

Amendment to the Conference Report for S. 524

1 At the appropriate place insert the following:

2 **TITLE ____—DELAYS OF GENERIC**
3 **DRUGS AND BIOSIMILAR BIO-**
4 **LOGICAL PRODUCTS**

5 **SEC. ____01. SHORT TITLE.**

6 This title may be cited as the “Creating and Restor-
7 ing Equal Access to Equivalent Samples Act of 2016” or
8 the “CREATES Act of 2016”.

9 **SEC. ____02. FINDINGS.**

10 Congress finds the following:

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

16 (2) Since their enactment in 1984 and 2010 re-
17 spectively, the Drug Price Competition and Patent
18 Term Restoration Act of 1984 (Public Law 98–417;
19 98 Stat. 1585) and the Biologics Price Competition
20 and Innovation Act of 2009 (Subtitle A of title VII
21 of Public Law 111–148; 124 Stat. 804), have pro-
22 vided pathways for making lower-cost versions of

1 previously approved drugs and previously licensed bi-
2 ological products available to the people of the
3 United States in a timely manner, thereby lowering
4 overall prescription drug costs for patients and tax-
5 payers by billions of dollars each year.

6 (3) In order for these pathways to function as
7 intended, developers of generic drugs and biosimilar
8 biological products (referred to in this section as
9 “generic product developers”) must be able to obtain
10 quantities of the reference listed drug or biological
11 product with which the generic drug or biosimilar bi-
12 ological product is intended to compete (referred to
13 in this section as a “covered product”) for purposes
14 of supporting an application for approval by the
15 Food and Drug Administration, including for testing
16 to show that—

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

24 (B) a prospective biosimilar biological
25 product is biosimilar to or interchangeable with

1 its reference biological product under section
2 351(k) of the Public Health Service Act (42
3 U.S.C. 262(k)), as applicable.

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

20 (5) The Director of the Center for Drug Eval-
21 uation and Research at the Food and Drug Admin-
22 istration has testified that some manufacturers of
23 covered products have used REMS and distribution
24 restrictions adopted by the manufacturer on their
25 own behalf as reasons to not sell quantities of a cov-

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

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

15 (7) While the antitrust laws may address the
16 refusal by some license holders to provide quantities
17 of a covered product to a generic product developer,
18 a more tailored legal pathway would help ensure
19 that generic product developers can obtain necessary
20 quantities of a covered product in a timely way for
21 purposes of developing a generic drug or biosimilar
22 biological product, facilitating competition in the
23 marketplace for drugs and biological products.

1 **SEC. ____ 03. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**
2 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

3 (a) DEFINITIONS.—In this section—

4 (1) the term “covered product”—

5 (A) means—

6 (i) any drug approved under sub-
7 section (b) or (j) of section 505 of the Fed-
8 eral Food, Drug, and Cosmetic Act (21
9 U.S.C. 355) or biological product licensed
10 under subsection (a) or (k) of section 351
11 of the Public Health Service Act (42
12 U.S.C. 262);

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

15 (iii) when reasonably necessary to
16 demonstrate sameness, biosimilarity, or
17 interchangeability for purposes of section
18 505 of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 355), or section 351
20 of the Public Health Service Act (42
21 U.S.C. 262), as applicable, any product,
22 including any device, that is marketed or
23 intended for use with such drug or biologi-
24 cal product; and

25 (B) does not include any drug or biological
26 product that the Secretary has determined to be

1 currently in shortage and that appears on the
2 drug shortage list in effect under section 506E
3 of the Federal Food, Drug, and Cosmetic Act
4 (21 U.S.C.356e), unless the shortage will not be
5 promptly resolved—

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

9 (ii) as otherwise determined by the
10 Secretary;

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

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

22 (4) the term “license holder” means the holder
23 of an application approved under subsection (c) or
24 (j) of section 505 of the Federal Food, Drug, and
25 Cosmetic Act (21 U.S.C. 355) or the holder of a li-

1 cense under subsection (a) or (k) of section 351 of
2 the Public Health Service Act (42 U.S.C. 262) for
3 a covered product;

4 (5) the term “REMS” means a risk evaluation
5 and mitigation strategy under section 505–1 of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 355–1);

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

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

14 (8) 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—

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

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

1 (B) fulfill any regulatory requirements re-
2 lating to such an application for approval or li-
3 censing.

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

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

14 (2) ELEMENTS.—

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

19 (i) that—

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

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

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

1 product authorization from the
2 Secretary in accordance with sub-
3 paragraph (B); and

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

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

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

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

22 (I) for a covered product that is
23 not subject to a REMS with ETASU,
24 by the date that is 31 days after the
25 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 90 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) submitted protocols, in-
14 formed consent documents, and
15 informational materials for test-
16 ing that include protections that
17 provide safety protections com-
18 parable to those provided by the
19 REMS for the covered product;
20 or

21 (bb) otherwise satisfied the
22 Secretary that such protections
23 will be provided.

24 (iii) NOTICE.—A covered product au-
25 thorization issued under this subparagraph

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

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

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

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

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

25 (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 arising
6 out of the failure of an eligible product developer to follow
7 adequate safeguards to assure safe use of the covered
8 product during development or testing activities described
9 in this section, including transportation, handling, use, or
10 disposal of the covered product by the eligible product de-
11 veloper.

12 (d) RULE OF CONSTRUCTION.—

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

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

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

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