

116TH CONGRESS
1ST SESSION

S. _____

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

_____ introduced the following bill; which was read twice
and referred to the Committee on _____

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,*

3 **SECTION 1. SHORT TITLE.**

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

7 **SEC. 2. FINDINGS.**

8 Congress finds the following:

1 (1) It is the policy of the United States to pro-
2 mote competition in the market for drugs and bio-
3 logical products by facilitating the timely entry of
4 low-cost generic and biosimilar versions of those
5 drugs and biological products.

6 (2) Since their enactment in 1984 and 2010,
7 respectively, the Drug Price Competition and Patent
8 Term Restoration Act of 1984 (Public Law 98–417;
9 98 Stat. 1585) and the Biologics Price Competition
10 and Innovation Act of 2009 (subtitle A of title VII
11 of Public Law 111–148; 124 Stat. 804), have pro-
12 vided pathways for making lower-cost versions of
13 previously approved drugs and previously licensed bi-
14 ological products available to the people of the
15 United States in a timely manner, thereby lowering
16 overall prescription drug costs for patients and tax-
17 payers by billions of dollars each year.

18 (3) In order for these pathways to function as
19 intended, developers of generic drugs and biosimilar
20 biological products (referred to in this section as
21 “generic product developers”) must be able to obtain
22 quantities of the reference listed drug or biological
23 product with which the generic drug or biosimilar bi-
24 ological product is intended to compete (referred to
25 in this section as a “covered product”) for purposes

1 of supporting an application for approval by the
2 Food and Drug Administration, including for testing
3 to show that—

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

11 (B) a prospective biosimilar biological
12 product is biosimilar to or interchangeable with
13 its reference biological product under section
14 351(k) of the Public Health Service Act (42
15 U.S.C. 262(k)), as applicable.

16 (4) For drugs and biological products that are
17 subject to a risk evaluation and mitigation strategy,
18 another essential component in the creation of low-
19 cost generic and biosimilar versions of covered prod-
20 ucts is the ability of generic product developers to
21 join the manufacturer of the covered product (re-
22 ferred to in this section as the “license holder”) in
23 a single, shared system of elements to assure safe
24 use and supporting agreements as required by sec-
25 tion 505–1 of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 355–1), or secure a variance there-
2 from.

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

19 (6) The Director of the Center for Drug Eval-
20 uation and Research of the Food and Drug Adminis-
21 tration has testified that some manufacturers of cov-
22 ered products have used risk evaluation and mitiga-
23 tion strategies and distribution restrictions adopted
24 by the manufacturer on their own behalf as reasons
25 to not sell quantities of a covered product to generic

1 product developers, causing barriers and delays in
2 getting generic products on the market. The Food
3 and Drug Administration has reported receiving sig-
4 nificant numbers of inquiries from generic product
5 developers who were unable to obtain samples of cov-
6 ered products to conduct necessary testing and oth-
7 erwise meet requirements for approval of generic
8 drugs.

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

16 (8) Also contrary to the policy of the United
17 States to promote competition in the market for
18 drugs and biological products by facilitating the
19 timely entry of lower-cost generic and biosimilar
20 versions of those drugs and biological products, cer-
21 tain license holders are impeding the prompt nego-
22 tiation and development on commercially reasonable
23 terms of a single, shared system of elements to as-
24 sure safe use, which may be necessary for the ge-

1 generic product developer to gain approval for its drug
2 or licensing for its biological product.

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

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

1 **SEC. 3. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**
2 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

3 (a) DEFINITIONS.—In this section—

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

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

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

16 (C) no additional conditions are imposed
17 on the sale of the covered product;

18 (2) the term “covered product”—

19 (A) means—

20 (i) any drug approved under sub-
21 section (c) or (j) of section 505 of the Fed-
22 eral Food, Drug, and Cosmetic Act (21
23 U.S.C. 355) or biological product licensed
24 under subsection (a) or (k) of section 351
25 of the Public Health Service Act (42
26 U.S.C. 262);

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

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

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

20 (i) as demonstrated by the fact that
21 the drug or biological product has been in
22 shortage for more than 6 months; or

23 (ii) as otherwise determined by the
24 Secretary;

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

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

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

19 (6) the term “REMS” means a risk evaluation
20 and mitigation strategy under section 505–1 of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 355–1);

23 (7) the term “REMS with ETASU” means a
24 REMS that contains elements to assure safe use

1 under section 505–1(f) of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 355–1(f));

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

5 (9) the term “single, shared system of elements
6 to assure safe use” means a single, shared system
7 of elements to assure safe use under section 505–
8 1(f) of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 355–1(f)); and

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

13 (A) conduct testing to support an applica-
14 tion under—

15 (i) subsection (b)(2) or (j) of section
16 505 of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 355); or

18 (ii) section 351(k) of the Public
19 Health Service Act (42 U.S.C. 262(k));
20 and

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

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

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

9 (2) ELEMENTS.—

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

14 (i) that—

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

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

19 (aa) the eligible product de-
20 veloper has obtained a covered
21 product authorization from the
22 Secretary in accordance with sub-
23 paragraph (B); and

24 (bb) the eligible product de-
25 veloper has provided a copy of

1 the covered product authorization
2 to the license holder;

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

8 (iii) that the eligible product developer
9 has requested to purchase sufficient quan-
10 tities of the covered product from the li-
11 cense holder; and

12 (iv) that the license holder has not de-
13 livered to the eligible product developer
14 sufficient quantities of the covered product
15 on commercially reasonable, market-based
16 terms—

17 (I) for a covered product that is
18 not subject to a REMS with ETASU,
19 by the date that is 31 days after the
20 date on which the license holder re-
21 ceived the request for the covered
22 product; and

23 (II) for a covered product that is
24 subject to a REMS with ETASU, by
25 31 days after the later of—

1 (aa) the date on which the
2 license holder received the re-
3 quest for the covered product; or

4 (bb) the date on which the
5 license holder received a copy of
6 the covered product authorization
7 issued by the Secretary in ac-
8 cordance with subparagraph (B).

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

11 (i) REQUEST.—An eligible product de-
12 veloper may submit to the Secretary a
13 written request for the eligible product de-
14 veloper to be authorized to obtain suffi-
15 cient quantities of an individual covered
16 product subject to a REMS with ETASU.

17 (ii) AUTHORIZATION.—Not later than
18 120 days after the date on which a request
19 under clause (i) is received, the Secretary
20 shall, by written notice, authorize the eligi-
21 ble product developer to obtain sufficient
22 quantities of an individual covered product
23 subject to a REMS with ETASU for pur-
24 poses of—

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

6 (II) development and testing that
7 involves human clinical trials, if the
8 eligible product developer has—

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

17 (BB) otherwise satisfied the
18 Secretary that such protections
19 will be provided; and

20 (bb) met any other require-
21 ments the Secretary may estab-
22 lish.

23 (iii) NOTICE.—A covered product au-
24 thorization issued under this subparagraph
25 shall state that the provision of the covered

1 product by the license holder under the
2 terms of the authorization will not be a
3 violation of the REMS for the covered
4 product.

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

9 (A) that, on the date on which the eligible
10 product developer requested to purchase suffi-
11 cient quantities of the covered product from the
12 license holder—

13 (i) neither the license holder nor any
14 of its agents, wholesalers, or distributors
15 was engaged in the manufacturing or com-
16 mercial marketing of the covered product;
17 and

18 (ii) neither the license holder nor any
19 of its agents, wholesalers, or distributors
20 otherwise had access to inventory of the
21 covered product to supply to the eligible
22 product developer on commercially reason-
23 able, market-based terms; or

24 (B) that—

1 (i) the license holder sells the covered
2 product through agents, distributors, or
3 wholesalers;

4 (ii) the license holder has placed no
5 restrictions, explicit or implicit, on its
6 agents, distributors, or wholesalers to sell
7 covered products to eligible product devel-
8 opers; and

9 (iii) the covered product can be pur-
10 chased by the eligible product developer in
11 sufficient quantities on commercially rea-
12 sonable, market-based terms from the
13 agents, distributors, or wholesalers of the
14 license holder.

15 (4) REMEDIES.—

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

19 (i) order the license holder to provide
20 to the eligible product developer without
21 delay sufficient quantities of the covered
22 product on commercially reasonable, mar-
23 ket-based terms;

1 (ii) award to the eligible product de-
2 veloper reasonable attorney's fees and costs
3 of the civil action; and

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

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

17 (II) that the license holder failed
18 to comply with an order issued under
19 clause (i).

20 (B) MAXIMUM MONETARY AMOUNT.—A
21 monetary amount awarded under subparagraph
22 (A)(iii) shall not be greater than the revenue
23 that the license holder earned on the covered
24 product during the period—

25 (i) beginning on—

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

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

10 (aa) the date on which the
11 license holder received the re-
12 quest; or

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

19 (ii) ending on the date on which the
20 eligible product developer received suffi-
21 cient quantities of the covered product.

22 (C) AVOIDANCE OF DELAY.—The court
23 may issue an order under subparagraph (A)(i)
24 before conducting further proceedings that may
25 be necessary to determine whether the eligible

1 product developer is entitled to an award under
2 clause (ii) or (iii) of subparagraph (A), or the
3 amount of any such award.

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

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

19 (e) RULE OF CONSTRUCTION.—

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

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

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

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

8 **SEC. 4. REMS APPROVAL PROCESS FOR SUBSEQUENT FIL-**
9 **ERS.**

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

12 (1) in subsection (g)(4)(B)—

13 (A) in clause (i) by striking “or” after the
14 semicolon;

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

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

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

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

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

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

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

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

19 “(1) SEPARATE REMS.—When used in this section,
20 the terms “different, comparable aspect of the elements
21 to assure safe use” or “different, comparable approved
22 risk evaluation and mitigation strategies” means a risk
23 evaluation and mitigation strategy for a drug that is the
24 subject of an application under section 505(j) that uses
25 different methods or operational means than the strategy

1 required under subsection (a) for the applicable listed
2 drug, or other application under section 505(j) with the
3 same such listed drug, but achieves the same level of safe-
4 ty as such strategy.”.