118TH 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, Ms. SMITH, and Mr. BLUMENTHAL) 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 EXPIRATION DATES FOR LIFE-SAVING DRUGS.

''(a) IN GENERAL.—A manufacturer of a life-saving drug shall—

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

''(2) conduct and submit the results, data, and information 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 life-saving 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 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 a life-saving drug to, by a specified date, make any labeling change regarding the expiration date that the Secretary determines to be appropriate based on the data and information required to be submitted under this section in accordance with labeling requirements under subparts F and G of part 211 of title 21, Code of Federal Regulations (or any successor regulations) or any other data and information available to the Secretary.

"(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.

"(e) DEFINITION.—In this section, the term 'life-saving drug' means a drug described in section 506C(a).".

(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)(A) If a manufacturer fails to submit data and information as required under section 506C–2(b)(1), fails to conduct or submit the results, data, and information generated by 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.

''(B) If a violation described in subparagraph (A) is not corrected within the 30-day period following notification by the Secretary of a violation described in subparagraph (A), the manufacturer shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected.''.

SEC. 3. REPORTING ON INCREASES IN DEMAND FOR A DRUG.

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

(1) in the section heading, by inserting ''**OR INCREASE IN DEMAND FOR**'' after ''**PRODUCTION OF**'';

(2) in subsection (a), in the matter following paragraph (2), by striking ''drug, and the reasons for such discontinuance or interruption'' and inserting ''drug, or increase in the demand for such drug that is likely to lead to a shortage of the drug, and the reasons for such discontinuance, interruption, or increase in demand'';

(3) in subsection (b)—

(A) in paragraph (1), by striking ''; or'' and inserting a semicolon;

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

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

''(2) in the case of an increase in the demand for a drug, not later than 30 days after the manufacture has knowledge of such increase; or''; and

(D) in paragraph (3), as so redesignated, by striking ''paragraph (1)'' and inserting ''paragraph (1) or (2)''; and

(4) in subsection (c), by inserting '', or increase in demand for,'' after ''the manufacture of''.

(b) PROHIBITED ACT.—

(1) 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:

''(jjj) The failure to notify the Secretary as required under section 506C(a).''.

(2) ENFORCEMENT.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(c)) is amended—

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

(B) by adding at the end the following:

''(h) Notwithstanding subsection (a), any manufacturer who violates section 301(jjj) shall be subject to a civil penalty in an amount not to exceed $50,000 per violation.''.

SEC. 4. SUPPORTING CONTINUOUS MANUFACTURING TO PREVENT SHORTAGES FOR SUSCEPTIBLE DRUGS.

(a) IN GENERAL.—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 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 for grants from institutions of higher education or 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, including as determined through notifications submitted to the Secretary under section 506C.

''(c) GRANT SELECTION.—As a condition for accepting a grant under this section, an institution of higher education and nonprofit entity shall agree to develop and carrying out a robust plan focused on sustainability of the continuous manufacturing or other advanced manufacturing capabilities supported by the grant.

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, in additional to amounts otherwise made available for such purposes, there is authorized to be appropriated $1,000,000,000 for the period of fiscal years 2024 through 2029.

''(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 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 trans-

formed 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, that is intended for injection for intravenous use of infusion and whose manufacturing, distribution, and administration processes require sterile conditions.".

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

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

SEC. 5. AUTHORITY TO USE ALTERNATIVE PAYMENT UNDER THE MEDICARE PROGRAM FOR DRUGS AND BIOLOGICALS TO PREVENT POTENTIAL DRUG SHORTAGES.

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

(1) by striking ''PAYMENT IN RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case'' and inserting ''PAYMENTS.—

''(1) IN RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case''; and

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

''(2) PREVENTING POTENTIAL DRUG SHORTAGES.—

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

after the date on which the Secretary determines the drug or biological is described in such subparagraph and for subsequent quarters until the end of the quarter in which such drug or biological is removed from the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act, or in the case of a drug or biological described in subparagraph (B)(ii)(II), the date on which the Secretary determines the manufacturing capacity or the number of manufacturers of such drug or biological is sufficient to prevent a potential shortage of the drug or biological.

"(B) DRUG OR BIOLOGICAL DESCRIBED.—For purposes of subparagraph (A), a drug or biological described in this subparagraph is a drug or biological—

"(i) that is life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition (as those terms are defined for purposes of section 506C of the Federal Food, Drug, and Cosmetic Act and is subject to the reporting requirements 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 discontinuance or an interruption that is likely to lead to a meaningful disruption in the manufacturer's supply of that drug or biological 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 approved application for such drug or biological, or the number of manufacturers with an approved application for such drug or biological, declines during a 6-month period, as determined by the Secretary.

"(C) PROVISION OF ADDITIONAL INFORMATION.—For each quarter in which the amount of payment for a drug or biological described in subparagraph (B) pursuant to subparagraph (A) exceeds the amount of payment for the drug or biological otherwise applicable under this section, the manufacturer of such drug or biological shall provide to the Secretary information related to the potential cause or causes of the shortage and the expected length of the shortage with respect to such drug.".

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

"(N) The Secretary shall establish a modifier or other mechanism for purposes of tracking utilization of drugs on the shortage list pursuant to section 506E of the Federal Food, Drug, and Cosmetic Act, and update the modifier to reflect the drugs on such list each calendar year.".

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

(1) conduct a study on—

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

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

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

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

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