institution or entity manufactures a drug that—

"(1) is categorized as an essential medicine under Executive Order 13944;

"(2) is a sterile injectable drug; and

"(3) is vulnerable to shortage.

"(c) GRANT SELECTION.—As a condition for accepting a grant under this section, an institution of higher education and nonprofit entity shall agree to participate in the Quality Management Maturity Sterile Injectable Drug Pilot Program established under section 3 of the Drug Shortages Prevention and Quality Improvement Act.

"(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $1,000,000,000 for the period of fiscal years 2022 through 2027.

"(e) DEFINITIONS.—In this section:

"(1) ADVANCED MANUFACTURING.—The term 'advanced manufacturing' means an approach for the manufacturing of drugs that incorporates novel technology, or uses an established technique or technology in a new or innovative way (such as continuous manufacturing where the input materials are continuously transformed within the process by 2 or

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

"(2) CONTINUOUS MANUFACTURING.—The term 'continuous manufacturing'—

"(A) means a process where the input materials are continuously fed into and transformed within the process, and the processed output materials are continuously removed from the system; and

"(B) consists of an integrated process that consists of a series of 2 or more unit operations.

"(3) STERILE INJECTABLE DRUG.—The term 'sterile injectable drug' means a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a combination product (as described in section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) whose primary mode of action is that of a drug or biological product, whose manufacturing, distribution, and administration processes require sterile conditions.".