

114TH CONGRESS  
2D SESSION

**S.** \_\_\_\_\_

To provide for certain causes of action relating to delays of generic drugs  
and biosimilar biological products.

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IN THE SENATE OF THE UNITED STATES

Mr. LEAHY (for himself, Mr. GRASSLEY, Ms. KLOBUCHAR, and Mr. LEE) in-  
troduced the following bill; which was read twice and referred to the Com-  
mittee on \_\_\_\_\_

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## **A BILL**

To provide for certain causes of action relating to delays  
of generic drugs and biosimilar biological products.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

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

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-

1       logical products by facilitating the timely entry of  
2       low-cost generic and biosimilar versions of those  
3       drugs and biological products.

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

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

1 Food and Drug Administration, including for testing  
2 to show that—

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

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

15 (4) For drugs and biological products that are  
16 subject to a risk evaluation and mitigation strategy,  
17 another essential component in the creation of low-  
18 cost generic and biosimilar versions of covered prod-  
19 ucts is the ability of generic product developers to  
20 join the manufacturer of the covered product (re-  
21 ferred to in this section as the “license holder”) in  
22 a single, shared system of elements to assure safe  
23 use and supporting agreements, or secure a variance  
24 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) While the antitrust laws may address ac-  
11 tions by license holders who impede the prompt ne-  
12 gotiation and development on commercially reason-  
13 able terms of a single, shared system of elements to  
14 assure safe use, a more tailored legal pathway would  
15 help ensure that license holders negotiate such  
16 agreements in good faith and in a timely manner,  
17 facilitating competition in the marketplace for drugs  
18 and biological products.

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

21 (a) **DEFINITIONS.**—In this section—

22           (1) the term “covered product”—

23                   (A) means—

24                           (i) any drug approved under sub-  
25                           section (b) or (j) of section 505 of the Fed-

1           eral Food, Drug, and Cosmetic Act (21  
2           U.S.C. 355) or biological product licensed  
3           under subsection (a) or (k) of section 351  
4           of the Public Health Service Act (42  
5           U.S.C. 262);

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

8                   (iii) when reasonably necessary to  
9           demonstrate sameness, biosimilarity, or  
10          interchangeability for purposes of section  
11          505 of the Federal Food, Drug, and Cos-  
12          metic Act (21 U.S.C. 355), or section 351  
13          of the Public Health Service Act (42  
14          U.S.C. 262), as applicable, any product,  
15          including any device, that is marketed or  
16          intended for use with such drug or biologi-  
17          cal product; and

18                   (B) does not include any drug or biological  
19          product that the Secretary has determined to be  
20          currently in shortage and that appears on the  
21          drug shortage list in effect under section 506E  
22          of the Federal Food, Drug, and Cosmetic Act  
23          (21 U.S.C.356e), unless the shortage will not be  
24          promptly resolved—

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

4 (ii) as otherwise determined by the  
5 Secretary;

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

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

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

24 (5) the term “REMS” means a risk evaluation  
25 and mitigation strategy under section 505–1 of the

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

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

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

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

14 (9) 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 ACTIONS.—

5 (1) FAILURE TO PROVIDE SUFFICIENT QUAN-  
6 TITIES OF A COVERED PRODUCT.—

7 (A) IN GENERAL.—An eligible product de-  
8 veloper may bring a civil action against the li-  
9 cense holder for a covered product seeking relief  
10 under this paragraph in an appropriate district  
11 court of the United States alleging that the li-  
12 cense holder has declined to provide sufficient  
13 quantities of the covered product to the eligible  
14 product developer on commercially reasonable,  
15 market-based terms.

16 (B) ELEMENTS.—

17 (i) IN GENERAL.—To prevail in a civil  
18 action brought under subparagraph (A), an  
19 eligible product developer shall prove, by a  
20 preponderance of the evidence—

21 (I) that—

22 (aa) the covered product is  
23 not subject to a REMS with  
24 ETASU; or

1 (bb) if the covered product  
2 is subject to a REMS with  
3 ETASU—

4 (AA) the eligible prod-  
5 uct developer has obtained a  
6 covered product authoriza-  
7 tion from the Secretary in  
8 accordance with clause (ii);  
9 and

10 (BB) the eligible prod-  
11 uct developer has provided a  
12 copy of the covered product  
13 authorization to the license  
14 holder;

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

21 (III) that the eligible product de-  
22 veloper has requested to purchase suf-  
23 ficient quantities of the covered prod-  
24 uct from the license holder; and

## 12

1 (IV) that the license holder has  
2 not delivered to the eligible product  
3 developer sufficient quantities of the  
4 covered product on commercially rea-  
5 sonable, market-based terms—

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

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

17 (AA) the date on which  
18 the license holder received  
19 the request for the covered  
20 product; or

21 (BB) the date on which  
22 the license holder received a  
23 copy of the covered product  
24 authorization issued by the

1 Secretary in accordance with  
2 clause (ii).

3 (ii) AUTHORIZATION FOR COVERED  
4 PRODUCT SUBJECT TO A REMS WITH  
5 ETASU.—

6 (I) REQUEST.—An eligible prod-  
7 uct developer may submit to the Sec-  
8 retary a written request for the eligi-  
9 ble product developer to be authorized  
10 to obtain sufficient quantities of an  
11 individual covered product subject to a  
12 REMS with ETASU.

13 (II) AUTHORIZATION.—Not later  
14 than 90 days after the date on which  
15 a request under subclause (I) is re-  
16 ceived, the Secretary shall, by written  
17 notice, authorize the eligible product  
18 developer to obtain sufficient quan-  
19 tities of an individual covered product  
20 subject to a REMS with ETASU for  
21 purposes of—

22 (aa) development and test-  
23 ing that does not involve human  
24 clinical trials, if the eligible prod-  
25 uct developer has agreed to com-

1                   ply with any conditions the Sec-  
2                   retary determines necessary; or

3                               (bb) development and test-  
4                   ing that involves human clinical  
5                   trials, if the eligible product de-  
6                   veloper has—

7                                       (AA) submitted proto-  
8                                       cols, informed consent docu-  
9                                       ments, and informational  
10                                      materials for testing that in-  
11                                     clude protections that pro-  
12                                    vide safety protections com-  
13                                   parable to those provided by  
14                                   the REMS for the covered  
15                                   product; or

16                                    (BB) otherwise satis-  
17                                    fied the Secretary that such  
18                                    protections will be provided.

19                               (III) NOTICE.—A covered prod-  
20                   uct authorization issued under this  
21                   clause shall state that the provision of  
22                   the covered product by the license  
23                   holder under the terms of the author-  
24                   ization will not be a violation of the  
25                   REMS for the covered product.

1           (C) AFFIRMATIVE DEFENSE.—In a civil  
2           action brought under subparagraph (A), it shall  
3           be an affirmative defense, on which the defend-  
4           ant has the burden of persuasion by a prepon-  
5           derance of the evidence—

6                   (i) that, on the date on which the eli-  
7                   gible product developer requested to pur-  
8                   chase sufficient quantities of the covered  
9                   product from the license holder—

10                   (I) neither the license holder nor  
11                   any of its agents, wholesalers, or dis-  
12                   tributors was engaged in the manufac-  
13                   turing or commercial marketing of the  
14                   covered product; and

15                   (II) neither the license holder nor  
16                   any of its agents, wholesalers, or dis-  
17                   tributors otherwise had access to in-  
18                   ventory of the covered product to sup-  
19                   ply to the eligible product developer  
20                   on commercially reasonable, market-  
21                   based terms; or

22                   (ii) that—

23                   (I) the license holder sells the  
24                   covered product through agents, dis-  
25                   tributors, or wholesalers;

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

6 (III) the covered product can be  
7 purchased by the eligible product de-  
8 veloper in sufficient quantities on  
9 commercially reasonable, market-  
10 based terms from the agents, distribu-  
11 tors, or wholesalers of the license  
12 holder.

13 (D) REMEDIES.—

14 (i) IN GENERAL.—If an eligible prod-  
15 uct developer prevails in a civil action  
16 brought under subparagraph (A), the court  
17 shall—

18 (I) order the license holder to  
19 provide to the eligible product devel-  
20 oper without delay sufficient quan-  
21 tities of the covered product on com-  
22 mercially reasonable, market-based  
23 terms;

1 (II) award to the eligible product  
2 developer reasonable attorney fees and  
3 costs of the civil action; and

4 (III) award to the eligible prod-  
5 uct developer a monetary amount suf-  
6 ficient to deter the license holder from  
7 failing to provide other eligible prod-  
8 uct developers with sufficient quan-  
9 tities of a covered product on commer-  
10 cially reasonable, market-based terms,  
11 if the court finds, by a preponderance  
12 of the evidence—

13 (aa) that the license holder  
14 delayed providing sufficient quan-  
15 tities of the covered product to  
16 the eligible product developer  
17 without a legitimate business jus-  
18 tification; or

19 (bb) that the license holder  
20 failed to comply with an order  
21 issued under subclause (I).

22 (ii) MAXIMUM MONETARY AMOUNT.—  
23 A monetary amount awarded under clause  
24 (i)(III) shall not be greater than the rev-



1 sufficient quantities of the covered  
2 product.

3 (iii) AVOIDANCE OF DELAY.—The  
4 court may issue an order under clause  
5 (i)(I) before conducting further pro-  
6 ceedings that may be necessary to deter-  
7 mine whether the eligible product developer  
8 is entitled to an award under subclause  
9 (II) or (III) of clause (i), or the amount of  
10 any such award.

11 (2) FAILURE TO REACH AGREEMENT ON  
12 SHARED SYSTEM.—

13 (A) IN GENERAL.—An eligible product de-  
14 veloper may bring a civil action against the li-  
15 cense holder for a covered product seeking relief  
16 under this paragraph in an appropriate district  
17 court of the United States alleging the license  
18 holder—

19 (i) failed to reach agreement with re-  
20 spect to a single, shared system of ele-  
21 ments to assure safe use with respect to  
22 the covered product; or

23 (ii) refused to allow the eligible prod-  
24 uct developer to join a previously approved

1 system of elements to assure safe use with  
2 respect to that product.

3 (B) ELEMENTS.—To prevail in a civil ac-  
4 tion brought under subparagraph (A), an eligi-  
5 ble product developer shall prove, by a prepon-  
6 derance of the evidence, that—

7 (i) the eligible product developer has  
8 sought approval of an application for ap-  
9 proval under subsection (b)(2) or (j) of  
10 section 505 of the Federal Food, Drug,  
11 and Cosmetic Act (21 U.S.C. 355) or has  
12 sought a license for a biological product  
13 under section 351(k) of the Public Health  
14 Service Act (42 U.S.C. 262(k)) referencing  
15 a covered product subject to a REMS with  
16 ETASU;

17 (ii) the covered product is subject to  
18 a REMS with ETASU that requires a sin-  
19 gle, shared system of elements to assure  
20 safe use with respect to the covered prod-  
21 uct;

22 (iii) at least 120 days have elapsed  
23 since the developer first initiated an at-  
24 tempt to reach an agreement with the li-  
25 cense holder that would allow the product

1 developer to participate in a single, shared  
2 system of elements to assure safe use;

3 (iv) the license holder and eligible  
4 product developer have not reached an  
5 agreement that would allow the eligible  
6 product developer to participate in a single,  
7 shared system of elements to assure safe  
8 use on commercially reasonable terms; and

9 (v) the Secretary has not waived the  
10 requirement for the covered product to be  
11 part of such a single, shared system.

12 (C) REMEDIES.—

13 (i) IN GENERAL.—If an eligible prod-  
14 uct developer prevails in a civil action  
15 brought under subparagraph (A), the court  
16 shall—

17 (I) order the license holder to—

18 (aa) with the approval of the  
19 Secretary, enter into a single,  
20 shared system of elements to as-  
21 sure safe use with the eligible  
22 product developer on commer-  
23 cially reasonable terms;

24 (bb) with the approval of the  
25 Secretary, allow the eligible prod-

1                   uct developer to join a previously  
2                   approved system of elements to  
3                   assure safe use with respect to  
4                   the covered product on commer-  
5                   cially reasonable terms; or

6                   (cc) demonstrate that the  
7                   Secretary has waived the require-  
8                   ment for the covered product to  
9                   be part of a single, shared system  
10                  of elements to assure safe use;

11                  (II) award to the eligible product  
12                  developer reasonable attorney fees and  
13                  costs of the civil action; and

14                  (III) award to the eligible prod-  
15                  uct developer a monetary amount suf-  
16                  ficient to deter the license holder from  
17                  failing to reach agreements that would  
18                  allow other eligible product developers  
19                  to participate in a single, shared sys-  
20                  tem of elements to assure safe use on  
21                  commercially reasonable terms if the  
22                  court finds, by a preponderance of the  
23                  evidence—

1 (aa) that the license holder,  
2 without a legitimate business jus-  
3 tification, delayed—

4 (AA) the entry of the  
5 eligible product developer  
6 into a single, shared system  
7 of elements to assure safe  
8 use with respect to the cov-  
9 ered product; or

10 (BB) the securing of a  
11 waiver of the requirement of  
12 a single, shared system of  
13 elements to assure safe use  
14 with respect to the covered  
15 product; or

16 (bb) that the license holder  
17 failed to comply with an order  
18 issued under subclause (I).

19 (ii) MAXIMUM MONETARY AMOUNT.—  
20 A monetary amount awarded under clause  
21 (i)(III) shall not be greater than the rev-  
22 enue that the license holder earned on the  
23 covered product during the period—

24 (I) beginning on the date that is  
25 121 days after the date on which the

1 product developer first initiated an at-  
2 tempt to reach an agreement with the  
3 license holder that would allow the  
4 product developer to participate in a  
5 single, shared system of elements to  
6 assure safe use with respect to the  
7 covered product; and

8 (II) ending on the date on which  
9 the eligible product developer and li-  
10 cense holder reached an agreement  
11 that would allow the product devel-  
12 oper to participate in a single, shared  
13 system of elements to assure safe use  
14 with respect to the covered product.

15 (iii) AVOIDANCE OF DELAY.—The  
16 court may issue an order under clause  
17 (i)(I) before conducting further pro-  
18 ceedings that may be necessary to deter-  
19 mine whether the eligible product developer  
20 is entitled to an award under subclause  
21 (II) or (III) of clause (i), or the amount of  
22 any such award.

23 (c) LIMITATION OF LIABILITY.—A license holder  
24 shall not be liable for any claim arising out of the failure  
25 of an eligible product developer to follow adequate safe-

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

5 (d) RULE OF CONSTRUCTION.—

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

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

11 (B) includes section 5 of the Federal  
12 Trade Commission Act (15 U.S.C. 45) to the  
13 extent that such section applies to unfair meth-  
14 ods of competition.

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