

## Committee Print

[SHOWING THE TEXT OF H.R. 965 AS FAVORABLY FORWARDED BY THE  
SUBCOMMITTEE ON HEALTH ON MARCH 27, 2019]

116TH CONGRESS  
1ST SESSION

# H. R. 965

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 HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2019

Mr. CICILLINE (for himself, Mr. SENSENBRENNER, Mr. NADLER, Mr. COLLINS of Georgia, Mr. WELCH, and Mr. MCKINLEY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

## 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 2019” or the  
4 “CREATES Act of 2019”.

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 as required by sec-  
5 tion 505–1 of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 355–1), or secure a variance there-  
7 from.

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 of the Food and Drug Adminis-

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

14                 (7) In 2018, the Acting Chairman of the Fed-  
15          eral Trade Commission testified that the Federal  
16          Trade Commission continues to be very concerned  
17          about potential abuses by manufacturers of brand  
18          drugs of risk evaluation and mitigation strategies or  
19          other closed distribution systems to impede generic  
20          competition.

21                 (8) Also contrary to the policy of the United  
22          States to promote competition in the market for  
23          drugs and biological products by facilitating the  
24          timely entry of lower-cost generic and biosimilar  
25          versions of those drugs and biological products, cer-

1       tain license holders are impeding the prompt nego-  
2       tiation and development on commercially reasonable  
3       terms of a single, shared system of elements to as-  
4       sure safe use, which may be necessary for the ge-  
5       neric product developer to gain approval for its drug  
6       or licensing for its biological product.

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

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

1 delay generic approval. At the same time, clearer  
2 regulatory authority would ensure all systems pro-  
3 tect patient safety.

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

6 (a) DEFINITIONS.—In this section—

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

9 (A) a nondiscriminatory price for the sale  
10 of the covered product at or below, but not  
11 greater than, the most recent wholesale acquisi-  
12 tion cost for the drug, as defined in section  
13 1847A(c)(6)(B) of the Social Security Act (42  
14 U.S.C. 1395w–3a(c)(6)(B));

15 (B) a schedule for delivery that results in  
16 the transfer of the covered product to the eligi-  
17 ble product developer consistent with the timing  
18 under subsection (b)(2)(A)(iv); and

19 (C) no additional conditions are imposed  
20 on the sale of the covered product;

21 (2) the term “covered product”—

22 (A) means—

23 (i) any drug approved under sub-  
24 section (c) or (j) of section 505 of the Fed-  
25 eral Food, Drug, and Cosmetic Act (21

1 U.S.C. 355) or biological product licensed  
2 under subsection (a) or (k) of section 351  
3 of the Public Health Service Act (42  
4 U.S.C. 262);

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

7 (iii) when reasonably necessary to  
8 support approval of an application under  
9 section 505 of the Federal Food, Drug,  
10 and Cosmetic Act (21 U.S.C. 355), or sec-  
11 tion 351 of the Public Health Service Act  
12 (42 U.S.C. 262), as applicable, or other-  
13 wise meet the requirements for approval  
14 under either such section, any product, in-  
15 cluding any device, that is marketed or in-  
16 tended for use with such a drug or biologi-  
17 cal product; and

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

23 (i) the drug or biological product has  
24 been on such shortage list continuously for  
25 more than 6 months; or



1 (ii) the Secretary determines that in-  
2 clusion of the drug or biological product in  
3 the definition of the term “covered prod-  
4 uct” for purposes of this section would  
5 likely contribute to alleviating or pre-  
6 venting a shortage.

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

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

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

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

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

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

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

16           (10) the term “sufficient quantities” means an  
17 amount of a covered product that allows the eligible  
18 product developer to—

19                   (A) conduct testing to support an applica-  
20 tion under—

21                           (i) subsection (b)(2) or (j) of section  
22 505 of the Federal Food, Drug, and Cos-  
23 metic Act (21 U.S.C. 355); or

1 (ii) section 351(k) of the Public  
2 Health Service Act (42 U.S.C. 262(k));  
3 and

4 (B) fulfill any regulatory requirements re-  
5 lating to approval of such an application.

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

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

16 (2) ELEMENTS.—

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

21 (i) that—

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

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

1 (aa) the eligible product de-  
2 veloper has obtained a covered  
3 product authorization from the  
4 Secretary in accordance with sub-  
5 paragraph (B); and

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

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

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

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

24 (I) for a covered product that is  
25 not subject to a REMS with ETASU,

1 by the date that is 31 days after the  
2 date on which the license holder re-  
3 ceived the request for the covered  
4 product; and

5 (II) for a covered product that is  
6 subject to a REMS with ETASU, by  
7 31 days after the later of—

8 (aa) the date on which the  
9 license holder received the re-  
10 quest for the covered product; or

11 (bb) the date on which the  
12 license holder received a copy of  
13 the covered product authorization  
14 issued by the Secretary in ac-  
15 cordance with subparagraph (B).

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

18 (i) REQUEST.—An eligible product de-  
19 veloper may submit to the Secretary a  
20 written request for the eligible product de-  
21 veloper to be authorized to obtain suffi-  
22 cient quantities of an individual covered  
23 product subject to a REMS with ETASU.

24 (ii) AUTHORIZATION.—Not later than  
25 120 days after the date on which a request

1 under clause (i) is received, the Secretary  
2 shall, by written notice, authorize the eligi-  
3 ble product developer to obtain sufficient  
4 quantities of an individual covered product  
5 subject to a REMS with ETASU for pur-  
6 poses of—

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

12 (II) development and testing that  
13 involves human clinical trials, if the  
14 eligible product developer has—

15 (aa)(AA) submitted proto-  
16 cols, informed consent docu-  
17 ments, and informational mate-  
18 rials for testing that include pro-  
19 tections that provide safety pro-  
20 tections comparable to those pro-  
21 vided by the REMS for the cov-  
22 ered product; or

23 (BB) otherwise satisfied the  
24 Secretary that such protections  
25 will be provided; and

1 (bb) met any other require-  
2 ments the Secretary may estab-  
3 lish.

4 (iii) NOTICE.—A covered product au-  
5 thorization issued under this subparagraph  
6 shall state that the provision of the covered  
7 product by the license holder under the  
8 terms of the authorization will not be a  
9 violation of the REMS for the covered  
10 product.

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

15 (A) that, on the date on which the eligible  
16 product developer requested to purchase suffi-  
17 cient quantities of the covered product from the  
18 license holder—

19 (i) neither the license holder nor any  
20 of its agents, wholesalers, or distributors  
21 was engaged in the manufacturing or com-  
22 mercial marketing of the covered product;  
23 and

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

1 otherwise had access to inventory of the  
2 covered product to supply to the eligible  
3 product developer on commercially reason-  
4 able, market-based terms; or

5 (B) that—

6 (i) the license holder sells the covered  
7 product through agents, distributors, or  
8 wholesalers;

9 (ii) the license holder has placed no  
10 restrictions, explicit or implicit, on its  
11 agents, distributors, or wholesalers to sell  
12 covered products to eligible product devel-  
13 opers; and

14 (iii) the covered product can be pur-  
15 chased by the eligible product developer in  
16 sufficient quantities on commercially rea-  
17 sonable, market-based terms from the  
18 agents, distributors, or wholesalers of the  
19 license holder.

20 (4) REMEDIES.—

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

24 (i) order the license holder to provide  
25 to the eligible product developer without



1 delay sufficient quantities of the covered  
2 product on commercially reasonable, mar-  
3 ket-based terms;

4 (ii) award to the eligible product de-  
5 veloper reasonable attorney's fees and costs  
6 of the civil action; and

7 (iii) award to the eligible product de-  
8 veloper a monetary amount sufficient to  
9 deter the license holder from failing to pro-  
10 vide eligible product developers with suffi-  
11 cient quantities of a covered product on  
12 commercially reasonable, market-based  
13 terms, if the court finds, by a preponder-  
14 ance of the evidence—

15 (I) that the license holder delayed  
16 providing sufficient quantities of the  
17 covered product to the eligible product  
18 developer without a legitimate busi-  
19 ness justification; or

20 (II) that the license holder failed  
21 to comply with an order issued under  
22 clause (i).

23 (B) MAXIMUM MONETARY AMOUNT.—A  
24 monetary amount awarded under subparagraph  
25 (A)(iii) shall not be greater than the revenue

1           that the license holder earned on the covered  
2           product during the period—

3                   (i) beginning on—

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

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

13                                   (aa) the date on which the  
14                                   license holder received the re-  
15                                   quest; or

16                                   (bb) the date on which the  
17                                   license holder received a copy of  
18                                   the covered product authorization  
19                                   issued by the Secretary in ac-  
20                                   cordance with paragraph (2)(B);  
21                                   and

22                           (ii) ending on the date on which the  
23                           eligible product developer received suffi-  
24                           cient quantities of the covered product.

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

8           (e) LIMITATION OF LIABILITY.—A license holder for  
9           a covered product shall not be liable for any claim under  
10          Federal, State, or local law arising out of the failure of  
11          an eligible product developer to follow adequate safeguards  
12          to assure safe use of the covered product during develop-  
13          ment or testing activities described in this section, includ-  
14          ing transportation, handling, use, or disposal of the cov-  
15          ered product by the eligible product developer.

16          (d) NO VIOLATION OF REMS.—The provision of  
17          samples of a drug pursuant to an authorization under sub-  
18          section (b)(2)(B) shall not be considered a violation of the  
19          requirements of any risk evaluation and mitigation strat-  
20          egy that may be in place under section 505–1 of the Fed-  
21          eral Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for  
22          such drug.

23          (e) RULE OF CONSTRUCTION.—

24                  (1) DEFINITION.—In this subsection, the term  
25          “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. 4. REMS APPROVAL PROCESS FOR SUBSEQUENT FIL-**  
12 **ERS.**

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, com-  
22 parable aspects of the elements to assure  
23 safe use for a drug that is the subject of  
24 an application under section 505(j), and  
25 the applicable listed drug.”;

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

3           “(C)(i) Elements to assure safe use, if re-  
4 quired under subsection (f) for the listed drug,  
5 which, subject to clause (ii), for a drug that is  
6 the subject of an application under section  
7 505(j) may use—

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

10           “(II) a different, comparable aspect of  
11 the elements to assure safe use under sub-  
12 section (f).

13           “(ii) The Secretary may require a drug  
14 that is the subject of an application under sec-  
15 tion 505(j) and the listed drug to use a single,  
16 shared system under subsection (f), if the Sec-  
17 retary determines that no different, comparable  
18 aspect of the elements to assure safe use could  
19 satisfy the requirements of subsection (f).”;

20           (3) in subsection (i), by adding at the end the  
21 following:

22           “(3) SHARED REMS.—If the Secretary ap-  
23 proves, in accordance with paragraph (1)(C)(i)(II), a  
24 different, comparable aspect of the elements to as-  
25 sure safe use under subsection (f) for a drug that

1 is the subject of an abbreviated new drug application  
2 under section 505(j), the Secretary may require that  
3 such different comparable aspect of the elements to  
4 assure safe use can be used with respect to any  
5 other drug that is the subject of an application  
6 under section 505(j) or 505(b) that references the  
7 same listed drug.”; and

8 (4) by adding at the end the following:

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