

# Union Calendar No. 33

116TH CONGRESS  
1ST SESSION

# H. R. 965

**[Report No. 116–55, Parts I and II]**

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.

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## 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

MAY 10, 2019

Additional sponsors: Mr. MEADOWS, Ms. FINKENAUER, Mr. DOGGETT, Mr. COLE, Mr. GALLAGHER, Mr. LIPINSKI, Mr. RUSH, Ms. MCCOLLUM, Mr. PALLONE, Mr. PERRY, Mr. RUIZ, Mrs. DINGELL, Ms. ESHOO, Ms. MATSUI, Mrs. CRAIG, Mr. TONKO, Mr. GOHMERT, Mr. VAN DREW, Ms. CLARKE of New York, Mr. COURTNEY, Mr. ALLRED, Ms. SCHAKOWSKY, Mr. CROW, Mr. GONZALEZ of Ohio, Mr. LARSON of Connecticut, Mr. MCADAMS, Mr. SCHRADER, Mr. RODNEY DAVIS of Illinois, Mr. PAPPAS, Mr. KENNEDY, Ms. DAVIDS of Kansas, Mr. NORCROSS, Ms. SPANBERGER, Mr. QUIGLEY, Mr. DEUTCH, Mr. LANGEVIN, Mr. COOPER, Mrs. MCBATH, Mr. RASKIN, Ms. MUCARSEL-POWELL, Mr. STANTON, Mr. JORDAN, Ms. WILD, Mr. COHEN, Mr. KIM, Ms. SCHRIER, Mr. JOYCE of Ohio, Mr. CASE, Mr. KHANNA, Mr. DAVID SCOTT of Georgia, Ms. HOULAHAN, Mr. CASTEN of Illinois, Mr. NORMAN, Ms. PINGREE, Mr. CARBAJAL, Mr. SMITH of Washington, Ms. WEXTON, Mr. CISNEROS, Mr. CONNOLLY, Ms. UNDERWOOD, Ms. GARCIA of Texas, Ms. MENG, and Mrs. BUSTOS

MAY 10, 2019

Reported from the Committee on Energy and Commerce with an amendment

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

MAY 10, 2019

Reported from the Committee on the Judiciary; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on February 5, 2019]

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## **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,*

3 **SECTION 1. SHORT TITLE.**

4        *This Act may be cited as the “Creating and Restoring*  
5 *Equal Access to Equivalent Samples Act of 2019” or the*  
6 *“CREATES Act of 2019”.*

7 **SEC. 2. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIO-**  
8 **SIMILAR BIOLOGICAL PRODUCTS.**

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

10            (1) *the term “commercially reasonable, market-*  
11 *based terms” means—*

12                    (A) *a nondiscriminatory price for the sale*  
13 *of the covered product at or below, but not great-*  
14 *er than, the most recent wholesale acquisition*  
15 *cost for the drug, as defined in section*  
16 *1847A(c)(6)(B) of the Social Security Act (42*  
17 *U.S.C. 1395w–3a(c)(6)(B));*

18                    (B) *a schedule for delivery that results in*  
19 *the transfer of the covered product to the eligible*  
20 *product developer consistent with the timing*  
21 *under subsection (b)(2)(A)(iv); and*

22                    (C) *no additional conditions are imposed*  
23 *on the sale of the covered product;*

24            (2) *the term “covered product”—*

25                    (A) *means—*

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

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

10          (iii) when reasonably necessary to sup-  
11          port approval of an application under sec-  
12          tion 505 of the Federal Food, Drug, and  
13          Cosmetic Act (21 U.S.C. 355), or section  
14          351 of the Public Health Service Act (42  
15          U.S.C. 262), as applicable, or otherwise  
16          meet the requirements for approval under  
17          either such section, any product, including  
18          any device, that is marketed or intended for  
19          use with such a drug or biological product;  
20          and

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

1                   (i) the drug or biological product has  
2                   been on the drug shortage list in effect  
3                   under such section 506E continuously for  
4                   more than 6 months; or

5                   (ii) the Secretary determines that in-  
6                   clusion of the drug or biological product as  
7                   a covered product is likely to contribute to  
8                   alleviating or preventing a shortage.

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

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

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

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

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

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

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

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

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

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

23 (i) *subsection (b)(2) or (j) of section*  
24 *505 of the Federal Food, Drug, and Cos-*  
25 *metic Act (21 U.S.C. 355); or*

1                   (ii) section 351(k) of the Public Health  
2                   Service Act (42 U.S.C. 262(k)); and  
3                   (B) fulfill any regulatory requirements re-  
4                   lating to approval of such an application.

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

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

15                  (2) ELEMENTS.—

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

20                                 (i) that—

21   (I) the covered product is not sub-  
22   ject to a REMS with ETASU; or

23   (II) if the covered product is sub-  
24   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 the  
8                   covered product authorization to  
9                   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 the  
13                  covered product on commercially reasonable,  
14                  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 license  
18                  holder; and

19                  (iv) that the license holder has not de-  
20                  livered to the eligible product developer suf-  
21                  ficient quantities of the covered product on  
22                  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 prod-  
4                   uct; 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 li-  
9                   cense holder received the request  
10                  for the covered product; or

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

22                               (BB) otherwise satisfied the  
23                               Secretary that such protections  
24                               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 vio-*  
9                    *lation of the REMS for the covered product.*

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

14                    *(A) that, on the date on which the eligible*  
15                    *product developer requested to purchase sufficient*  
16                    *quantities of the covered product from the license*  
17                    *holder—*

18                    *(i) neither the license holder nor any of*  
19                    *its agents, wholesalers, or distributors was*  
20                    *engaged in the manufacturing or commer-*  
21                    *cial marketing of the covered product; and*

22                    *(ii) neither the license holder nor any*  
23                    *of its agents, wholesalers, or distributors*  
24                    *otherwise had access to inventory of the cov-*  
25                    *ered product to supply to the eligible prod-*

1            *uct developer on commercially reasonable,*  
2            *market-based terms;*

3            *(B) that—*

4                    *(i) the license holder sells the covered*  
5                    *product through agents, distributors, or*  
6                    *wholesalers;*

7                    *(ii) the license holder has placed no re-*  
8                    *strictions, explicit or implicit, on its agents,*  
9                    *distributors, or wholesalers to sell covered*  
10                   *products to eligible product developers; and*

11                   *(iii) the covered product can be pur-*  
12                   *chased by the eligible product developer in*  
13                   *sufficient quantities on commercially rea-*  
14                   *sonable, market-based terms from the*  
15                   *agents, distributors, or wholesalers of the li-*  
16                   *cence holder; or*

17            *(C) that the license holder made an offer to*  
18            *sell sufficient quantities of the covered product to*  
19            *the eligible product developer at commercially*  
20            *reasonable market-based terms—*

21                    *(i) for a covered product that is not*  
22                    *subject to a REMS with ETASU, by the*  
23                    *date that is 14 days after the date on which*  
24                    *the license holder received the request for the*  
25                    *covered product, and the eligible product de-*

1            *veloper did not accept such offer by the date*  
2            *that is 7 days after the date on which the*  
3            *eligible product developer received such offer*  
4            *from the license holder; or*

5            *(ii) for a covered product that is sub-*  
6            *ject to a REMS with ETASU, by the date*  
7            *that is 20 days after the date on which the*  
8            *license holder received the request for the*  
9            *covered product, and the eligible product de-*  
10           *veloper did not accept such offer by the date*  
11           *that is 10 days after the date on which the*  
12           *eligible product developer received such offer*  
13           *from the license holder.*

14           *(4) METHODS FOR TRANSMISSION OF REQUESTS*  
15           *FOR COVERED PRODUCTS.—A written request for a*  
16           *covered product, offer to sell a covered product, or ac-*  
17           *ceptance of such an offer between the eligible product*  
18           *developer and the license holder shall be made by—*

19           *(A) certified or registered mail with return*  
20           *receipt requested;*

21           *(B) personal delivery; or*

22           *(C) electronic means.*

23           *(5) REMEDIES.—*

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

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

9                   (ii) *award to the eligible product devel-*  
10 *oper reasonable attorney’s fees and costs of*  
11 *the civil action; and*

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

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

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

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

9                   (i) beginning on—

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

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

18                   (aa) the date on which the li-  
19                   cense holder received the request;  
20                   or

21                   (bb) the date on which the li-  
22                   cense holder received a copy of the  
23                   covered product authorization  
24                   issued by the Secretary in accord-  
25                   ance with paragraph (2)(B); and

1                   (ii) ending on the date on which the el-  
2                   igible product developer received sufficient  
3                   quantities of the covered product.

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

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

19               (d) NO VIOLATION OF REMS.—Section 505–1 of the  
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1)  
21 is amended by adding at the end the following new sub-  
22 section:

23               “(l) PROVISION OF SAMPLES NOT A VIOLATION OF  
24 STRATEGY.—The provision of samples of a covered product  
25 to an eligible product developer (as those terms are defined



1 *in section 2(a) of the Creating and Restoring Equal Access*  
2 *to Equivalent Samples Act of 2019) shall not be considered*  
3 *a violation of the requirements of any risk evaluation and*  
4 *mitigation strategy that may be in place under this section*  
5 *for such drug.”.*

6 *(e) RULE OF CONSTRUCTION.—*

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

9 *(A) has the meaning given the term in sub-*  
10 *section (a) of the first section of the Clayton Act*  
11 *(15 U.S.C. 12); and*

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

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

19 **SEC. 3. REMS APPROVAL PROCESS FOR SUBSEQUENT FIL-**  
20 **ERS.**

21 *Section 505–1 of the Federal Food, Drug, and Cos-*  
22 *metic Act (21 U.S.C. 355–1), as amended by section 2, is*  
23 *further amended—*

24 *(1) in subsection (g)(4)(B)—*

1           (A) in clause (i) by striking “or” after the  
2           semicolon;

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

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

6                   “(iii) accommodate different, com-  
7                   parable aspects of the elements to assure  
8                   safe use for a drug that is the subject of an  
9                   application under section 505(j), and the  
10                  applicable listed drug.”;

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

13                   “(C)(i) Elements to assure safe use, if re-  
14                   quired under subsection (f) for the listed drug,  
15                   which, subject to clause (ii), for a drug that is  
16                   the subject of an application under section 505(j)  
17                   may use—

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

20                           “(II) a different, comparable aspect of  
21                           the elements to assure safe use under sub-  
22                           section (f).

23                   “(ii) The Secretary may require a drug that  
24                   is the subject of an application under section  
25                   505(j) and the listed drug to use a single, shared

1           system under subsection (f), if the Secretary de-  
2           termines that no different, comparable aspect of  
3           the elements to assure safe use could satisfy the  
4           requirements of subsection (f).”;

5           (3) in subsection (i), by adding at the end the  
6           following:

7           “(3) *SHARED REMS.*—If the Secretary approves,  
8           in accordance with paragraph (1)(C)(i)(II), a dif-  
9           ferent, comparable aspect of the elements to assure  
10          safe use under subsection (f) for a drug that is the  
11          subject of an abbreviated new drug application under  
12          section 505(j), the Secretary may require that such  
13          different comparable aspect of the elements to assure  
14          safe use can be used with respect to any other drug  
15          that is the subject of an application under section  
16          505(j) or 505(b) that references the same listed drug.”;  
17          and

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

19          “(m) *SEPARATE REMS.*—When used in this section,  
20          the terms ‘different, comparable aspect of the elements to  
21          assure safe use’ or ‘different, comparable approved risk eval-  
22          uation and mitigation strategies’ means a risk evaluation  
23          and mitigation strategy for a drug that is the subject of  
24          an application under section 505(j) that uses different  
25          methods or operational means than the strategy required

1 *under subsection (a) for the applicable listed drug, or other*  
2 *application under section 505(j) with the same such listed*  
3 *drug, but achieves the same level of safety as such strategy.”.*

4 **SEC. 4. RULE OF CONSTRUCTION.**

5 *(a) IN GENERAL.—Nothing in this Act, the amend-*  
6 *ments made by this Act, or in section 505–1 of the Federal*  
7 *Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), shall be*  
8 *construed as—*

9 *(1) prohibiting a license holder from providing*  
10 *an eligible product developer access to a covered prod-*  
11 *uct in the absence of an authorization under this Act;*  
12 *or*

13 *(2) in any way negating the applicability of a*  
14 *REMS with ETASU, as otherwise required under*  
15 *such section 505–1, with respect to such covered prod-*  
16 *uct.*

17 *(b) DEFINITIONS.—In this section, the terms “covered*  
18 *product”, “eligible product developer”, “license holder”, and*  
19 *“REMS with ETASU” have the meanings given such terms*  
20 *in section 3(a).*



Union Calendar No. 33

116<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**H. R. 965**

[Report No. 116-55, Parts I and II]

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**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.

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MAY 10, 2019

Reported from the Committee on Energy and Commerce  
with an amendment

MAY 10, 2019

Reported from the Committee on the Judiciary; committed to the Committee of the Whole House on the State of the Union and ordered to be printed