

Richard Blumenthal
S.L.C.

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AMENDMENT NO. _____ Calendar No. _____

Purpose: To establish a critical drug reinforcement program and provide authorities to address drug shortages.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

S. 3187

To am	AMENDMENT NO 2135	to
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GPO: 2010 69-070 (mac)

AMENDMENT intended to be proposed by Mr. BLUMENTHAL

Viz:

- 1 At the end of title X, add the following:
- 2 **SEC. 10__ . CRITICAL DRUG SUPPLY REINFORCEMENT**
- 3 **PROGRAM.**
- 4 Chapter V of the Federal Food, Drug, and Cosmetic
- 5 Act (21 U.S.C. 351 et seq.) is amended by adding at the
- 6 end the following:
- 7 **“Subchapter G—Drug Shortages**
- 8 **“SEC. 575. DEFINITIONS.**
- 9 **“For purposes of this subchapter—**

1 “(1) the term ‘critical reinforcement drug’
2 means a drug that—

3 “(A) is the subject of a permanent dis-
4 continuance or an interruption in the manufac-
5 ture of the drug that could lead to a meaningful
6 disruption in the supply of that drug in the
7 United States, as defined in section 506C(f)(3);
8 and

9 “(B) is identified as vulnerable to a drug
10 shortage based on the criteria established under
11 section 575A;

12 “(2) the term ‘drug’—

13 “(A) means a drug (as defined in section
14 201(g)) that is intended for human use and is
15 the subject of an approved application under
16 section 505(j); and

17 “(B) does not include biological products
18 (as defined in section 351 of the Public Health
19 Service Act); and

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

1 **“SEC. 575A. CRITICAL DRUG SUPPLY EVALUATION AND RE-**
2 **INFORCEMENT.**

3 “(a) DEVELOPMENT OF CRITERIA FOR EVALUATION
4 OF CRITICAL REINFORCEMENT NEED.—

5 “(1) EVALUATION.—Not later than 180 days
6 after the date of enactment of this section, the Sec-
7 retary, in consultation with Office of Drug Short-
8 ages, shall conduct an evaluation to establish evi-
9 dence-based criteria for identifying drugs that are
10 vulnerable to a drug shortage.

11 “(2) CONTENT.—The evaluation under para-
12 graph (1) shall include a comprehensive trend anal-
13 ysis to forecast drug shortages and target drugs that
14 are vulnerable to a shortage. The Secretary is au-
15 thorized to contract with a third party to conduct or
16 participate in such evaluation. In conducting such
17 evaluation, the Secretary or any authorized third
18 party shall not use any confidential, trade secret, or
19 proprietary information of any other entity without
20 such entity’s consent.

21 “(3) CONSULTATION WITH STAKEHOLDERS.—
22 The Secretary, as part of the evaluation under para-
23 graph (1), shall convene a discussion with stake-
24 holders to assess methodology and findings applica-
25 ble to such evaluation.

1 “(4) REPORT TO CONGRESS.—Not later than 2
2 years after the date of enactment of this section, the
3 Secretary shall submit a report to Congress that de-
4 scribes the methods and processes used to conduct
5 the evaluation under this subsection.

6 “(b) CRITICAL REINFORCEMENT.—To carry out this
7 section, the Secretary may award the incentives under
8 subsection (d) to qualified manufacturers to secure an
9 agreement—

10 “(1) for the rapid production of a critical rein-
11 forcement drug;

12 “(2) that the qualified manufacturer will main-
13 tain production of a critical reinforcement drug; or

14 “(3) that would allow the Secretary to purchase
15 supply of a critical reinforcement drug from the
16 qualified manufacturer under certain market condi-
17 tions and on terms and conditions mutually agreed
18 upon.

19 “(c) QUALIFIED MANUFACTURERS.—To be a quali-
20 fied manufacturer for purposes of this section—

21 “(1) an entity shall be a drug manufacturer;
22 and

23 “(2) the Secretary shall ensure that the manu-
24 facturer—

1 “(A) is in compliance with good manufac-
2 turing practice regulations of the Food and
3 Drug Administration to produce a critical rein-
4 forcement drug or a similar product; and

5 “(B)(i) currently produces a critical rein-
6 forcement drug or a similar product and can in-
7 crease production immediately to address the
8 shortage with no regulatory approvals required;

9 “(ii) does not currently produce a critical
10 reinforcement drug but has the capability, ca-
11 pacity and regulatory authority to do so and
12 could commence supply in time to address need;
13 or

14 “(iii) has capability and capacity to
15 produce a critical reinforcement drug but not
16 the regulatory authority and could commence
17 supply upon regulatory filing and approval.

18 “(d) INCENTIVES.—

19 “(1) IN GENERAL.—If the Secretary ensures a
20 manufacturer is a qualified manufacturer, the Sec-
21 retary shall negotiate a manufacturing contingency
22 plan with the manufacturer to meet an identified
23 critical reinforcement in subsection (c). The Sec-
24 retary may—

1 “(A) expedite the review of any abbrevi-
2 viated new drug application submitted under
3 section 505 by the qualified manufacturer for a
4 drug that is vulnerable to shortage as identified
5 pursuant to the criteria established under sub-
6 section (a); and

7 “(B) waive any application fees related to
8 such an abbreviated new drug application.

9 “(2) LIMITATION.—If the qualified manufac-
10 turer fails to meet benchmarks specified by the Sec-
11 retary in the agreement between the Secretary and
12 the manufacturer, or otherwise violates such agree-
13 ment, the Secretary may retroactively assess the ap-
14 plication fees waived under paragraph (1)(B).

15 “(e) TRADEMARK PROTECTION.—Nothing in this
16 section shall be construed to alter or modify in any way,
17 any applicable patent, copyright, trademark, or other in-
18 tellectual property rights of any holder of a new drug ap-
19 plication, an abbreviated new drug application, or a bio-
20 logics license application, including any applicable regu-
21 latory exclusivity periods or periods during which the Sec-
22 retary may not accept for filing or approve any new drug
23 application, an abbreviated new drug application, or a bio-
24 logics license application, and procedures associated there-
25 with, under this Act or the Public Health Service Act.”.