112TH CONGRESS
2D SESSION

S. _____

To promote public notification and provide incentives to reduce drug shortages.

IN THE SENATE OF THE UNITED STATES

_____

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To promote public notification and provide incentives to reduce drug shortages.

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 ''Patient Access to Drugs in Shortage Act''.

SEC. 2. IMPROVING NOTIFICATION AND REPORTING ON DRUG SHORTAGES.

(a) IN GENERAL.—

(1) DEFINITIONS AND NOTIFICATION.—Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended—

(A) in the section heading, by striking "**DISCONTINUANCE OF A LIFE SAVING PRODUCT**" and inserting "**DISCONTINUANCE OR INTERRUPTION OF THE MANUFACTURE OF CERTAIN DRUGS**"; and

(B) by amending subsection (a) to read as follows:

"(a) IN GENERAL.—

"(1) DEFINITIONS.—In this section:

"(A) DRUG SHORTAGE.—The term 'drug shortage' means a period of time when patient care is likely to be compromised due to the available supply of a drug.

"(B) INTERRUPTION.—The term 'interruption', with respect to the manufacture of a drug, means a change in production of the drug that is likely to cause a significant shortage in the supply of the drug from a manufacturer.

"(2) NOTIFICATIONS.—A manufacturer of a drug—

"(A) that is—

"(i) life-supporting;

"(ii) life-sustaining;

"(iii) intended for use in the prevention of a debilitating disease or condition; or

"(iv) a sterile injectable product;

"(B) for which an application has been approved under section 505(b) or 505(j); and

"(C) that is not a product that was originally derived from human tissue and was replaced by a recombinant product,

shall notify the Secretary of a discontinuance or interruption of the manufacture of the drug at least 6 months prior to the date of the discontinuance or interruption.

"(3) EFFECT OF NOTIFICATIONS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), a failure to take action in accordance with this subsection (including a failure to submit a report or a failure to provide adequate information in a report submitted under this section) may not be admitted as evidence or used for any purpose in any civil action in a Federal or State court or any Federal or State administrative proceeding.

"(B) LIMITATION.—Subparagraph (A) shall not apply to a civil action or administrative proceeding brought by the United States to enforce the requirements under this subsection.

"(C) CONSTRUCTION REGARDING OFF-LABEL USE.—In no case may activities taken in connection with compliance with the notification requirements specified in this subsection be construed as evidence of an intention to promote or market the drug for an indication or use in a manner for which the drug has not been approved by the Secretary.

"(4) EFFECT OF NONCOMPLIANCE.—If a manufacturer of a drug described in paragraph (2) fails to submit a notification to the Secretary in accordance with this subsection, then—

"(A) beginning on the date of such failure, sections 1833(t)(14)(I), 1847A(b)(9), and 1927(a)(8) of the Social Security Act and section 340B(f) of the Public Health Service Act shall not apply to any drug manufactured by such manufacturer; and

"(B) section 524A of this Act shall not apply to such manufacturer with respect to the submission of an application as described in

subsection (a)(1) of such section or commencement of manufacturing of a drug as described in subsection (a)(2) of such section after the date of such failure.''.

(2) CONFORMING AMENDMENT.—Section 506C(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(b)) is amended in the matter preceding paragraph (1) by striking ''under subsection (a)'' and inserting ''under subsection (a) with respect to a discontinuance''.

(b) DISTRIBUTION; EXPEDITED REVIEWS AND INSPECTIONS; REPORTING.—Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended—

(1) in subsection (c)—

(A) by striking ''the discontinuation of the drugs described in subsection (a)'' and inserting ''discontinuations or interruptions relating to a drug described in subsection (a)(2)''; and

(B) by adding at the end the following: ''Any distribution under the preceding sentence shall not include any confidential commercial information or trade secret.''; and

(2) by adding at the end the following:

''(d) EXPEDITED INSPECTIONS AND REVIEWS.—[To be supplied.]

''(e) REPORTING BY OTHER ENTITIES.—The Secretary shall establish a mechanism by which health care providers and other third-party organizations may report evidence of a drug shortage under this section.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of enactment of this Act and shall apply to discontinuances and interruptions described under section 506C of the Federal Food, Drug, and Cosmetic Act (as amended by this section) that occur after the date of enactment of this Act.

SEC. 3. MARKET STABILITY INCENTIVES.

(a) MEDICARE.—

(1) IN GENERAL.—Section 1847A(b) of the Social Security Act (42 U.S.C. 1395w–3a(b)) is amended—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking ''paragraph (7)'' and inserting ''paragraphs (7) and (9)''; and

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

''(9) STERILE INJECTABLE PRODUCTS WITH 4 OR FEWER ACTIVE MANUFACTURERS.—

"(A) IN GENERAL.—Subject to section 506C(a)(4) of the Federal Food, Drug, and Cosmetic Act, the payment amount for a drug described in subparagraph (B) that is furnished on or after January 1, 2013, and before January 1, 2020, shall be equal to—

"(i) in the case of a drug described in subparagraph (B)(i), the amount determined under subparagraph (C) for the drug; and

"(ii) in the case of a drug described in subparagraph (B)(ii), the wholesale acquisition cost (as defined in subsection (c)) of the drug.

"(B) DRUG DESCRIBED.—A drug described in this subparagraph is a sterile injectable product that is manufactured by 4 or fewer active manufacturers (as determined by the Secretary) and is—

"(i) a multiple source drug (as described in subsection (c)(6)(C)) for which there is no period of exclusivity in effect or available under section 505(j), 505A, or 527 of the Federal Food, Drug, and Cosmetic Act; or

"(ii) a single source drug (as described in subsection (c)(6)(D)(ii)) for which there is no period of exclusivity in effect or available under section 505(c), 505A, or 527 of the Federal Food, Drug, and Cosmetic Act.

"(C) USE OF VOLUME-WEIGHTED AVERAGE WHOLESALE ACQUISITION COSTS FOR MULTIPLE SOURCE DRUGS.—

"(i) IN GENERAL.—For all drugs described in subparagraph (B) included within the same multiple source drug billing and payment code, the amount specified in this subparagraph is the volume-weighted average of the wholesale acquisition costs reported under section 1927(b)(3)(A)(iii) determined by—

"(I) computing the sum of the products (for each National Drug Code assigned to such drugs) of—

"(aa) the manufacturer's wholesale acquisition cost (as defined in subsection (c)), determined by the Secretary without dividing such cost by the total

number of billing units for the National Drug Code for the billing and payment code; and

"(bb) the total number of units specified under paragraph (2) sold; and

"(II) dividing the sum determined under subclause (I) by the sum of the products (for each National Drug Code assigned to such drugs) of—

"(aa) the total number of units specified under paragraph (2) sold; and

"(bb) the total number of billing units for the National Drug Code for the billing and payment code.

"(ii) BILLING UNIT DEFINED.—For purposes of this subparagraph, the term 'billing unit' means the identifiable quantity associated with a billing and payment code, as established by the Secretary.".

(2) HOPD PROSPECTIVE PAYMENT SYSTEM.—Section 1833(t)(14) of the Social Security Act (42 U.S.C. 1395l(t)(14)) is amended—

(A) in subparagraph (A)(iii), in the matter preceding subclause (I), by striking ''subparagraph (E)'' and inserting ''subparagraphs (E) and (I)''; and

(B) by adding at the end the following new subparagraph:

''(I) STERILE INJECTABLE PRODUCTS WITH 4 OR FEWER ACTIVE MANUFACTURERS.—Subject to section 506C(a)(4) of the Federal Food, Drug, and Cosmetic Act, the amount of payment for a drug described in section 1847A(b)(9)(B) that is furnished on or after January 1, 2013, and before January 1, 2020, shall be equal to—

''(i) in the case of a drug described in clause (i) of such section, the amount determined under section 1847A(b)(9)(C) for the drug; and

''(ii) in the case of a drug described in clause (ii) of section 1847A(b)(9)(B), the wholesale acquisition cost (as defined in section 1847A(c)) of the drug.''.

(b) MEDICAID.—

(1) IN GENERAL.—Section 1927(a) of the Social Security Act (42 U.S.C. 1396r–8(a)) is amended by adding at the end the following new paragraph:

"(8) STERILE INJECTABLE PRODUCTS WITH 4 OR FEWER ACTIVE MANUFACTURERS.—

"(A) IN GENERAL.—Subject to section 506C(a)(4) of the Federal Food, Drug, and Cosmetic Act, paragraph (1) of this subsection and section 1903(i)(10)(A) shall not apply to a drug described in subparagraph (B) that is furnished on or after January 1, 2013, and before January 1, 2020.

"(B) DRUG DESCRIBED.—A drug described in this subparagraph is a sterile injectable product that is manufactured by 4 or fewer active manufacturers (as determined by the Secretary) and is—

"(i) a multiple source drug (as described in subsection (k)(7)(A)(i)) for which there is no period of exclusivity in effect or available under section 505(j), 505A, or 527 of the Federal Food, Drug, and Cosmetic Act; or

"(ii) a single source drug (as described in subsection (k)(7)(A)(iv)) for which there is no period of exclusivity in effect or available under section 505(c), 505A, or 527 of the Federal Food, Drug, and Cosmetic Act.".

(2) CONFORMING AMENDMENT.—Section 1903(i)(10)(A) of the Social Security Act (42 U.S.C. 1396b(i)(10)(A)) is amended by striking "unless section 1927(a)(3) applies" and inserting "unless paragraph (3) or (8) of section 1927(a) applies".

(c) 340B PROGRAM.—

(1) IN GENERAL.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by inserting after subsection (e) the following:

"(f) EXCLUSION OF CERTAIN STERILE INJECTABLE PRODUCTS.—

"(1) IN GENERAL.—For purposes of this section (including with respect to the prohibition described in subsection (a)(5)(L)(iii)), the term 'covered outpatient drug' shall not include a drug that is a sterile injectable product that is manufactured by 4 or fewer active manufacturers (as determined by the Secretary) and is—

''(A) a multiple source drug (as described in section 1927(k)(7)(A)(i) of the Social Security Act) for which there is no period of exclusivity in effect or available under section 505(j), 505A, or 527 of the Federal Food, Drug, and Cosmetic Act; or

''(B) a single source drug (as described in section 1927(k)(7)(A)(iv) of the Social Security Act) for which there is no period of exclusivity in effect or available under section 505(c), 505A, or 527 of the Federal Food, Drug, and Cosmetic Act.

''(2) SUNSET.—Paragraph (1) shall cease to have force or effect on December 31, 2019.''.

(d) TRANSFER OF EXCLUSIVITY.—

(1) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524A. ACTION TO ADDRESS A DRUG SHORTAGE.

''(a) IN GENERAL.—Subsection (b) shall apply to a sponsor or holder, as applicable, if—

''(1) the sponsor submits an application under subsection (b) or (j) of section 505 for a drug that will mitigate a shortage of a drug that is designated

as a drug in shortage by the Secretary as of the date of such submission; or

''(2) the holder of an application approved under subsection (b) or (j) of section 505 commences to manufacture a drug pursuant to such application that will mitigate a shortage of a drug that is designated as a drug in shortage by the Secretary as of the date of such commencement.

''(b) EFFECT OF SUBSECTION.—If a sponsor submits an application described in subsection (a)(1) or a holder commences manufacturing as described in subsection (a)(2), the sponsor or holder may elect to extend by 5 years any period of exclusivity applicable under this Act with respect to a drug for which the sponsor or holder receives approval under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of submission of the application described in subsection (a)(1) or commencement of the manufacturing described in subsection (a)(2), as applicable.

''(c) APPLICABILITY.—This section shall apply to—

''(1) sponsors that submit an application as described in subsection (a)(1) before December 31, 2015; and

"(2) holders that commence manufacturing of a drug as described in subsection (a)(2) before December 31, 2015.

"(d) EFFECT OF REMOVAL FROM DRUG SHORTAGE LIST.—If, pursuant to this section, a sponsor or holder extends by 5 years any exclusivity applicable under this Act with respect to a drug as described under subsection (b), the subsequent removal of the drug described under paragraph (1) or (2) of subsection (a) from designation as a drug in shortage shall have no effect on such extension.".

(e) STUDY AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall contract with an independent entity to study the effects of the amendments made by this section on patient access to sterile injectable products.

(2) REPORT.—As a condition of the contract described under paragraph (1), the independent entity shall agree to submit to Congress and such Secretary, not later than 3 years after the date of enactment of this Act, a report that describes the results of the study conducted under paragraph (1).

SEC. 4. DRUG SHORTAGE LIST.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506C the following:

"SEC. 506D. DRUG SHORTAGE LIST.

"(a) ESTABLISHMENT.—The Secretary shall maintain an up-to-date list of drugs that are verified to be in shortage in the United States.

"(b) CONTENTS.—For each drug on such list, the Secretary shall include the following information:

"(1) The name of the drug in shortage.

"(2) The name of each manufacturer of such drug.

"(3) The reason for the shortage, as determined by the Secretary, selecting from the following categories:

"(A) Requirements related to complying with good manufacturing practices.

"(B) Regulatory delay.

"(C) Shortage of an active ingredient.

"(D) Shortage of a nonactive pharmaceutical ingredient component.

"(E) Discontinuation of the manufacture of the drug.

"(F) Delay in shipping of the drug.

"(G) Demand increase for the drug.

''(4) The anticipated duration of the shortage as determined by the Secretary.

''(c) PUBLIC AVAILABILITY.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary shall make the information in such list publicly available.

''(2) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section alters or amends section 1905 of title 18, United States Code, or section 552(b)(4) of title 5 of such Code.

''(3) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publicly available under paragraph (1) if the Secretary determines that disclosure of such information would adversely affect the public health.''.

SEC. 5. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.

Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended by adding at the end the following:

''(h)(1) Not later than 30 days after the receipt of a request described in paragraph (2), the Attorney General shall—

''(A) complete review of such request; and

''(B) as necessary to address a shortage of a controlled substance, increase the aggregate and individual production quotas under this section applicable to such controlled substance and any ingredient therein.

''(2) A request is described in this paragraph if—

''(A) the request pertains to a controlled substance on the list of drugs in shortage maintained under section 506D of the Federal Food, Drug, and Cosmetic Act;

''(B) the request is submitted by the manufacturer of the controlled substance; and

''(C) the controlled substance is in schedule II.''.