

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S. 974

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.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by _____

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Creating and Restoring
5 Equal Access to Equivalent Samples Act of 2018” or the
6 “CREATES Act of 2018”.

7 **SEC. 2. FINDINGS.**

8 Congress finds the following:

9 (1) It is the policy of the United States to pro-
10 mote competition in the market for drugs and bio-
11 logical products by facilitating the timely entry of

1 low-cost generic and biosimilar versions of those
2 drugs and biological products.

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

15 (3) In order for these pathways to function as
16 intended, developers of generic drugs and biosimilar
17 biological products (referred to in this section as
18 “generic product developers”) must be able to obtain
19 quantities of the reference listed drug or biological
20 product with which the generic drug or biosimilar bi-
21 ological product is intended to compete (referred to
22 in this section as a “covered product”) for purposes
23 of supporting an application for approval by the
24 Food and Drug Administration, including for testing
25 to show that—

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

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

13 (4) For drugs and biological products that are
14 subject to a risk evaluation and mitigation strategy,
15 another essential component in the creation of low-
16 cost generic and biosimilar versions of covered prod-
17 ucts is the ability of generic product developers to
18 join the manufacturer of the covered product (re-
19 ferred to in this section as the “license holder”) in
20 a single, shared system of elements to assure safe
21 use and supporting agreements, or secure a variance
22 therefrom, as required by section 505–1 of the Fed-
23 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355–
24 1).

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

17 (6) The Director of the Center for Drug Eval-
18 uation and Research at the Food and Drug Admin-
19 istration has testified that some manufacturers of
20 covered products have used REMS and distribution
21 restrictions adopted by the manufacturer on their
22 own behalf as reasons to not sell quantities of a cov-
23 ered product to generic product developers, causing
24 barriers and delays in getting generic products on
25 the market. The Food and Drug Administration has

1 reported receiving significant numbers of inquiries
2 from generic product developers who were unable to
3 obtain samples of covered products to conduct nec-
4 essary testing and otherwise meet requirements for
5 approval of generic drugs.

6 (7) The Chairwoman of the Federal Trade
7 Commission has testified that the Federal Trade
8 Commission continues to be very concerned about
9 potential abuses by manufacturers of brand drugs of
10 REMS or other closed distribution systems to im-
11 pede generic competition.

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

23 (9) While the antitrust laws may address the
24 refusal by some license holders to provide quantities
25 of a covered product to a generic product developer,

1 a more tailored legal pathway would help ensure
2 that generic product developers can obtain necessary
3 quantities of a covered product in a timely way for
4 purposes of developing a generic drug or biosimilar
5 biological product, facilitating competition in the
6 marketplace for drugs and biological products.

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

20 **SEC. 3. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**
21 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

22 (a) DEFINITIONS.—In this section—

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

1 (A) a non-discriminatory price for the sale
2 of the covered product at or below, but not
3 greater than, the most recent wholesale acquisition
4 cost for the drug, as defined in section
5 1847A(c)(6)(B) of the Social Security Act (42
6 U.S.C. 1395w-3a(c)(6)(B));

7 (B) a schedule for delivery that results in
8 the transfer of the covered product to the eligi-
9 ble product developer consistent with the timing
10 under subsection (b)(2)(A)(iv); and

11 (C) no additional conditions are imposed
12 on the sale of the covered product;

13 (2) the term “covered product”—

14 (A) means—

15 (i) any drug approved under sub-
16 section (b) or (j) of section 505 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21
18 U.S.C. 355) or biological product licensed
19 under subsection (a) or (k) of section 351
20 of the Public Health Service Act (42
21 U.S.C. 262);

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

24 (iii) when reasonably necessary to
25 support approval of an application under

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

10 (B) does not include any drug or biological
11 product that the Secretary has determined to be
12 currently in shortage and that appears on the
13 drug shortage list in effect under section 506E
14 of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 356e), unless the shortage will not
16 be promptly resolved—

17 (i) as demonstrated by the fact that
18 the drug or biological product has been in
19 shortage for more than 6 months; or

20 (ii) as otherwise determined by the
21 Secretary;

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

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

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

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

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

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

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

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

9 (A) conduct testing to support an applica-
10 tion—

11 (i) for approval under subsection
12 (b)(2) or (j) of section 505 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C.
14 355); or

15 (ii) for licensing under section 351(k)
16 of the Public Health Service Act (42
17 U.S.C. 262(k)); and

18 (B) fulfill any regulatory requirements re-
19 lating to such an application for approval or li-
20 censing.

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

23 (1) IN GENERAL.—An eligible product developer
24 may bring a civil action against the license holder
25 for a covered product seeking relief under this sub-

1 section in an appropriate district court of the United
2 States alleging that the license holder has declined
3 to provide sufficient quantities of the covered prod-
4 uct to the eligible product developer on commercially
5 reasonable, market-based terms.

6 (2) ELEMENTS.—

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

11 (i) that—

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

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

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

21 (bb) the eligible product de-
22 veloper has provided a copy of
23 the covered product authorization
24 to the license holder;

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

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

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

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

21 (II) for a covered product that is
22 subject to a REMS with ETASU, by
23 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—

14

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 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 abbreviated new drug appli-
22 cation, and its reference drug product.”;

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

1 “(B) Elements to assure safe use, if re-
2 quired under subsection (f) for the listed drug.

3 “(i) Subject to clause (ii), a drug that
4 is the subject of an abbreviated new drug
5 application may use—

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

9 “(II) a different, comparable as-
10 pect of the elements to assure safe use
11 under subsection (f).

12 “(ii) The Secretary may require a
13 drug that is the subject of an abbreviated
14 new drug application and the listed drug to
15 use a single, shared system under sub-
16 section (f), if the Secretary determines
17 that no different, comparable aspect of the
18 elements to assure safe use could satisfy
19 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 reference
4 drug, or other application under section 505(j) with the
5 same such reference listed drug, but achieves the same
6 level of safety as such strategy.”.