

1 Title: To amend the Federal Food, Drug, and Cosmetic Act to address drug shortages.

2 **TITLE X—DRUG SHORTAGES**

3 ~~Be it enacted by the Senate and House of Representatives of the~~  
4 ~~United States of America in Congress assembled,~~

5 ~~SECTION 1. SHORT TITLE.~~

6 ~~This Act may be cited as [the “\_\_\_\_\_ Act of \_\_\_\_\_”].~~

7 ~~SEC. 2~~ **SEC. 1001. DRUG SHORTAGES.**

8 (a) In General.—Section 506C of the Federal Food, Drug, and Cosmetic Act(21 U.S.C. 356c)  
9 is amended to read as follows:

10 **“SEC. 506C. DISCONTINUANCE OR INTERRUPTION IN**  
11 **THE PRODUCTION OF LIFE-SAVING DRUGS.**

12 “(a) In General.—A manufacturer of a drug—

13 “(1) that is—

14 “(A) life-supporting;

15 “(B) life-sustaining; or

16 “(C) intended for use in the prevention of a debilitating disease or condition;

17 ~~and~~

18 **“(D) a sterile injectable product; or**

19 **“(E) used in emergency medical care or during surgery; and**

20 “(2) that is not a radio pharmaceutical drug product, a human tissue replaced by a  
21 recombinant product, a product derived from human plasma protein, or any other product as  
22 designated by the Secretary,

23 shall notify the Secretary ~~of a~~, **in accordance with subsection (b), of a permanent**  
24 **discontinuance or interruption of in** the manufacture of the drug **or an interruption of the**  
25 **manufacture of the drug** that could lead to a meaningful disruption in the supply **of that drug**  
26 ~~in the United States of that drug.~~

27 **“(b) Timing.—A notice required under subsection (a) shall be submitted to the**  
28 **Secretary—**

29 **“(1) at least 6 months prior to the date of the discontinuance or interruption; or-**

30 ~~“(b) Reduction in Notification Period.—The notification period required under subsection~~  
31 ~~(a) for a manufacturer—~~

32 ~~“(1) may be deemed to be reduced if the manufacturer notifies the Secretary“(2) if~~  
33 **compliance with paragraph (1) is impossible, as soon as practicable after becoming aware**

1 of such discontinuance or interruption; and

2 ~~“(2) may be reduced if the manufacturer certifies to the Secretary that good cause exists~~  
3 ~~for the reduction, such as a situation in which—~~

4 ~~“(A) a public health problem may result from continuation of the manufacturing for the~~  
5 ~~6-month period;~~

6 ~~“(B) a biomaterials shortage prevents the continuation of the manufacturing for the 6-~~  
7 ~~month period;~~

8 ~~“(C) a liability problem may exist for the manufacturer if the manufacturing is continued~~  
9 ~~for the 6-month period;~~

10 ~~“(D) continuation of the manufacturing for the 6-month period may cause substantial~~  
11 ~~economic hardship for the manufacturer; or~~

12 ~~“(E) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United~~  
13 ~~States Code.~~

14 “(c) Expedited Inspections and Reviews.—If, based on notifications described in subsection  
15 (a) or any other relevant information, the Secretary concludes that there is, or is likely to be, a  
16 drug shortage of a drug described in subsection (a), the Secretary may—

17 “(1) expedite the review of a supplement to a new drug application submitted under  
18 section 505(b), an abbreviated new drug application submitted under section 505(j), or a  
19 supplement to such an application submitted under section 505(j) that could help mitigate or  
20 prevent such shortage; or

21 “(2) expedite an inspection or reinspection of an establishment that could help mitigate or  
22 prevent such drug shortage.

23 “(d) Coordination.—

24 “(1) ~~TASK FORCE.—~~ **FORCE AND STRATEGIC PLAN.—**

25 ~~“(A) In general.—As”~~**(A) IN GENERAL.—**

26 **“(i) TASK FORCE.—**As soon as practicable after the date of enactment of the  
27 **[insert short title] Food and Drug Administration Safety and Innovation Act,**  
28 **the Secretary shall establish a Task Force to** ~~mitigate drug shortages ongoing as of~~  
29 ~~such date and to prevent future drug shortages through~~ **develop and implement a**  
30 **strategic plan for enhancing the Secretary’s response to preventing and**  
31 **mitigating drug shortages.**

32 **“(ii) STRATEGIC PLAN.—**The strategic plan described in clause (i) shall  
33 **include—**

34 **“(I) plans for** enhanced interagency and intraagency coordination,  
35 communication, ~~strategic planning and decisionmaking, as well as through~~  
36 ~~appropriate interaction and consultation with relevant experts and other~~  
37 ~~stakeholders.~~ **In and decisionmaking;**

38 **“(II) plans for ensuring that drug shortages are considered when the**  
39 **Secretary initiates a regulatory action that could precipitate a drug**  
40 **shortage or exacerbate an existing drug shortage;**

1                   **“(III) plans for effective communication with outside stakeholders,**  
2                   **including who the Secretary should alert about potential or actual drug**  
3                   **shortages, how the communication should occur, and what types of**  
4                   **information should be shared; and**

5                   **“(IV) plans for considering the impact of drug shortages on research**  
6                   **and clinical trials.**

7                   **“(iii) CONSULTATION.—In carrying out this subparagraph, the Task Force**  
8                   **shall ensure that consultation with the appropriate offices are consulted and**  
9                   **involved in coordination within the Food and Drug Administration, including**  
10                   **the Office of the Commissioner, the Center for Drug Evaluation and Research, the**  
11                   **Office of Regulatory Affairs, and employees within the Department of Health and**  
12                   **Human Services with expertise regarding drug shortages. The Secretary shall**  
13                   **engage external stakeholders and experts as appropriate.**~~“(B) Strategic~~  
14                   ~~plan.—The Task Force—~~

15                   ~~“(i) shall develop a strategic plan and implementation plan to ensure that drug~~  
16                   ~~shortages are considered when the Secretary initiates a regulatory action that could~~  
17                   ~~precipitate a drug shortage or exacerbate an existing drug shortage; and~~

18                   ~~“(ii) not~~**“(B) TIMING.—Not later than 1 year after the date of enactment of the**  
19                   ~~[insert short title] shall—~~ **Food and Drug Administration Safety and Innovation**  
20                   **Act, the Task Force shall—**

21                   ~~“(I) publish the implementation plan addressing any necessary additional~~  
22                   ~~coordination and communication activities to effectively prevent and mitigate~~  
23                   ~~drug shortages; and~~**“(i) publish the strategic plan described in subparagraph**  
24                   **(A); and**

25                   ~~“(H)~~**“(ii) submit such plan to Congress and the Secretary.**

26                   **“(2) COMMUNICATION.—The Secretary shall ensure that, prior to any enforcement action**  
27                   **or issuance of a warning letter that the Secretary determines could reasonably be anticipated**  
28                   **to lead to a meaningful disruption in the supply in the United States of a drug described**  
29                   **under subsection (a), there is communication with the Commissioner or a designee of the**  
30                   ~~Commissioner~~ **appropriate office of the Food and Drug Administration with expertise**  
31                   **regarding drug shortages regarding whether the action or letter could cause, or exacerbate, a**  
32                   **shortage of the drug.**

33                   **“(3) ACTION.—If the Secretary determines, after the communication described in**  
34                   **paragraph (2), that an enforcement action or a warning letter could reasonably cause or**  
35                   **exacerbate a shortage of a drug described under subsection (a), then the Secretary shall**  
36                   **evaluate the risks associated with the impact of such shortage upon patients and those risks**  
37                   **associated with the violation involved before taking such action or issuing such letter,**  
38                   **unless there is imminent risk of serious adverse health consequences or death to humans.**

39                   **“(4) REPORTING BY OTHER ENTITIES.—The Secretary shall identify or establish a**  
40                   **mechanism by which healthcare providers and other third-party organizations may**  
41                   **report to the Secretary evidence of a drug shortage.**

42                   **“(5) REVIEW AND CONSTRUCTION.—No determination, finding, action, or omission of the**

1 Secretary under this subsection shall—

2 “(A) be subject to judicial review; or

3 “(B) be construed to establish a defense to an enforcement action by the Secretary.

4 “(e) Recordkeeping and Reporting.—

5 “(1) RECORDKEEPING.—The Secretary shall maintain records related to drug shortages,  
6 including with respect to— **to each of the following:**

7 ~~“(A) the~~“(A) **The number of manufacturers that reported submitted a notification**  
8 **to the Secretary under subsection (a) in each calendar year;**

9 ~~“(B) the~~“(B) **The number of drug shortages that occurred in each calendar year and a list**  
10 **of drug names, drug types, and classes that were the subject of such shortages;**

11 ~~“(C) a~~“(C) **A list of the known factors contributing to the drug shortages described in**  
12 **subparagraph (B);**

13 ~~“(D) a~~“(D)(i) **A list of the steps major actions** taken by the Secretary to prevent or  
14 **mitigate the drug shortages described in subparagraph (B);**

15 ~~“(E) the~~“(ii) **The Secretary shall include in the list under clause (i) the following:**

16 ~~“(I) The~~“(I) **The number of applications for which the Secretary expedited review**  
17 **under subsection (c)(1) in each calendar year;**

18 ~~“(F) the~~“(II) **The number of expedited establishment inspections or**  
19 **reinspections that the Secretary expedited under subsection (c)(2) in each calendar**  
20 **year;**

21 ~~“(G) the~~“(E) **The number of notifications reported submitted to the Secretary under**  
22 **subsection (a) in each calendar year;**

23 ~~“(H) the~~“(F) **The names of manufacturers who that the Secretary has learned did**  
24 **not comply with the notification requirement under subsection (a) in each calendar**  
25 **year;**

26 ~~“(I) a summary of consultations and actions taken under subsection (d) in each~~  
27 ~~calendar year;~~

28 ~~“(J) the~~“(G) **The number of times in each calendar year that the Secretary**  
29 **determined under subsection (d)(3) that an enforcement action or a warning letter**  
30 **could reasonably cause or exacerbate a shortage of a drug described under subsection**  
31 **(a), but did not evaluate the risks associated with the impact of such shortage upon**  
32 **patients and those risks associated with the violation involved before taking such**  
33 **action or issuing such letter on the grounds that there was imminent risk of serious**  
34 **adverse health consequences or death to humans, and a description of each such**  
35 **imminent risk determination; and summary of the determinations.**

36 ~~“(K) any~~“(H) **A summary of the communications made and actions taken under**  
37 **subsection (d) in each calendar year.**

38 “(I) **Any other information the Secretary deems appropriate to better prevent and**  
39 **mitigate drug shortages.**

1           “(2) TREND ANALYSIS.—The Secretary is authorized to retain a third party to conduct a  
2 study, if the Secretary believes such a study would help clarify the causes, trends, or  
3 solutions related to drug shortages.

4           “(3) ANNUAL REPORT.—~~NOT SUMMARY.~~—**Not** later than 18 months after the date of  
5 enactment of the [~~insert short title~~] **Food and Drug Administration Safety and**  
6 **Innovation Act**, and annually thereafter, the Secretary shall submit to the Committee on  
7 Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and  
8 Commerce of the House of Representatives a report summarizing ~~the findings described in~~  
9 ~~paragraph (1)~~, with respect to the 1-year period preceding such report, **the findings**  
10 **described in paragraph (1)**. Such report shall not include any ~~proprietary information.~~  
11 **information that is exempt from disclosure under section 552 of title 5, United States**  
12 **Code, by reason of subsection (b)(4) of such section.**

13           “(f) Definitions.—For purposes of this section—

14           “(1) the term ‘drug’—

15                   “(A) means a drug **(as defined in section 201(g)) that is** intended for human use;  
16                   and

17                   “(B) does not include biological products (as defined in section 351 of the Public  
18 Health Service Act), unless otherwise provided by the Secretary in the regulations  
19 promulgated under subsection (h);

20           “(2) the term ‘drug shortage’ or ‘shortage’, with respect to a drug, means a period of time  
21 when the demand or projected demand for the drug within the United States exceeds the  
22 supply of the drug; and

23           “(3) the term ‘meaningful disruption’—

24                   “(A) means a change in production that is ~~highly~~ **reasonably** likely to lead to a  
25 reduction in the supply of a drug by a manufacturer that is more than negligible and  
26 impacts the ability of the manufacturer to fill orders or meet expected demand for its  
27 product; and

28                   “(B) does not include interruptions in manufacturing due to matters such as routine  
29 maintenance or insignificant changes in manufacturing so long as the manufacturer  
30 expects to resume operations in a short period of time.

31           “(g) Distribution.—To the maximum extent practicable, the Secretary may distribute  
32 information on drug shortages and on the permanent discontinuation of the drugs described in  
33 this section to appropriate provider and patient organizations, **except that any such distribution**  
34 **shall not include any information that is exempt from disclosure under section 552 of title**  
35 **5, United States Code, by reason of subsection (b)(4) of such section.**

36           “(h) Regulations.—

37           “(1) IN GENERAL.—Not later than 18 months after the date of enactment of the [~~insert~~  
38 ~~short title~~] **Food and Drug Administration Safety and Innovation Act**, the Secretary  
39 shall adopt a final regulation implementing this section.

40           “(2) INCLUSION OF BIOLOGICAL PRODUCTS.—~~THE PRODUCTS.~~—

1           “(A) **IN GENERAL.**—The Secretary may by regulation apply this section to  
2 biological products (as defined in section 351 of the Public Health Service Act) if the  
3 Secretary determines such inclusion would benefit the public health.

4           “(B) **RULE FOR VACCINES.**—If the Secretary applies this section to vaccines  
5 pursuant to subparagraph (A), the Secretary shall—

6                   “(i) consider whether the notification requirement under subsection (a)  
7 may be satisfied by submitting a notification to the Centers for Disease  
8 Control and Prevention under the vaccine shortage notification program of  
9 such Centers; and

10                   “(ii) explain the determination made by the Secretary under clause (i) in  
11 the regulation.

12           “(3) **PROCEDURE.**—In promulgating a regulation implementing ~~the amendment made by~~  
13 this section, the Secretary shall—

14                   “(A) issue a notice of proposed rulemaking that includes a copy of the proposed  
15 regulation;

16                   “(B) provide a period of not less than 60 days for comments on the proposed  
17 regulation; and

18                   “(C) publish the final regulation not less than 30 days before the regulation’s  
19 effective date.

20           “(4) **RESTRICTIONS.**—Notwithstanding any other provision of Federal law, in  
21 implementing this section, the Secretary shall only promulgate regulations as described in  
22 paragraph (3).”.

23           (b) ~~Internal Review.~~—~~Not later than 2 years after the date of enactment of this Act,~~ **Effect of**  
24 **Notification.**—**The submission of a notification to the Secretary of Health and Human**  
25 **Services (referred to in this section as the “Secretary”) for purposes of complying with the**  
26 **requirement in section 506C(a) of the Federal Food, Drug, and Cosmetic Act (as amended**  
27 **by subsection (a)) shall not be construed—**

28                   (1) as an admission that any product that is the subject of such notification violates  
29 any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

30                   (2) as evidence of an intention to promote or market the product for an indication or  
31 use for which the product has not been approved by the Secretary.

32           (c) **Internal Review.**—**Not later than 2 years after the date of enactment of this Act, the**  
33 **Secretary shall—**

34                   (1) analyze and review the regulations promulgated under the Federal Food, Drug, and  
35 Cosmetic Act (21 U.S.C. 301 et seq.), the guidances or policies issued under such Act  
36 related to drugs intended for human use, and the practices of the Food and Drug  
37 Administration regarding enforcing such Act related to manufacturing of such drugs, to  
38 identify any such regulations, guidances, policies, or practices that cause, exacerbate,  
39 prevent, or mitigate drug shortages (as defined in section 506C of the Federal Food, Drug,  
40 and Cosmetic Act (as amended by subsection (a))); and

1 (2) determine how regulations, guidances, policies, or practices identified under  
2 paragraph (1) should be modified, streamlined, expanded, or discontinued in order to reduce  
3 or prevent such drug shortages, taking into consideration the effect of any changes on the  
4 public health.

5 ~~(e) Study on Drug Pricing Practices.~~—**(d) Study on Market Factors Contributing to Drug**  
6 **Shortages and Stockpiling.**—

7 (1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the  
8 **Secretary Comptroller General of the United States**, in consultation with **the Secretary**,  
9 the Department of Health and Human Services Office of the Inspector General, the Attorney  
10 General, and Chairman of the Federal Trade Commission, shall publish a report reviewing  
11 any findings that drug shortages (as so defined) have led market participants to stockpile  
12 affected drugs or sell them at significantly increased prices, the impact of such activities on  
13 Federal revenue, and any economic factors that have exacerbated or created a market for  
14 such actions.

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

16 (A) an analysis of the incidence of any of the activities described in paragraph (1)  
17 and the effect of such activities on the public health;

18 (B) an evaluation of whether in such cases there is a correlation between drugs in  
19 shortage and—

20 (i) the number of manufacturers producing such drugs;

21 (ii) the pricing structure, including Federal reimbursements, for such drugs  
22 before such drugs were in shortage, and to the extent possible, revenue received  
23 by each such manufacturer of such drugs;

24 (iii) pricing structure and revenue, to the extent possible, for the same drugs  
25 when sold under the conditions described in paragraph (1); and

26 (iv) the impact of contracting practices by market participants (including  
27 manufacturers, distributors, group purchasing organizations, and providers) on  
28 competition, access to drugs, and pricing of drugs;

29 (C) whether the activities described in paragraph (1) are consistent with applicable  
30 law; and

31 (D) recommendations to Congress on what, if any, additional reporting or  
32 enforcement actions are necessary.

33 **(e) Trade Secret and Confidential Information.**—**Nothing in this section alters or amends**  
34 **section 1905 of title 18, United States Code, or section 552(b)(4) of title 5, United States**  
35 **Code.**