

112TH CONGRESS
2D SESSION

S. _____

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

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 “_____ Act
5 of _____”].

6 **SEC. 2. DRUG SHORTAGES.**

7 (a) IN GENERAL.—Section 506C of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 356c) is amend-
9 ed to read as follows:

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

3 “(a) IN GENERAL.—A manufacturer of a drug—

4 “(1) that is—

5 “(A) life-supporting;

6 “(B) life-sustaining; or

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

9 “(2) that is not a radio pharmaceutical drug
10 product, a human tissue replaced by a recombinant
11 product, a product derived from human plasma pro-
12 tein, or any other product as designated by the Sec-
13 retary,

14 shall notify the Secretary of a discontinuance or interrup-
15 tion of the manufacture of the drug that could lead to
16 a meaningful disruption in the supply in the United States
17 of that drug at least 6 months prior to the date of the
18 discontinuance or interruption.

19 “(b) REDUCTION IN NOTIFICATION PERIOD.—The
20 notification period required under subsection (a) for a
21 manufacturer—

22 “(1) may be deemed to be reduced if the manu-
23 facturer notifies the Secretary as soon as practicable
24 after becoming aware of such discontinuance or
25 interruption; and

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

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

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

10 “(C) a liability problem may exist for the
11 manufacturer if the manufacturing is continued
12 for the 6-month period;

13 “(D) continuation of the manufacturing
14 for the 6-month period may cause substantial
15 economic hardship for the manufacturer; or

16 “(E) the manufacturer has filed for bank-
17 ruptcy under chapter 7 or 11 of title 11, United
18 States Code.

19 “(c) **EXPEDITED INSPECTIONS AND REVIEWS.**—If,
20 based on notifications described in subsection (a) or any
21 other relevant information, the Secretary concludes that
22 there is, or is likely to be, a drug shortage of a drug de-
23 scribed in subsection (a), the Secretary may—

24 “(1) expedite the review of a supplement to a
25 new drug application submitted under section

1 505(b), an abbreviated new drug application sub-
2 mitted under section 505(j), or a supplement to such
3 an application submitted under section 505(j) that
4 could help mitigate or prevent such shortage; or

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

8 “(d) COORDINATION.—

9 “(1) TASK FORCE.—

10 “(A) IN GENERAL.—As soon as practicable
11 after the date of enactment of the [insert short
12 title], the Secretary shall establish a Task
13 Force to mitigate drug shortages ongoing as of
14 such date and to prevent future drug shortages
15 through enhanced interagency and intraagency
16 coordination, communication, strategic planning
17 and decisionmaking, as well as through appro-
18 priate interaction and consultation with relevant
19 experts and other stakeholders. In carrying out
20 this subparagraph, the Task Force shall ensure
21 that the appropriate offices are consulted and
22 involved in coordination, including the Office of
23 the Commissioner, the Center for Drug Evalua-
24 tion and Research, the Office of Regulatory Af-
25 fairs, and employees within the Department of

1 Health and Human Services with expertise re-
2 garding drug shortages.

3 “(B) STRATEGIC PLAN.—The Task
4 Force—

5 “(i) shall develop a strategic plan and
6 implementation plan to ensure that drug
7 shortages are considered when the Sec-
8 retary initiates a regulatory action that
9 could precipitate a drug shortage or exac-
10 erbate an existing drug shortage; and

11 “(ii) not later than 1 year after the
12 date of enactment of the [insert short
13 title] shall—

14 “(I) publish the implementation
15 plan addressing any necessary addi-
16 tional coordination and communica-
17 tion activities to effectively prevent
18 and mitigate drug shortages; and

19 “(II) submit such plan to Con-
20 gress and the Secretary.

21 “(2) COMMUNICATION.—The Secretary shall
22 ensure that, prior to any enforcement action or
23 issuance of a warning letter that the Secretary de-
24 termines could reasonably be anticipated to lead to
25 a meaningful disruption in the supply in the United

1 States of a drug described under subsection (a),
2 there is communication with the Commissioner or a
3 designee of the Commissioner with expertise regard-
4 ing drug shortages regarding whether the action or
5 letter could cause, or exacerbate, a shortage of the
6 drug.

7 “(3) ACTION.—If the Secretary determines,
8 after the communication described in paragraph (2),
9 that an enforcement action or a warning letter could
10 reasonably cause or exacerbate a shortage of a drug
11 described under subsection (a), then the Secretary
12 shall evaluate the risks associated with the impact of
13 such shortage upon patients and those risks associ-
14 ated with the violation involved before taking such
15 action or issuing such letter, unless there is immi-
16 nent risk of serious adverse health consequences or
17 death to humans.

18 “(4) REVIEW AND CONSTRUCTION.—No deter-
19 mination, finding, action, or omission of the Sec-
20 retary under this subsection shall—

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

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

24 “(e) RECORDKEEPING AND REPORTING.—

1 “(1) RECORDKEEPING.—The Secretary shall
2 maintain records related to drug shortages, includ-
3 ing with respect to—

4 “(A) the number of manufacturers that re-
5 ported to the Secretary under subsection (a) in
6 each calendar year;

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

11 “(C) a list of the known factors contrib-
12 uting to the drug shortages described in sub-
13 paragraph (B);

14 “(D) a list of the steps taken by the Sec-
15 retary to prevent or mitigate the drug shortages
16 described in subparagraph (B);

17 “(E) the number of applications for which
18 the Secretary expedited review under subsection
19 (c)(1) in each calendar year;

20 “(F) the number of establishment inspec-
21 tions or reinspections that the Secretary expe-
22 dited under subsection (c)(2) in each calendar
23 year;

1 “(G) the number of notifications reported
2 to the Secretary under subsection (a) in each
3 calendar year;

4 “(H) the names of manufacturers who did
5 not comply with the notification requirement
6 under subsection (a) in each calendar year;

7 “(I) a summary of consultations and ac-
8 tions taken under subsection (d) in each cal-
9 endar year;

10 “(J) the number of times in each calendar
11 year that the Secretary determined under sub-
12 section (d)(3) that an enforcement action or a
13 warning letter could reasonably cause or exacer-
14 bate a shortage of a drug described under sub-
15 section (a), but did not evaluate the risks asso-
16 ciated with the impact of such shortage upon
17 patients and those risks associated with the vio-
18 lation involved before taking such action or
19 issuing such letter on the grounds that there
20 was imminent risk of serious adverse health
21 consequences or death to humans, and a de-
22 scription of each such imminent risk determina-
23 tion; and

1 “(K) any other information the Secretary
2 deems appropriate to better prevent and miti-
3 gate drug shortages.

4 “(2) TREND ANALYSIS.—The Secretary is au-
5 thorized to retain a third party to conduct a study,
6 if the Secretary believes such a study would help
7 clarify the causes, trends, or solutions related to
8 drug shortages.

9 “(3) ANNUAL REPORT.—Not later than 18
10 months after the date of enactment of the [insert
11 short title], and annually thereafter, the Secretary
12 shall submit to the Committee on Health, Edu-
13 cation, Labor, and Pensions of the Senate and the
14 Committee on Energy and Commerce of the House
15 of Representatives a report summarizing the find-
16 ings described in paragraph (1) with respect to the
17 1-year period preceding such report. Such report
18 shall not include any proprietary information.

19 “(f) DEFINITIONS.—For purposes of this section—

20 “(1) the term ‘drug’—

21 “(A) means a drug intended for human
22 use; and

23 “(B) does not include biological products
24 (as defined in section 351 of the Public Health
25 Service Act), unless otherwise provided by the

1 Secretary in the regulations promulgated under
2 subsection (h);

3 “(2) the term ‘drug shortage’ or ‘shortage’,
4 with respect to a drug, means a period of time when
5 the demand or projected demand for the drug within
6 the United States exceeds the supply of the drug;
7 and

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

9 “(A) means a change in production that is
10 highly likely to lead to a reduction in the supply
11 of a drug by a manufacturer that is more than
12 negligible and impacts the ability of the manu-
13 facturer to fill orders or meet expected demand
14 for its product; and

15 “(B) does not include interruptions in
16 manufacturing due to matters such as routine
17 maintenance or insignificant changes in manu-
18 facturing so long as the manufacturer expects
19 to resume operations in a short period of time.

20 “(g) DISTRIBUTION.—To the maximum extent prac-
21 ticable, the Secretary may distribute information on drug
22 shortages and on the permanent discontinuation of the
23 drugs described in this section to appropriate provider and
24 patient organizations.

25 “(h) REGULATIONS.—

1 “(1) IN GENERAL.—Not later than 18 months
2 after the date of enactment of the [insert short
3 title], the Secretary shall adopt a final regulation
4 implementing this section.

5 “(2) INCLUSION OF BIOLOGICAL PRODUCTS.—
6 The Secretary may by regulation apply this section
7 to biological products (as defined in section 351 of
8 the Public Health Service Act) if the Secretary de-
9 termines such inclusion would benefit the public
10 health.

11 “(3) PROCEDURE.—In promulgating a regula-
12 tion implementing the amendment made by this sec-
13 tion, the Secretary shall—

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

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

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

22 “(4) RESTRICTIONS.—Notwithstanding any
23 other provision of Federal law, in implementing this
24 section, the Secretary shall only promulgate regula-
25 tions as described in paragraph (3).”.

1 (b) INTERNAL REVIEW.—Not later than 2 years after
2 the date of enactment of this Act, the Secretary of Health
3 and Human Services (referred to in this section as the
4 “Secretary”) shall—

5 (1) analyze and review the regulations promul-
6 gated under the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 301 et seq.), the guidances or poli-
8 cies issued under such Act related to drugs intended
9 for human use, and the practices of the Food and
10 Drug Administration regarding enforcing such Act
11 related to manufacturing of such drugs, to identify
12 any such regulations, guidances, policies, or prac-
13 tices that cause, exacerbate, prevent, or mitigate
14 drug shortages (as defined in section 506C of the
15 Federal Food, Drug, and Cosmetic Act (as amended
16 by subsection (a))); and

17 (2) determine how regulations, guidances, poli-
18 cies, or practices identified under paragraph (1)
19 should be modified, streamlined, expanded, or dis-
20 continued in order to reduce or prevent such drug
21 shortages, taking into consideration the effect of any
22 changes on the public health.

23 (c) STUDY ON DRUG PRICING PRACTICES.—

24 (1) IN GENERAL.—Not later than 1 year after
25 the date of enactment of this Act, the Secretary, in

1 consultation with the Department of Health and
2 Human Services Office of the Inspector General, the
3 Attorney General, and Chairman of the Federal
4 Trade Commission, shall publish a report reviewing
5 any findings that drug shortages (as so defined)
6 have led market participants to stockpile affected
7 drugs or sell them at significantly increased prices,
8 the impact of such activities on Federal revenue, and
9 any economic factors that have exacerbated or cre-
10 ated a market for such actions.

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

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

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

19 (i) the number of manufacturers pro-
20 ducing such drugs;

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

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

5 (iv) the impact of contracting prac-
6 tices by market participants (including
7 manufacturers, distributors, group pur-
8 chasing organizations, and providers) on
9 competition, access to drugs, and pricing
10 of drugs;

11 (C) whether the activities described in
12 paragraph (1) are consistent with applicable
13 law; and

14 (D) recommendations to Congress on what,
15 if any, additional reporting or enforcement ac-
16 tions are necessary.