

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

A BILL

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

6 **SEC. 2. PRIORITIZE REVIEWS OF DRUG APPLICATIONS; IN-**
7 **CENTIVES.**

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

1 (1) in the matter preceding paragraph (1), by
 2 striking “the Secretary may” and inserting “the
 3 Secretary shall”;

4 (2) in paragraph (1), by inserting “prioritize
 5 and” before “expedite the review”; and

6 (3) in paragraph (2), by inserting “prioritize
 7 and” before “expedite an inspection”.

8 (b) REPORT.—Not later than one year after the date
 9 of enactment of this Act, the Secretary of Health and
 10 Human Services shall develop and submit to the Com-
 11 mittee on Health, Education, Labor, and Pensions of the
 12 Senate and the Committee on Energy and Commerce of
 13 the House of Representatives a report containing legisla-
 14 tive and regulatory recommendations—

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

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

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

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

23 (2) to expand the Emerging Technology Pro-
 24 gram of the Food and Drug Administration to cre-
 25 ate or upgrade existing technologies to address drug

1 shortage challenges and promote modern, reliable
 2 manufacturing strategies.

3 **SEC. 3. ADDITIONAL MANUFACTURER REPORTING RE-**
 4 **QUIREMENTS IN RESPONSE TO DRUG SHORT-**
 5 **AGES.**

6 (a) EXPANSION TO INCLUDE ACTIVE PHARMA-
 7 CEUTICAL INGREDIENTS.—Subsection (a) of section 506C
 8 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 9 356c) is amended—

10 (1) in the matter preceding paragraph (1), by
 11 inserting “or its active pharmaceutical ingredients”
 12 after “a drug”; and

13 (2) in the flush text at the end—

14 (A) by inserting “or its active pharma-
 15 ceutical ingredients” before “that is likely”;

16 (B) “or its active pharmaceutical ingredi-
 17 ents” after “that drug”; and

18 (C) by adding at the end the following:

19 “Notification under this subsection shall include
 20 full disclosure of the problems resulting in the
 21 shortage, the source of the active pharma-
 22 ceutical ingredient, associated medical devices
 23 used for preparation or administration included
 24 in the finished dosage form, any alternative
 25 sources for the active pharmaceutical ingredient

1 that are known or contacted by manufacturer,
2 information concerning the extent of the short-
3 age, the expected duration of the shortage, the
4 expected impact to distribution and availability
5 in pharmacies, and such other information as
6 the Secretary may require.”.

7 (b) MANUFACTURING REPORTING.—Section 506C of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 356c) is amended by adding at the end the following:

10 “(j) MANUFACTURER REPORTING.—Each manufac-
11 turer of a drug described in subsection (a) or of any active
12 pharmaceutical ingredient or associated medical devices
13 used for preparation or administration included in the fin-
14 ished dosage form of such a drug, shall report in such
15 manufacturer’s annual establishment registration and
16 product listing under subsections (b) and (j) of section
17 510 the specific facilities in which such drug or ingredient
18 is manufactured and contingency and redundancy plans
19 to help ensure uninterrupted supply of the drug or ingre-
20 dient. Additional manufacturer reporting requirements
21 under this section shall be maintained by the Secretary
22 in a confidential and internal manner for use by the agen-
23 cy to help ensure continued supply of such drugs.”.

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

1 shall develop and submit to the Committee on Health,
 2 Education, Labor, and Pensions of the Senate and the
 3 Committee on Energy and Commerce of the House of
 4 Representatives legislative and regulatory recommenda-
 5 tions for consumer notification in the case of a drug short-
 6 age, discontinuance, or interruption of the manufacture of
 7 a drug described in section 506C(a) of the Federal Food,
 8 Drug, and Cosmetic Act (21 U.S.C. 356c(a)), including
 9 recommendations for notification to patients and physi-
 10 cians, pharmacists, and other practitioners authorized
 11 under applicable State law to prescribe or dispense drugs.

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

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

17 (2) by striking “(b) Upon completion” and in-
 18 serting “(b)(1) Upon completion”; and

19 (3) by adding at the end the following:

20 “(2) In carrying out this subsection with respect to
 21 any establishment manufacturing a drug approved under
 22 subsection (c) or (j) of section 505 that is described in
 23 506C(a) or 505(j)(11)(A), a copy of the report shall be
 24 sent promptly to the appropriate offices of the Food and
 25 Drug Administration with expertise regarding drug short-

1 ages. Such offices shall ensure timely and effective coordi-
 2 nation regarding the reviews of such report and overseeing
 3 the alignment of any feedback regarding such report, or
 4 corrective or preventative actions, after consideration of
 5 the systematic benefits and risks to public health, patient
 6 safety, the drug supply and drug supply chain, and timely
 7 patient access to such drugs.”.

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

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

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

21 (b) CONTENT.—The report shall include—

22 (1) consideration of—

23 (A) risks associated with violations of cur-
 24 rent good manufacturing practices;

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

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

8 (D) efforts to prioritize review of applica-
9 tions for drugs that the Secretary has deter-
10 mined under section 506E of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 356e) to be
12 in shortage; and

13 (E) efforts to prioritize inspections of fa-
14 cilities necessary for approval of applications for
15 drugs described in subparagraph (D);

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

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

1 **SEC. 5. MODIFICATIONS TO DRUG SHORTAGE LIST MAIN-**
 2 **TAINED BY FDA.**

3 (a) IN GENERAL.—Section 506E of the Federal
 4 Food, Drug, and Cosmetic Act (21 U.S.C. 356e) is amend-
 5 ed—

6 (1) in subsection (a), by striking the period and
 7 inserting the following: “, by region, including States
 8 and localities, where the shortages exist. The Sec-
 9 retary may enter into a private-public partnership to
 10 maintain such list.”; and

11 (2) in subsection (b)(3)(C), by inserting before
 12 the period the following: “, strength, or dosage
 13 form”.

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

20 **SEC. 6. NATIONAL SECURITY RISK ASSESSMENT OF DRUG,**
 21 **ACTIVE PHARMACEUTICAL INGREDIENT AND**
 22 **MEDICAL DEVICE MANUFACTURING OPER-**
 23 **ATIONS.**

24 (a) ASSESSMENT AND REPORT.—

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

1 of Homeland Security and in consultation with
2 stakeholders (including pharmacists, hospitals, phy-
3 sicians, and pharmaceutical and medical device man-
4 ufacturers), shall conduct a risk assessment of na-
5 tional security threats arising from, or related to,
6 the manufacture and distribution of drugs described
7 in 506C(a) of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 356c(a)) or of any active pharma-
9 ceutical ingredients of such drugs or associated med-
10 ical devices used for preparation or administration of
11 such drugs. Not later than 18 months after the date
12 of enactment of this Act, the Secretary shall submit
13 to the Committee on Health, Education, Labor, and
14 Pensions of the Senate and the Committee on En-
15 ergy and Commerce of the House of Representatives
16 a report outlining findings under such assessment
17 and any recommended actions.

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

20 (A) a review of manufacturing and dis-
21 tribution of drugs described in such section
22 506C(a), active pharmaceutical ingredients of
23 such drugs, and associated medical devices used
24 for preparation or administration of such drugs,
25 that includes consideration of whether manufac-

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

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

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

10 (b) STANDING FORUM.—The Secretary of Health
11 and Human Services, in collaboration with the Secretary
12 of Homeland Security, shall establish a standing forum
13 to engage stakeholders, including pharmacists, hospitals,
14 physicians, and pharmaceutical and medical device manu-
15 facturers, to mitigate risks identified through the assess-
16 ment conducted under subsection (a).

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