

AMENDMENT NO. _____ Calendar No. _____

Purpose: 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—114th Cong., 2d Sess.

H. R. 34

To authorize and strengthen the tsunami detection, forecast, warning, research, and mitigation program of the National Oceanic and Atmospheric Administration, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by

Viz:

1 At the end of title III of division A, add the following:

2 **Subtitle K—CREATES Act**

3 **SEC. 3201. SHORT TITLE.**

4 This subtitle may be cited as the “Creating and Re-
5 storing Equal Access to Equivalent Samples Act of 2016”
6 or the “CREATES Act of 2016”.

7 **SEC. 3202. 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, or secure a variance
25 therefrom, as required by section 505–1 of the Fed-

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

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 at the Food and Drug Admin-
21 istration has testified that some manufacturers of
22 covered products have used REMS and distribution
23 restrictions adopted by the manufacturer on their
24 own behalf as reasons to not sell quantities of a cov-
25 ered product to generic product developers, causing

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

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

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

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

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

23 **SEC. 3203. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**
24 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

25 (a) DEFINITIONS.—In this section—

1 (1) the term “covered product”—

2 (A) means—

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

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

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

22 (B) does not include any drug or biological
23 product that the Secretary has determined to be
24 currently in shortage and that appears on the
25 drug shortage list in effect under section 506E

1 of the Federal Food, Drug, and Cosmetic Act
2 (21 U.S.C. 356e), unless the shortage will not
3 be promptly resolved—

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

7 (ii) as otherwise determined by the
8 Secretary;

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

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

20 (4) the term “license holder” means the holder
21 of an application approved under subsection (c) or
22 (j) of section 505 of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355) or the holder of a li-
24 cense under subsection (a) or (k) of section 351 of

1 the Public Health Service Act (42 U.S.C. 262) for
2 a covered product;

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

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

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

13 (8) the term “single, shared system of elements
14 to assure safe use” means a single, shared system
15 of elements to assure safe use under section 505–1
16 of the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 355–1); and

18 (9) the term “sufficient quantities” means an
19 amount of a covered product that allows the eligible
20 product developer to—

21 (A) conduct testing to support an applica-
22 tion—

23 (i) for approval under subsection
24 (b)(2) or (j) of section 505 of the Federal

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

3 (ii) for licensing under section 351(k)
4 of the Public Health Service Act (42
5 U.S.C. 262(k)); and

6 (B) fulfill any regulatory requirements re-
7 lating to such an application for approval or li-
8 censing.

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

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

19 (2) ELEMENTS.—

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

24 (i) that—

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

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

5 (aa) the eligible product de-
6 veloper has obtained a covered
7 product authorization from the
8 Secretary in accordance with sub-
9 paragraph (B); and

10 (bb) the eligible product de-
11 veloper has provided a copy of
12 the covered product authorization
13 to the license holder;

14 (ii) that, as of the date on which the
15 civil action is filed, the product developer
16 has not obtained sufficient quantities of
17 the covered product on commercially rea-
18 sonable, market-based terms;

19 (iii) that the eligible product developer
20 has requested to purchase sufficient quan-
21 tities of the covered product from the li-
22 cense holder; and

23 (iv) that the license holder has not de-
24 livered to the eligible product developer
25 sufficient quantities of the covered product

1 on commercially reasonable, market-based
2 terms—

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

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

12 (aa) the date on which the
13 license holder received the re-
14 quest for the covered product; or

15 (bb) the date on which the
16 license holder received a copy of
17 the covered product authorization
18 issued by the Secretary in ac-
19 cordance with subparagraph (B).

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

22 (i) REQUEST.—An eligible product de-
23 veloper may submit to the Secretary a
24 written request for the eligible product de-
25 veloper to be authorized to obtain suffi-

1 cient quantities of an individual covered
2 product subject to a REMS with ETASU.

3 (ii) AUTHORIZATION.—Not later than
4 90 days after the date on which a request
5 under clause (i) is received, the Secretary
6 shall, by written notice, authorize the eligi-
7 ble product developer to obtain sufficient
8 quantities of an individual covered product
9 subject to a REMS with ETASU for pur-
10 poses of—

11 (I) development and testing that
12 does not involve human clinical trials,
13 if the eligible product developer has
14 agreed to comply with any conditions
15 the Secretary determines necessary; or

16 (II) development and testing that
17 involves human clinical trials, if the
18 eligible product developer has—

19 (aa)(AA) submitted proto-
20 cols, informed consent docu-
21 ments, and informational mate-
22 rials for testing that include pro-
23 tections that provide safety pro-
24 tections comparable to those pro-

1 vided by the REMS for the cov-
2 ered product; or

3 (BB) otherwise satisfied the
4 Secretary that such protections
5 will be provided; and

6 (bb) met any other require-
7 ments the Secretary may estab-
8 lish.

9 (iii) NOTICE.—A covered product au-
10 thorization issued under this subparagraph
11 shall state that the provision of the covered
12 product by the license holder under the
13 terms of the authorization will not be a
14 violation of the REMS for the covered
15 product.

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

20 (A) that, on the date on which the eligible
21 product developer requested to purchase suffi-
22 cient quantities of the covered product from the
23 license holder—

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

1 was engaged in the manufacturing or com-
2 mercial marketing of the covered product;
3 and

4 (ii) neither the license holder nor any
5 of its agents, wholesalers, or distributors
6 otherwise had access to inventory of the
7 covered product to supply to the eligible
8 product developer on commercially reason-
9 able, market-based terms; or

10 (B) that—

11 (i) the license holder sells the covered
12 product through agents, distributors, or
13 wholesalers;

14 (ii) the license holder has placed no
15 restrictions, explicit or implicit, on its
16 agents, distributors, or wholesalers to sell
17 covered products to eligible product devel-
18 opers; and

19 (iii) the covered product can be pur-
20 chased by the eligible product developer in
21 sufficient quantities on commercially rea-
22 sonable, market-based terms from the
23 agents, distributors, or wholesalers of the
24 license holder.

25 (4) REMEDIES.—

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

4 (i) order the license holder to provide
5 to the eligible product developer without
6 delay sufficient quantities of the covered
7 product on commercially reasonable, mar-
8 ket-based terms;

9 (ii) award to the eligible product de-
10 veloper reasonable attorney fees and costs
11 of the civil action; and

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

20 (I) that the license holder delayed
21 providing sufficient quantities of the
22 covered product to the eligible product
23 developer without a legitimate busi-
24 ness justification; or

1 (II) that the license holder failed
2 to comply with an order issued under
3 clause (i).

4 (B) MAXIMUM MONETARY AMOUNT.—A
5 monetary amount awarded under subparagraph
6 (A)(iii) shall not be greater than the revenue
7 that the license holder earned on the covered
8 product during the period—

9 (i) beginning on—

10 (I) for a covered product that is
11 not subject to a REMS with ETASU,
12 the date that is 31 days after the date
13 on which the license holder received
14 the request; or

15 (II) for a covered product that is
16 subject to a REMS with ETASU, the
17 date that is 31 days after the later
18 of—

19 (aa) the date on which the
20 license holder received the re-
21 quest; or

22 (bb) the date on which the
23 license holder received a copy of
24 the covered product authorization
25 issued by the Secretary in ac-

1 cordance with paragraph (2)(B);

2 and

3 (ii) ending on the date on which the
4 eligible product developer received suffi-
5 cient quantities of the covered product.

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

13 (c) LIMITATION OF LIABILITY.—A license holder for
14 a covered product shall not be liable for any claim arising
15 out of the failure of an eligible product developer to follow
16 adequate safeguards to assure safe use of the covered
17 product during development or testing activities described
18 in this section, including transportation, handling, use, or
19 disposal of the covered product by the eligible product de-
20 veloper.

21 (d) RULE OF CONSTRUCTION.—

22 (1) DEFINITION.—In this subsection, the term
23 “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. 3204. REMS APPROVAL PROCESS FOR SUBSEQUENT**
12 **FILERS.**

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 approved
22 risk evaluation and mitigation strategies
23 for a reference drug product and a drug
24 that is the subject of an abbreviated new
25 drug application.”; and

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

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

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

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

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

14 “(ii) The Secretary may require a
15 drug that is the subject of an abbreviated
16 new drug application and the listed drug to
17 use a single, shared system under sub-
18 section (f), if the Secretary determines
19 that no different, comparable aspect of the
20 elements to assure safe use could satisfy
21 the requirements of subsection (f).”.