116TH CONGRESS
1ST SESSION

S. 2723

To amend the Federal Food, Drug, and Cosmetic Act to reduce drug shortages, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 29, 2019

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

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reduce drug shortages, 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 ''Mitigating Emergency Drug Shortages Act''.

SEC. 2. PRIORITIZE REVIEWS OF DRUG APPLICATIONS; INCENTIVES.

(a) PRIORITIZED REVIEWS AND INSPECTIONS.—Section 506C(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(g)) is amended—

(1) in the matter preceding paragraph (1), by striking ''the Secretary may'' and inserting ''the Secretary shall'';

(2) in paragraph (1), by inserting ''prioritize and'' before ''expedite the review''; and

(3) in paragraph (2), by inserting ''prioritize and'' before ''expedite an inspection''.

(b) REPORT.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall develop and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing legislative and regulatory recommendations—

(1) to create market-based incentives or other appropriate mechanisms, sufficient to encourage—

(A) the manufacture of drugs in shortage or at risk of shortage;

(B) the domestic manufacture of finished dosage forms of such drugs; and

(C) the domestic manufacture of active pharmaceutical ingredients for such drugs; and

(2) to expand the Emerging Technology Program of the Food and Drug Administration to create or upgrade existing technologies to address drug

shortage challenges and promote modern, reliable manufacturing strategies.

SEC. 3. ADDITIONAL MANUFACTURER REPORTING REQUIREMENTS IN RESPONSE TO DRUG SHORTAGES.

(a) EXPANSION TO INCLUDE ACTIVE PHARMACEUTICAL INGREDIENTS.—Subsection (a) of section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended—

(1) in the matter preceding paragraph (1), by inserting ''or its active pharmaceutical ingredients'' after ''a drug''; and

(2) in the flush text at the end—

(A) by inserting ''or its active pharmaceutical ingredients'' before ''that is likely'';

(B) ''or its active pharmaceutical ingredients'' after ''that drug''; and

(C) by adding at the end the following: ''Notification under this subsection shall include full disclosure of the problems resulting in the shortage, the source of the active pharmaceutical ingredient, associated medical devices used for preparation or administration included in the finished dosage form, any alternative sources for the active pharmaceutical ingredient

that are known or contacted by manufacturer, information concerning the extent of the shortage, the expected duration of the shortage, the expected impact to distribution and availability in pharmacies, and such other information as the Secretary may require.''.

(b) MANUFACTURING REPORTING.—Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amended by adding at the end the following:

''(j) MANUFACTURER REPORTING.—Each manufacturer of a drug described in subsection (a) or of any active pharmaceutical ingredient or associated medical devices used for preparation or administration included in the finished dosage form of such a drug, shall report in such manufacturer's annual establishment registration and product listing under subsections (b) and (j) of section 510 the specific facilities in which such drug or ingredient is manufactured and contingency and redundancy plans to help ensure uninterrupted supply of the drug or ingredient. Additional manufacturer reporting requirements under this section shall be maintained by the Secretary in a confidential and internal manner for use by the agency to help ensure continued supply of such drugs.''.

(c) CONSUMER NOTIFICATION.—Not later than one year after the date of enactment of this Act, the Secretary

shall develop and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives legislative and regulatory recommendations for consumer notification in the case of a drug shortage, discontinuance, or interruption of the manufacture of a drug described in section 506C(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(a)), including recommendations for notification to patients and physicians, pharmacists, and other practitioners authorized under applicable State law to prescribe or dispense drugs.

(d) REPORTING AFTER FACTORY INSPECTIONS.—Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)) is amended—

(1) by redesignating paragraphs (1) and (2) and subparagraphs (A) and (B);

(2) by striking ''(b) Upon completion'' and inserting ''(b)(1) Upon completion''; and

(3) by adding at the end the following:

''(2) In carrying out this subsection with respect to any establishment manufacturing a drug approved under subsection (c) or (j) of section 505 that is described in 506C(a) or 505(j)(11)(A), a copy of the report shall be sent promptly to the appropriate offices of the Food and Drug Administration with expertise regarding drug short-

ages. Such offices shall ensure timely and effective coordination regarding the reviews of such report and overseeing the alignment of any feedback regarding such report, or corrective or preventative actions, after consideration of the systematic benefits and risks to public health, patient safety, the drug supply and drug supply chain, and timely patient access to such drugs.''.

(e) EFFECTIVE DATE.—The amendments made by this section and section 2 shall take effect on the date that is 180 days after the date of enactment of this Act.

SEC. 4. GAO REPORT ON INTRA-AGENCY COORDINATION.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report examining the Food and Drug Administration's intra-agency coordination, communication, and decision making in assessing drug shortage risks, and taking corrective action.

(b) CONTENT.—The report shall include—

(1) consideration of—

(A) risks associated with violations of current good manufacturing practices;

(B) corrective and preventative actions with respect to such violations requested by the Food and Drug Administration;

(C) the effects of potential manufacturing slow-downs or shut-downs on potential drug shortages, including the discontinuance of drug manufacturing and marketing;

(D) efforts to prioritize review of applications for drugs that the Secretary has determined under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e) to be in shortage; and

(E) efforts to prioritize inspections of facilities necessary for approval of applications for drugs described in subparagraph (D);

(2) a description of how the Food and Drug Administration proactively coordinates strategies to mitigate the consequences of the violations, slow-downs, and shut-downs described in paragraph (1) across agencies; and

(3) an evaluation of changes in relevant Food and Drug Administration practices that such agency has proposed but not yet implemented.

SEC. 5. MODIFICATIONS TO DRUG SHORTAGE LIST MAINTAINED BY FDA.

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

(1) in subsection (a), by striking the period and inserting the following: ", by region, including States and localities, where the shortages exist. The Secretary may enter into a private-public partnership to maintain such list."; and

(2) in subsection (b)(3)(C), by inserting before the period the following: ", strength, or dosage form".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the date of enactment of this Act, and shall apply to updates made to the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act after the date of enactment of this Act.

SEC. 6. NATIONAL SECURITY RISK ASSESSMENT OF DRUG, ACTIVE PHARMACEUTICAL INGREDIENT AND MEDICAL DEVICE MANUFACTURING OPERATIONS.

(a) ASSESSMENT AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, in collaboration with the Secretary

of Homeland Security and in consultation with stakeholders (including pharmacists, hospitals, physicians, and pharmaceutical and medical device manufacturers), shall conduct a risk assessment of national security threats arising from, or related to, the manufacture and distribution of drugs described in 506C(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(a)) or of any active pharmaceutical ingredients of such drugs or associated medical devices used for preparation or administration of such drugs. Not later than 18 months after the date of enactment of this Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report outlining findings under such assessment and any recommended actions.

(2) CONTENT.—The assessment and report under paragraph (1) shall include—

(A) a review of manufacturing and distribution of drugs described in such section 506C(a), active pharmaceutical ingredients of such drugs, and associated medical devices used for preparation or administration of such drugs, that includes consideration of whether manufac-

turing sites and distribution systems should be considered critical infrastructure (as defined in section 1016(e) of the Critical Infrastructures Protection Act of 2001 (42 U.S.C. 5195c(e)));

(B) a review of risks associated with the foreign manufacture of such drugs, ingredients, or devices; and

(C) recommendations on how to mitigate any such risks.

(b) STANDING FORUM.—The Secretary of Health and Human Services, in collaboration with the Secretary of Homeland Security, shall establish a standing forum to engage stakeholders, including pharmacists, hospitals, physicians, and pharmaceutical and medical device manufacturers, to mitigate risks identified through the assessment conducted under subsection (a).

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