

Calendar No. 22116TH CONGRESS
1ST SESSION**S. 340**

To promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 5, 2019

Mr. LEAHY (for himself, Mr. GRASSLEY, Ms. KLOBUCHAR, Mr. LEE, Mrs. FEINSTEIN, Ms. BALDWIN, Mr. BLUMENTHAL, Mr. BOOKER, Mr. BROWN, Ms. COLLINS, Mr. COTTON, Mr. CRUZ, Mr. DAINES, Mr. DURBIN, Ms. ERNST, Mrs. FISCHER, Ms. HASSAN, Mr. KENNEDY, Mr. KING, Mr. MENENDEZ, Ms. MURKOWSKI, Mr. PAUL, Mr. ROUNDS, Ms. SMITH, Ms. STABENOW, Mr. TESTER, Mr. WHITEHOUSE, and Mr. YOUNG) introduced the following bill; which was read the first time

FEBRUARY 6, 2019

Read the second time and placed on the calendar

A BILL

To promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Creating and Restoring
3 Equal Access to Equivalent Samples Act of 2019” or the
4 “CREATES Act of 2019”.

5 **SEC. 2. FINDINGS.**

6 Congress finds the following:

7 (1) It is the policy of the United States to pro-
8 mote competition in the market for drugs and bio-
9 logical products by facilitating the timely entry of
10 low-cost generic and biosimilar versions of those
11 drugs and biological products.

12 (2) Since their enactment in 1984 and 2010,
13 respectively, the Drug Price Competition and Patent
14 Term Restoration Act of 1984 (Public Law 98–417;
15 98 Stat. 1585) and the Biologics Price Competition
16 and Innovation Act of 2009 (subtitle A of title VII
17 of Public Law 111–148; 124 Stat. 804), have pro-
18 vided pathways for making lower-cost versions of
19 previously approved drugs and previously licensed bi-
20 ological products available to the people of the
21 United States in a timely manner, thereby lowering
22 overall prescription drug costs for patients and tax-
23 payers by billions of dollars each year.

24 (3) In order for these pathways to function as
25 intended, developers of generic drugs and biosimilar
26 biological products (referred to in this section as

1 “generic product developers”) must be able to obtain
2 quantities of the reference listed drug or biological
3 product with which the generic drug or biosimilar bi-
4 ological product is intended to compete (referred to
5 in this section as a “covered product”) for purposes
6 of supporting an application for approval by the
7 Food and Drug Administration, including for testing
8 to show that—

9 (A) a prospective generic drug is bioequiva-
10 lent to the covered product in accordance with
11 subsection (j) of section 505 of the Federal,
12 Food, Drug, and Cosmetic Act (21 U.S.C.
13 355), or meets the requirements for approval of
14 an application submitted under subsection
15 (b)(2) of that section; or

16 (B) a prospective biosimilar biological
17 product is biosimilar to or interchangeable with
18 its reference biological product under section
19 351(k) of the Public Health Service Act (42
20 U.S.C. 262(k)), as applicable.

21 (4) For drugs and biological products that are
22 subject to a risk evaluation and mitigation strategy,
23 another essential component in the creation of low-
24 cost generic and biosimilar versions of covered prod-
25 ucts is the ability of generic product developers to

1 join the manufacturer of the covered product (re-
2 ferred to in this section as the “license holder”) in
3 a single, shared system of elements to assure safe
4 use and supporting agreements as required by sec-
5 tion 505–1 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 355–1), or secure a variance there-
7 from.

8 (5) Contrary to the policy of the United States
9 to promote competition in the market for drugs and
10 biological products by facilitating the timely entry of
11 lower-cost generic and biosimilar versions of those
12 drugs and biological products, certain license holders
13 are preventing generic product developers from ob-
14 taining quantities of the covered product necessary
15 for the generic product developer to support an ap-
16 plication for approval by the Food and Drug Admin-
17 istration, including testing to show bioequivalence,
18 biosimilarity, or interchangeability to the covered
19 product, in some instances based on the justification
20 that the covered product is subject to a risk evalua-
21 tion and mitigation strategy with elements to assure
22 safe use under section 505–1 of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 355–1).

24 (6) The Director of the Center for Drug Eval-
25 uation and Research of the Food and Drug Adminis-

1 tration has testified that some manufacturers of cov-
2 ered products have used risk evaluation and mitiga-
3 tion strategies and distribution restrictions adopted
4 by the manufacturer on their own behalf as reasons
5 to not sell quantities of a covered product to generic
6 product developers, causing barriers and delays in
7 getting generic products on the market. The Food
8 and Drug Administration has reported receiving sig-
9 nificant numbers of inquiries from generic product
10 developers who were unable to obtain samples of cov-
11 ered products to conduct necessary testing and oth-
12 erwise meet requirements for approval of generic
13 drugs.

14 (7) In 2018, the Acting Chairman of the Fed-
15 eral Trade Commission testified that the Federal
16 Trade Commission continues to be very concerned
17 about potential abuses by manufacturers of brand
18 drugs of risk evaluation and mitigation strategies or
19 other closed distribution systems to impede generic
20 competition.

21 (8) Also contrary to the policy of the United
22 States to promote competition in the market for
23 drugs and biological products by facilitating the
24 timely entry of lower-cost generic and biosimilar
25 versions of those drugs and biological products, cer-

1 tain license holders are impeding the prompt nego-
2 tiation and development on commercially reasonable
3 terms of a single, shared system of elements to as-
4 sure safe use, which may be necessary for the ge-
5 neric product developer to gain approval for its drug
6 or licensing for its biological product.

7 (9) While the antitrust laws may address the
8 refusal by some license holders to provide quantities
9 of a covered product to a generic product developer,
10 a more tailored legal pathway would help ensure
11 that generic product developers can obtain necessary
12 quantities of a covered product in a timely way for
13 purposes of developing a generic drug or biosimilar
14 biological product, facilitating competition in the
15 marketplace for drugs and biological products.

16 (10) The antitrust laws may address actions by
17 license holders who impede the prompt negotiation
18 and development of a single, shared system of ele-
19 ments to assure safe use, and the Food and Drug
20 Administration has some authority to waive the re-
21 quirement of a single, shared system. Clearer regu-
22 latory authority to approve different systems that
23 meet the statutory requirements to ensure patient
24 safety, however, would limit the effectiveness of bad
25 faith negotiations over single, shared systems to

1 delay generic approval. At the same time, clearer
2 regulatory authority would ensure all systems pro-
3 tect patient safety.

4 **SEC. 3. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**
5 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

6 (a) DEFINITIONS.—In this section—

7 (1) the term “commercially reasonable, market-
8 based terms” means—

9 (A) a non-discriminatory price for the sale
10 of the covered product at or below, but not
11 greater than, the most recent wholesale acquisi-
12 tion cost for the drug, as defined in section
13 1847A(c)(6)(B) of the Social Security Act (42
14 U.S.C. 1395w–3a(c)(6)(B));

15 (B) a schedule for delivery that results in
16 the transfer of the covered product to the eligi-
17 ble product developer consistent with the timing
18 under subsection (b)(2)(A)(iv); and

19 (C) no additional conditions are imposed
20 on the sale of the covered product;

21 (2) the term “covered product”—

22 (A) means—

23 (i) any drug approved under sub-
24 section (c) or (j) of section 505 of the Fed-
25 eral Food, Drug, and Cosmetic Act (21

1 U.S.C. 355) or biological product licensed
2 under subsection (a) or (k) of section 351
3 of the Public Health Service Act (42
4 U.S.C. 262);

5 (ii) any combination of a drug or bio-
6 logical product described in clause (i); or

7 (iii) when reasonably necessary to
8 support approval of an application under
9 section 505 of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 355), or sec-
11 tion 351 of the Public Health Service Act
12 (42 U.S.C. 262), as applicable, or other-
13 wise meet the requirements for approval
14 under either such section, any product, in-
15 cluding any device, that is marketed or in-
16 tended for use with such a drug or biologi-
17 cal product; and

18 (B) does not include any drug or biological
19 product that appears on the drug shortage list
20 in effect under section 506E of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C.
22 356e), unless the shortage will not be promptly
23 resolved—

1 (i) as demonstrated by the fact that
2 the drug or biological product has been in
3 shortage for more than 6 months; or

4 (ii) as otherwise determined by the
5 Secretary;

6 (3) the term “device” has the meaning given
7 the term in section 201 of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 321);

9 (4) the term “eligible product developer” means
10 a person that seeks to develop a product for ap-
11 proval pursuant to an application for approval under
12 subsection (b)(2) or (j) of section 505 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
14 for licensing pursuant to an application under sec-
15 tion 351(k) of the Public Health Service Act (42
16 U.S.C. 262(k));

17 (5) the term “license holder” means the holder
18 of an application approved under subsection (c) or
19 (j) of section 505 of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 355) or the holder of a li-
21 cense under subsection (a) or (k) of section 351 of
22 the Public Health Service Act (42 U.S.C. 262) for
23 a covered product;

24 (6) the term “REMS” means a risk evaluation
25 and mitigation strategy under section 505–1 of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 355–1);

3 (7) the term “REMS with ETASU” means a
4 REMS that contains elements to assure safe use
5 under section 505–1(f) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 355–1(f));

7 (8) the term “Secretary” means the Secretary
8 of Health and Human Services;

9 (9) the term “single, shared system of elements
10 to assure safe use” means a single, shared system
11 of elements to assure safe use under section 505–
12 1(f) of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 355–1(f)); and

14 (10) the term “sufficient quantities” means an
15 amount of a covered product that allows the eligible
16 product developer to—

17 (A) conduct testing to support an applica-
18 tion under—

19 (i) subsection (b)(2) or (j) of section
20 505 of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 355); or

22 (ii) section 351(k) of the Public
23 Health Service Act (42 U.S.C. 262(k));
24 and

1 (B) fulfill any regulatory requirements re-
2 lating to approval of such an application.

3 (b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-
4 CIENT QUANTITIES OF A COVERED PRODUCT.—

5 (1) IN GENERAL.—An eligible product developer
6 may bring a civil action against the license holder
7 for a covered product seeking relief under this sub-
8 section in an appropriate district court of the United
9 States alleging that the license holder has declined
10 to provide sufficient quantities of the covered prod-
11 uct to the eligible product developer on commercially
12 reasonable, market-based terms.

13 (2) ELEMENTS.—

14 (A) IN GENERAL.—To prevail in a civil ac-
15 tion brought under paragraph (1), an eligible
16 product developer shall prove, by a preponder-
17 ance of the evidence—

18 (i) that—

19 (I) the covered product is not
20 subject to a REMS with ETASU; or

21 (II) if the covered product is sub-
22 ject to a REMS with ETASU—

23 (aa) the eligible product de-
24 veloper has obtained a covered
25 product authorization from the

1 Secretary in accordance with sub-
2 paragraph (B); and

3 (bb) the eligible product de-
4 veloper has provided a copy of
5 the covered product authorization
6 to the license holder;

7 (ii) that, as of the date on which the
8 civil action is filed, the product developer
9 has not obtained sufficient quantities of
10 the covered product on commercially rea-
11 sonable, market-based terms;

12 (iii) that the eligible product developer
13 has requested to purchase sufficient quan-
14 tities of the covered product from the li-
15 cense holder; and

16 (iv) that the license holder has not de-
17 livered to the eligible product developer
18 sufficient quantities of the covered product
19 on commercially reasonable, market-based
20 terms—

21 (I) for a covered product that is
22 not subject to a REMS with ETASU,
23 by the date that is 31 days after the
24 date on which the license holder re-

1 ceived the request for the covered
2 product; and

3 (II) for a covered product that is
4 subject to a REMS with ETASU, by
5 31 days after the later of—

6 (aa) the date on which the
7 license holder received the re-
8 quest for the covered product; or

9 (bb) the date on which the
10 license holder received a copy of
11 the covered product authorization
12 issued by the Secretary in ac-
13 cordance with subparagraph (B).

14 (B) AUTHORIZATION FOR COVERED PROD-
15 UCT SUBJECT TO A REMS WITH ETASU.—

16 (i) REQUEST.—An eligible product de-
17 veloper may submit to the Secretary a
18 written request for the eligible product de-
19 veloper to be authorized to obtain suffi-
20 cient quantities of an individual covered
21 product subject to a REMS with ETASU.

22 (ii) AUTHORIZATION.—Not later than
23 120 days after the date on which a request
24 under clause (i) is received, the Secretary
25 shall, by written notice, authorize the eligi-

1 ble product developer to obtain sufficient
2 quantities of an individual covered product
3 subject to a REMS with ETASU for pur-
4 poses of—

5 (I) development and testing that
6 does not involve human clinical trials,
7 if the eligible product developer has
8 agreed to comply with any conditions
9 the Secretary determines necessary; or

10 (II) development and testing that
11 involves human clinical trials, if the
12 eligible product developer has—

13 (aa)(AA) submitted proto-
14 cols, informed consent docu-
15 ments, and informational mate-
16 rials for testing that include pro-
17 tections that provide safety pro-
18 tections comparable to those pro-
19 vided by the REMS for the cov-
20 ered product; or

21 (BB) otherwise satisfied the
22 Secretary that such protections
23 will be provided; and

1 (bb) met any other require-
2 ments the Secretary may estab-
3 lish.

4 (iii) NOTICE.—A covered product au-
5 thorization issued under this subparagraph
6 shall state that the provision of the covered
7 product by the license holder under the
8 terms of the authorization will not be a
9 violation of the REMS for the covered
10 product.

11 (3) AFFIRMATIVE DEFENSE.—In a civil action
12 brought under paragraph (1), it shall be an affirma-
13 tive defense, on which the defendant has the burden
14 of persuasion by a preponderance of the evidence—

15 (A) that, on the date on which the eligible
16 product developer requested to purchase suffi-
17 cient quantities of the covered product from the
18 license holder—

19 (i) neither the license holder nor any
20 of its agents, wholesalers, or distributors
21 was engaged in the manufacturing or com-
22 mercial marketing of the covered product;
23 and

24 (ii) neither the license holder nor any
25 of its agents, wholesalers, or distributors

1 otherwise had access to inventory of the
2 covered product to supply to the eligible
3 product developer on commercially reason-
4 able, market-based terms; or

5 (B) that—

6 (i) the license holder sells the covered
7 product through agents, distributors, or
8 wholesalers;

9 (ii) the license holder has placed no
10 restrictions, explicit or implicit, on its
11 agents, distributors, or wholesalers to sell
12 covered products to eligible product devel-
13 opers; and

14 (iii) the covered product can be pur-
15 chased by the eligible product developer in
16 sufficient quantities on commercially rea-
17 sonable, market-based terms from the
18 agents, distributors, or wholesalers of the
19 license holder.

20 (4) REMEDIES.—

21 (A) IN GENERAL.—If an eligible product
22 developer prevails in a civil action brought
23 under paragraph (1), the court shall—

24 (i) order the license holder to provide
25 to the eligible product developer without

1 delay sufficient quantities of the covered
2 product on commercially reasonable, mar-
3 ket-based terms;

4 (ii) award to the eligible product de-
5 veloper reasonable attorney's fees and costs
6 of the civil action; and

7 (iii) award to the eligible product de-
8 veloper a monetary amount sufficient to
9 deter the license holder from failing to pro-
10 vide other eligible product developers with
11 sufficient quantities of a covered product
12 on commercially reasonable, market-based
13 terms, if the court finds, by a preponder-
14 ance of the evidence—

15 (I) that the license holder delayed
16 providing sufficient quantities of the
17 covered product to the eligible product
18 developer without a legitimate busi-
19 ness justification; or

20 (II) that the license holder failed
21 to comply with an order issued under
22 clause (i).

23 (B) MAXIMUM MONETARY AMOUNT.—A
24 monetary amount awarded under subparagraph
25 (A)(iii) shall not be greater than the revenue

1 that the license holder earned on the covered
2 product during the period—

3 (i) beginning on—

4 (I) for a covered product that is
5 not subject to a REMS with ETASU,
6 the date that is 31 days after the date
7 on which the license holder received
8 the request; or

9 (II) for a covered product that is
10 subject to a REMS with ETASU, the
11 date that is 31 days after the later
12 of—

13 (aa) the date on which the
14 license holder received the re-
15 quest; or

16 (bb) the date on which the
17 license holder received a copy of
18 the covered product authorization
19 issued by the Secretary in ac-
20 cordance with paragraph (2)(B);
21 and

22 (ii) ending on the date on which the
23 eligible product developer received suffi-
24 cient quantities of the covered product.

1 (C) AVOIDANCE OF DELAY.—The court
2 may issue an order under subparagraph (A)(i)
3 before conducting further proceedings that may
4 be necessary to determine whether the eligible
5 product developer is entitled to an award under
6 clause (ii) or (iii) of subparagraph (A), or the
7 amount of any such award.

8 (e) LIMITATION OF LIABILITY.—A license holder for
9 a covered product shall not be liable for any claim under
10 Federal, State, or local law arising out of the failure of
11 an eligible product developer to follow adequate safeguards
12 to assure safe use of the covered product during develop-
13 ment or testing activities described in this section, includ-
14 ing transportation, handling, use, or disposal of the cov-
15 ered product by the eligible product developer.

16 (d) NO VIOLATION OF REMS.—The provision of
17 samples of a drug pursuant to an authorization under sub-
18 section (b)(2)(B) shall not be considered a violation of the
19 requirements of any risk evaluation and mitigation strat-
20 egy that may be in place under section 505–1 of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for
22 such drug.

23 (e) RULE OF CONSTRUCTION.—

24 (1) DEFINITION.—In this subsection, the term
25 “antitrust laws”—

1 (A) has the meaning given the term in
2 subsection (a) of the first section of the Clayton
3 Act (15 U.S.C. 12); and

4 (B) includes section 5 of the Federal
5 Trade Commission Act (15 U.S.C. 45) to the
6 extent that such section applies to unfair meth-
7 ods of competition.

8 (2) ANTITRUST LAWS.—Nothing in this section
9 shall be construed to limit the operation of any pro-
10 vision of the antitrust laws.

11 **SEC. 4. REMS APPROVAL PROCESS FOR SUBSEQUENT FIL-**
12 **ERS.**

13 Section 505–1 of the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 355–1) is amended—

15 (1) in subsection (g)(4)(B)—

16 (A) in clause (i) by striking “or” after the
17 semicolon;

18 (B) in clause (ii) by striking the period at
19 the end and inserting “; or”; and

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

21 “(iii) accommodate different, com-
22 parable approved risk evaluation and miti-
23 gation strategies for a drug that is the
24 subject of an application under section
25 505(j), and the applicable listed drug.”;

1 (2) in subsection (i)(1), by striking subpara-
2 graph (C) and inserting the following:

3 “(C)(i) Elements to assure safe use, if re-
4 quired under subsection (f) for the listed drug,
5 which, subject to clause (ii), for a drug that is
6 the subject of an application under section
7 505(j) may use—

8 “(I) a single, shared system with the
9 listed drug under subsection (f); or

10 “(II) a different, comparable aspect of
11 the elements to assure safe use under sub-
12 section (f).

13 “(ii) The Secretary may require a drug
14 that is the subject of an application under sec-
15 tion 505(j) and the listed drug to use a single,
16 shared system under subsection (f), if the Sec-
17 retary determines that no different, comparable
18 aspect of the elements to assure safe use could
19 satisfy the requirements of subsection (f).”; and

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

21 “(1) SEPARATE REMS.—When used in this section,
22 the terms “different, comparable aspect of the elements
23 to assure safe use” or “different, comparable approved
24 risk evaluation and mitigation strategies” means a risk
25 evaluation and mitigation strategy for a drug that is the

1 subject of an application under section 505(j) that uses
2 different methods or operational means than the strategy
3 required under subsection (a) for the applicable listed
4 drug, or other application under section 505(j) with the
5 same such listed drug, but achieves the same level of safe-
6 ty as such strategy.”.

Calendar No. 22

116TH CONGRESS
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A BILL

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