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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

APRIL 27, 2017

Mr. LEAHY (for himself, Mr. GRASSLEY, Ms. KLOBUCHAR, Mr. LEE, Mrs. FEINSTEIN, Mrs. MCCASKILL, Ms. COLLINS, Mr. MCCAIN, Mr. BLUMENTHAL, Mr. WHITEHOUSE, Mr. COTTON, Mr. DURBIN, Mr. CRUZ, Mr. PAUL, Ms. HASSAN, Mr. KENNEDY, Ms. SMITH, Ms. MURKOWSKI, Ms. BALDWIN, Mr. DAINES, Mr. KING, Mr. GRAHAM, Mr. BROWN, Mr. YOUNG, Ms. STABENOW, Mr. ROUNDS, Mr. TESTER, Mrs. ERNST, and Mr. MENENDEZ) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

JUNE 21, 2018

Reported by Mr. GRASSLEY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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 2017” or the
4 “CREATES Act of 2017”.

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, or secure a variance
5 therefrom, as required by section 505–1 of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355–
7 1).

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 at the Food and Drug Admin-

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

13 (7) The Chairwoman of the Federal Trade
14 Commission has testified that the Federal Trade
15 Commission continues to be very concerned about
16 potential abuses by manufacturers of brand drugs of
17 REMS or other closed distribution systems to im-
18 pede generic competition.

19 (8) Also contrary to the policy of the United
20 States to promote competition in the market for
21 drugs and biological products by facilitating the
22 timely entry of lower-cost generic and biosimilar
23 versions of those drugs and biological products, cer-
24 tain license holders are impeding the prompt nego-
25 tiation and development on commercially reasonable

1 terms of a single, shared system of elements to as-
2 sure safe use, which may be necessary for the ge-
3 neric product developer to gain approval for its drug
4 or licensing for its biological product.

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

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

1 regulatory authority would ensure all systems pro-
2 tect patient safety.

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

5 (a) DEFINITIONS.—In this section—

6 (1) the term “covered product”—

7 (A) means—

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

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

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

1 intended for use with such drug or biological
2 eal product; and

3 ~~(B)~~ does not include any drug or biological
4 product that the Secretary has determined to be
5 currently in shortage and that appears on the
6 drug shortage list in effect under section 506E
7 of the Federal Food, Drug, and Cosmetic Act
8 ~~(21 U.S.C. 356e)~~, unless the shortage will not
9 be promptly resolved—

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

13 (ii) as otherwise determined by the
14 Secretary;

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

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

1 (4) the term “license holder” means the holder
2 of an application approved under subsection (e) or
3 (j) of section 505 of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 355) or the holder of a li-
5 cense under subsection (a) or (k) of section 351 of
6 the Public Health Service Act (42 U.S.C. 262) for
7 a covered product;

8 (5) the term “REMS” means a risk evaluation
9 and mitigation strategy under section 505-1 of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 355-1);

12 (6) the term “REMS with ETASU” means a
13 REMS that contains elements to assure safe use
14 under section 505-1 of the Federal Food, Drug, and
15 Cosmetic Act (21 U.S.C. 355-1);

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

18 (8) the term “single, shared system of elements
19 to assure safe use” means a single, shared system
20 of elements to assure safe use under section 505-1
21 of the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 355-1); and

23 (9) the term “sufficient quantities” means an
24 amount of a covered product that allows the eligible
25 product developer to—

1 (A) conduct testing to support an applica-
2 tion—

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

7 (ii) for licensing under section 351(k)
8 of the Public Health Service Act (42
9 U.S.C. 262(k)); and

10 (B) fulfill any regulatory requirements re-
11 lating to such an application for approval or li-
12 censing.

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

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

23 (2) ELEMENTS.—

24 (A) IN GENERAL.—To prevail in a civil ac-
25 tion brought under paragraph (1), an eligible

1 product developer shall prove, by a preponderance of the evidence—
2

3 (i) that—

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

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

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

13 (bb) the eligible product de-
14 veloper has provided a copy of
15 the covered product authorization
16 to the license holder;

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

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

1 (iv) that the license holder has not de-
 2 livered to the eligible product developer
 3 sufficient quantities of the covered product
 4 on commercially reasonable, market-based
 5 terms—

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

12 (II) for a covered product that is
 13 subject to a REMS with ETASU, by
 14 31 days after the later of—

15 (aa) the date on which the
 16 license holder received the re-
 17 quest for the covered product; or

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

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

1 (i) REQUEST.—An eligible product de-
2 veloper may submit to the Secretary a
3 written request for the eligible product de-
4 veloper to be authorized to obtain suffi-
5 cient quantities of an individual covered
6 product subject to a REMS with ETASU.

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

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

20 (II) development and testing that
21 involves human clinical trials, if the
22 eligible product developer has—

23 (aa)(AA) submitted proto-
24 cols, informed consent docu-
25 ments, and informational mate-

1 rials for testing that include pro-
 2 tections that provide safety pro-
 3 tections comparable to those pro-
 4 vided by the REMS for the cov-
 5 ered product; or

6 (BB) otherwise satisfied the
 7 Secretary that such protections
 8 will be provided; and

9 (bb) met any other require-
 10 ments the Secretary may estab-
 11 lish.

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

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

23 (A) that, on the date on which the eligible
 24 product developer requested to purchase suffi-

1 sufficient quantities of the covered product from the
2 license holder—

3 (i) neither the license holder nor any
4 of its agents, wholesalers, or distributors
5 was engaged in the manufacturing or com-
6 mercial marketing of the covered product;
7 and

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

14 (B) that—

15 (i) the license holder sells the covered
16 product through agents, distributors, or
17 wholesalers;

18 (ii) the license holder has placed no
19 restrictions, explicit or implicit, on its
20 agents, distributors, or wholesalers to sell
21 covered products to eligible product devel-
22 opers; and

23 (iii) the covered product can be pur-
24 chased by the eligible product developer in
25 sufficient quantities on commercially rea-

1 sonable, market-based terms from the
2 agents, distributors, or wholesalers of the
3 license holder.

4 (4) REMEDIES.—

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

8 (i) order the license holder to provide
9 to the eligible product developer without
10 delay sufficient quantities of the covered
11 product on commercially reasonable, mar-
12 ket-based terms;

13 (ii) award to the eligible product de-
14 veloper reasonable attorney fees and costs
15 of the civil action; and

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

24 (I) that the license holder delayed
25 providing sufficient quantities of the

1 covered product to the eligible product
 2 developer without a legitimate busi-
 3 ness justification; or

4 (II) that the license holder failed
 5 to comply with an order issued under
 6 clause (i).

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

12 (i) beginning on—

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

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

22 (aa) the date on which the
 23 license holder received the re-
 24 quest; or

1 (bb) the date on which the
2 license holder received a copy of
3 the covered product authorization
4 issued by the Secretary in ac-
5 cordance with paragraph (2)(B);
6 and

7 (ii) ending on the date on which the
8 eligible product developer received suffi-
9 cient quantities of the covered product.

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

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

25 (d) RULE OF CONSTRUCTION.—

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

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

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

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

13 **SEC. 4. REMS APPROVAL PROCESS FOR SUBSEQUENT FIL-**
14 **ERS.**

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

17 (1) in subsection (g)(4)(B)—

18 (A) in clause (i) by striking “or” after the
19 semicolon;

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

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

23 “(iii) accommodate different approved
24 risk evaluation and mitigation strategies
25 for a reference drug product and a drug

1 that is the subject of an abbreviated new
2 drug application.”; and

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

5 “(B) Elements to assure safe use, if re-
6 quired under subsection (f) for the listed drug:

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

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

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

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

1 **SECTION 1. SHORT TITLE.**

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

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 biologi-*
9 *cal products by facilitating the timely entry of low-*
10 *cost generic and biosimilar versions of those drugs*
11 *and biological products.*

12 *(2) Since their enactment in 1984 and 2010, re-*
13 *spectively, 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 of*
17 *Public Law 111–148; 124 Stat. 804), have provided*
18 *pathways for making lower-cost versions of previously*
19 *approved drugs and previously licensed biological*
20 *products available to the people of the United States*
21 *in a timely manner, thereby lowering overall pre-*
22 *scription drug costs for patients and taxpayers by bil-*
23 *lions 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 “ge-*

1 *neric 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 in*
5 *this section as a “covered product”) for purposes of*
6 *supporting an application for approval by the Food*
7 *and Drug Administration, including for testing to*
8 *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, Food,*
12 *Drug, and Cosmetic Act (21 U.S.C. 355), or*
13 *meets the requirements for approval of an appli-*
14 *cation submitted under subsection (b)(2) of that*
15 *section; or*

16 *(B) a prospective biosimilar biological prod-*
17 *uct is biosimilar to or interchangeable with its*
18 *reference biological product under section 351(k)*
19 *of the Public Health Service Act (42 U.S.C.*
20 *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 join*

1 *the manufacturer of the covered product (referred to*
2 *in this section as the “license holder”) in a single,*
3 *shared system of elements to assure safe use and sup-*
4 *porting agreements as required by section 505–1 of*
5 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
6 *355–1), or secure a variance therefrom.*

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

23 *(6) The Director of the Center for Drug Evalua-*
24 *tion and Research at the Food and Drug Administra-*
25 *tion has testified that some manufacturers of covered*

1 *products have used risk evaluation and mitigation*
2 *strategies and distribution restrictions adopted by the*
3 *manufacturer on their own behalf as reasons to not*
4 *sell quantities of a covered product to generic product*
5 *developers, causing barriers and delays in getting ge-*
6 *neric products on the market. The Food and Drug*
7 *Administration has reported receiving significant*
8 *numbers of inquiries from generic product developers*
9 *who were unable to obtain samples of covered prod-*
10 *ucts to conduct necessary testing and otherwise meet*
11 *requirements for approval of generic drugs.*

12 *(7) The Acting Chairman of the Federal Trade*
13 *Commission has testified that the Federal Trade Com-*
14 *mission continues to be very concerned about poten-*
15 *tial abuses by manufacturers of brand drugs of risk*
16 *evaluation and mitigation strategies or other closed*
17 *distribution systems to impede generic competition.*

18 *(8) Also contrary to the policy of the United*
19 *States to promote competition in the market for drugs*
20 *and biological products by facilitating the timely*
21 *entry of lower-cost generic and biosimilar versions of*
22 *those drugs and biological products, certain license*
23 *holders are impeding the prompt negotiation and de-*
24 *velopment on commercially reasonable terms of a sin-*
25 *gle, shared system of elements to assure safe use,*

1 *which may be necessary for the generic product devel-*
2 *oper to gain approval for its drug or licensing for its*
3 *biological product.*

4 (9) *While the antitrust laws may address the re-*
5 *fusals by some license holders to provide quantities of*
6 *a covered product to a generic product developer, a*
7 *more tailored legal pathway would help ensure that*
8 *generic product developers can obtain necessary quan-*
9 *tities of a covered product in a timely way for pur-*
10 *poses of developing a generic drug or biosimilar bio-*
11 *logical product, facilitating competition in the mar-*
12 *ketplace for drugs and biological products.*

13 (10) *The antitrust laws may address actions by*
14 *license holders who impede the prompt negotiation*
15 *and development of a single, shared system of ele-*
16 *ments to assure safe use, and the Food and Drug Ad-*
17 *ministration has some authority to waive the require-*
18 *ment of a single, shared system. Clearer regulatory*
19 *authority to approve different systems that meet the*
20 *statutory requirements to ensure patient safety, how-*
21 *ever, would limit the effectiveness of bad faith negotia-*
22 *tions over single, shared systems to delay generic ap-*
23 *proval. At the same time, clearer regulatory authority*
24 *would ensure all systems protect patient safety.*

1 **SEC. 3. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIO-**
2 **SIMILAR 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 great-*
8 *er than, the most recent wholesale acquisition*
9 *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 eligible*
14 *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 (b) 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 of*
25 *the Public Health Service Act (42 U.S.C.*
26 *262);*

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

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

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

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

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

1 (3) the term “device” has the meaning given the
2 term in section 201 of the Federal Food, Drug, and
3 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 approval
6 pursuant to an application for approval under sub-
7 section (b)(2) or (j) of section 505 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for
9 licensing pursuant to an application under section
10 351(k) of the Public Health Service Act (42 U.S.C.
11 262(k));

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

1 *section 505–1(f) of the Federal Food, Drug, and Cos-*
 2 *metic Act (21 U.S.C. 355–1(f));*

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

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

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

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

21 *(B) fulfill any regulatory requirements re-*
 22 *lating to such an application for approval or li-*
 23 *censing.*

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

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

1 covered product authorization to
2 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 the
6 covered product on commercially reasonable,
7 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 license
11 holder; and

12 (iv) that the license holder has not de-
13 livered to the eligible product developer suf-
14 ficient quantities of the covered product on
15 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 prod-
22 uct; 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 li-*
2 *cence holder received the request*
3 *for the covered product; or*

4 (bb) *the date on which the li-*
5 *cence holder received a copy of the*
6 *covered product authorization*
7 *issued by the Secretary in accord-*
8 *ance 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 writ-*
13 *ten request for the eligible product developer*
14 *to be authorized to obtain sufficient quan-*
15 *tities of an individual covered product sub-*
16 *ject 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 protocols,
10 informed consent documents, and
11 informational materials for test-
12 ing that include protections that
13 provide safety protections com-
14 parable to those provided by the
15 REMS for the covered product; or

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

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

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

1 *terms of the authorization will not be a vio-*
2 *lation of the REMS for the covered product.*

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

7 (A) *that, on the date on which the eligible*
8 *product developer requested to purchase sufficient*
9 *quantities of the covered product from the license*
10 *holder—*

11 (i) *neither the license holder nor any of*
12 *its agents, wholesalers, or distributors was*
13 *engaged in the manufacturing or commer-*
14 *cial marketing of the covered product; and*

15 (ii) *neither the license holder nor any*
16 *of its agents, wholesalers, or distributors*
17 *otherwise had access to inventory of the cov-*
18 *ered product to supply to the eligible prod-*
19 *uct developer on commercially reasonable,*
20 *market-based terms; or*

21 (B) *that—*

22 (i) *the license holder sells the covered*
23 *product through agents, distributors, or*
24 *wholesalers;*

1 (ii) the license holder has placed no re-
2 strictions, explicit or implicit, on its agents,
3 distributors, or wholesalers to sell covered
4 products to eligible product developers; and

5 (iii) the covered product can be pur-
6 chased by the eligible product developer in
7 sufficient quantities on commercially rea-
8 sonable, market-based terms from the
9 agents, distributors, or wholesalers of the li-
10 cense holder.

11 (4) *REMEDIES.*—

12 (A) *IN GENERAL.*—If an eligible product de-
13 veloper prevails in a civil action brought under
14 paragraph (1), the court shall—

15 (i) order the license holder to provide
16 to the eligible product developer without
17 delay sufficient quantities of the covered
18 product on commercially reasonable, mar-
19 ket-based terms;

20 (ii) award to the eligible product devel-
21 oper reasonable attorney's fees and costs of
22 the civil action; and

23 (iii) award to the eligible product de-
24 veloper a monetary amount sufficient to
25 deter the license holder from failing to pro-

1 *vide other eligible product developers with*
2 *sufficient quantities of a covered product on*
3 *commercially reasonable, market-based*
4 *terms, if the court finds, by a preponder-*
5 *ance of the evidence—*

6 *(I) that the license holder delayed*
7 *providing sufficient quantities of the*
8 *covered product to the eligible product*
9 *developer without a legitimate business*
10 *justification; or*

11 *(II) that the license holder failed*
12 *to comply with an order issued under*
13 *clause (i).*

14 *(B) MAXIMUM MONETARY AMOUNT.—A*
15 *monetary amount awarded under subparagraph*
16 *(A)(iii) shall not be greater than the revenue that*
17 *the license holder earned on the covered product*
18 *during the period—*

19 *(i) beginning on—*

20 *(I) for a covered product that is*
21 *not subject to a REMS with ETASU,*
22 *the date that is 31 days after the date*
23 *on which the license holder received the*
24 *request; or*

1 (II) for a covered product that is
2 subject to a REMS with ETASU, the
3 date that is 31 days after the later of—

4 (aa) the date on which the li-
5 cense holder received the request;

6 or

7 (bb) the date on which the li-
8 cense holder received a copy of the
9 covered product authorization
10 issued by the Secretary in accord-
11 ance with paragraph (2)(B); and

12 (ii) ending on the date on which the el-
13 igible product developer received sufficient
14 quantities of the covered product.

15 (C) AVOIDANCE OF DELAY.—The court may
16 issue an order under subparagraph (A)(i) before
17 conducting further proceedings that may be nec-
18 essary to determine whether the eligible product
19 developer is entitled to an award under clause
20 (ii) or (iii) of subparagraph (A), or the amount
21 of any such award.

22 (c) LIMITATION OF LIABILITY.—A license holder for a
23 covered product shall not be liable for any claim under Fed-
24 eral, State, or local law arising out of the failure of an
25 eligible product developer to follow adequate safeguards to

1 *assure safe use of the covered product during development*
2 *or testing activities described in this section, including*
3 *transportation, handling, use, or disposal of the covered*
4 *product by the eligible product developer.*

5 *(d) NO VIOLATION OF REMS.—The provision of sam-*
6 *ples of a drug pursuant to an authorization under sub-*
7 *section (b)(2)(B) shall not be considered a violation of the*
8 *requirements of any risk evaluation and mitigation strat-*
9 *egy that may be in place under section 505–1 of the Federal*
10 *Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for such*
11 *drug.*

12 *(e) RULE OF CONSTRUCTION.—*

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

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

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

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

1 **SEC. 4. REMS APPROVAL PROCESS FOR SUBSEQUENT FIL-**
 2 **ERS.**

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

5 *(1) in subsection (g)(4)(B)—*

6 *(A) in clause (i) by striking “or” after the*
 7 *semicolon;*

8 *(B) in clause (ii) by striking the period at*
 9 *the end and inserting “; or”; and*

10 *(C) by adding at the end the following:*

11 *“(iii) accommodate different, com-*
 12 *parable approved risk evaluation and miti-*
 13 *gation strategies for a drug that is the sub-*
 14 *ject of an application under section 505(j),*
 15 *and the applicable listed drug.”;*

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

18 *“(B)(i) Elements to assure safe use, if re-*
 19 *quired under subsection (f) for the listed drug,*
 20 *which, subject to clause (ii), for a drug that is*
 21 *the subject of an application under section 505(j)*
 22 *may use—*

23 *“(I) a single, shared system with the*
 24 *listed drug under subsection (f); or*

1 “(II) a different, comparable aspect of
2 the elements to assure safe use under sub-
3 section (f).

4 “(ii) The Secretary may require a drug that
5 is the subject of an application under section
6 505(j) and the listed drug to use a single, shared
7 system under subsection (f), if the Secretary de-
8 termines that no different, comparable aspect of
9 the elements to assure safe use could satisfy the
10 requirements of subsection (f).”; and

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

12 “(l) *SEPARATE REMS*.—When used in this section, the
13 terms “different, comparable aspect of the elements to assure
14 safe use” or “different, comparable approved risk evaluation
15 and mitigation strategies” means a risk evaluation and
16 mitigation strategy for a drug that is the subject of an ap-
17 plication under section 505(j) that uses different methods
18 or operational means than the strategy required under sub-
19 section (a) for the applicable listed drug, or other applica-
20 tion under section 505(j) with the same such listed drug,
21 but achieves the same level of safety as such strategy.”.

Calendar No. 482

115TH CONGRESS
2^D SESSION

S. 974

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.

JUNE 21, 2018

Reported with an amendment