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116TH CONGRESS
2D SESSION

H. R. 6080

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 4, 2020

Mr. PETERS (for himself, Mr. ENGEL, Ms. ESHOO, Mr. GUTHRIE, Mr. SCHRADER, Mr. MCCAUL, Mr. HUDSON, and Mr. BILIRAKIS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 ''Preventing Drug Shortages Act''.

SEC. 2. ADDITIONAL MANUFACTURER REPORTING REQUIREMENTS IN RESPONSE TO SUPPLY DISRUPTIONS.

(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 matter following paragraph (2)—

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

(B) ''or its active pharmaceutical ingredient or 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 supply disruption, the source of the active pharmaceutical ingredient, any alternative sources for the active pharmaceutical ingredient that are known or contacted by manufacturer, information concerning the extent of the supply disruption, the expected duration of the supply disruption, 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 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 (including the volume manufactured at each such facility) to help ensure uninterrupted supply of the drug or ingredient. Information obtained through reporting under this section shall be maintained by the Secretary in a confidential and internal manner and shall be trade secret and/or confidential commercial or financial information pursuant to section 552(b)(4) of title 5, United States Code.''.

(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 Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate 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) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 180 days after the date of enactment of this Act.

SEC. 3. GAO REPORT ON INTRA-AGENCY COORDINATION.

(a) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate 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. 4. IMPROVING CRITICAL INFRASTRUCTURE BY REQUIRING RISK MANAGEMENT PLANS.

(a) RISK MANAGEMENT PLANS.—Section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c), as amended by section 2(b), is further amended by adding at the end the following:

''(k) RISK MANAGEMENT PLANS.—The Secretary may require a manufacturer of a drug described in subsection (a) to conduct periodic risk assessments—

''(1) to identify vulnerabilities in the manufacturing supply chain of such manufacturer; and

''(2) to develop plans to mitigate the risks associated with any vulnerabilities so identified.''.

(b) GUIDANCE.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize guidance implementing subsection (l) of section 506C of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a). Such guidance shall include guidance on—

(1) examples of what may be considered a vulnerability in the manufacturing supply chain in conducting a risk assessment pursuant to such subsection;

(2) the timeframe within which a manufacturer must conduct such an assessment and provide a response to the Food and Drug Administration;

(3) expectations of the Secretary of Health and Human Services for a manufacturer to mitigate in a reasonable manner any risks associated with vulnerabilities in the manufacturing supply chain identified in such an assessment; and

(4) how the Secretary will coordinate with other Federal agencies to communicate and resolve any such vulnerabilities.

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