

116TH CONGRESS  
1ST SESSION

# H. R. 985

To amend the Federal Food, Drug, and Cosmetic Act to ensure that eligible product developers have competitive access to approved drugs and licensed biological products, so as to enable eligible product developers to develop and test new products, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2019

Mr. WELCH (for himself, Mr. MCKINLEY, and Mr. CICILLINE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure that eligible product developers have competitive access to approved drugs and licensed biological products, so as to enable eligible product developers to develop and test new products, and for other purposes.

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 “Fair Access for Safe  
5 and Timely Generics Act of 2019” or the “FAST Generics  
6 Act of 2019”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds the following:

3 (1) Reference product license or approval hold-  
4 ers are restricting competitive access to reference  
5 products by sponsors seeking to develop drugs, ge-  
6 neric drugs, and biosimilars under section 505(b)(2)  
7 or 505(j) of the Food, Drug, and Cosmetic Act (21  
8 U.S.C. 355(b)(2) and 355(j)) and under section  
9 351(k) of the Public Health Service Act (42 U.S.C.  
10 262(k)). These restrictions are deterring and delay-  
11 ing development of drugs, generic drugs, and  
12 biosimilars by extending lawful patent-based monop-  
13 olies beyond their lawful patent life.

14 (2) The enforcement provisions set forth in sec-  
15 tion 505–1(f)(8) of the Federal Food, Drug, and  
16 Cosmetic Act (21 U.S.C. 355–1(f)(8)) have not been  
17 sufficient to prevent anti-competitive practices that  
18 interfere with access to reference products which is  
19 necessary for the timely development of affordable  
20 drugs, generic drugs, and biosimilars.

21 (3) There is not a regulatory structure in place  
22 that is sufficient to deter or remedy the anti-com-  
23 petitive harm that results when—

24 (A) access to reference products is re-  
25 stricted to sponsors developing drugs, generic  
26 drugs, or biosimilars in accordance with section

1           505(b)(2) or 505(j) of the Federal Food, Drug,  
2           and Cosmetic Act (21 U.S.C. 355(b)(2) or  
3           355(j)), and section 351(k) of the Public  
4           Health Service Act (42 U.S.C. 262(k)), respec-  
5           tively; or

6           (B) license holders impede the prompt ne-  
7           gotiation and development of a single, shared  
8           system of elements to assure safe use and sup-  
9           porting agreements under section 505-  
10          1(i)(1)(B) of such Act (21 U.S.C. 355-  
11          1(i)(1)(B)), on commercially reasonable terms.

12          (4) Requiring license holders to comply with re-  
13          quirements for competitive access to their products,  
14          and for the negotiation and development of single,  
15          shared systems of elements to assure safe use under  
16          section 505-1(i)(1)(B) of the Federal Food, Drug,  
17          and Cosmetic Act (21 U.S.C. 355-1(i)(1)(B)), and  
18          subjecting license holders to liability for failing to do  
19          so, will not impose obligations on the courts that  
20          they cannot adequately and reasonably adjudicate.

21 **SEC. 3. COMPETITIVE ACCESS TO COVERED PRODUCTS**  
22 **FOR DEVELOPMENT PURPOSES.**

23          (a) IN GENERAL.—Chapter V of the Federal Food,  
24          Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-

1 ed by inserting after section 505–1 of such Act (21 U.S.C.  
2 355–1) the following new section:

3 **“SEC. 505–2. COMPETITIVE ACCESS TO COVERED PROD-**  
4 **UCTS FOR DEVELOPMENT PURPOSES.**

5 “(a) DEFINITIONS.—In this section:

6 “(1) COVERED PRODUCT.—The term ‘covered  
7 product’—

8 “(A) means—

9 “(i) any drug approved under section  
10 505 or biological product licensed under  
11 section 351 of the Public Health Service  
12 Act;

13 “(ii) any combination thereof; or

14 “(iii) when reasonably necessary to  
15 demonstrate sameness, biosimilarity, or  
16 interchangeability for purposes of this sec-  
17 tion, section 505, or section 351 of the  
18 Public Health Service Act (as applicable),  
19 any product, including any device, that is  
20 marketed or intended for use with such  
21 drug or biological product; and

22 “(B) excludes any drug or biological prod-  
23 uct which the Secretary has determined to be  
24 currently in shortage and that appears on the  
25 drug shortage list in effect under section 506E,

1           unless the shortage will not be promptly re-  
2           solved—

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

6                   “(ii) as otherwise determined by the  
7                   Secretary.

8                   “(2) ELIGIBLE PRODUCT DEVELOPER.—The  
9                   term ‘eligible product developer’ means a person that  
10                  seeks to develop a product for approval pursuant to  
11                  an application under section 505(b)(2) or 505(j) or  
12                  for licensing pursuant to an application under sec-  
13                  tion 351(k) of the Public Health Service Act.

14                  “(3) LICENSE HOLDER.—The term ‘license  
15                  holder’ means the holder of an application approved  
16                  under section 505(b) or section 505(j) of this Act or  
17                  under section 351 of the Public Health Service Act  
18                  for a covered product (including the holder’s agents,  
19                  wholesalers, distributors, assigns, corporate affili-  
20                  ates, and contractors).

21                  “(4) REMS.—The term ‘REMS’ means a risk  
22                  evaluation and mitigation strategy under section  
23                  505–1.

24                  “(5) REMS PRODUCT.—The term ‘REMS  
25                  product’ means a covered product that—

1           “(A) is subject to a risk evaluation and  
2 mitigation strategy under section 505–1; or

3           “(B) is deemed under section 909(b) of the  
4 Food and Drug Administration Amendments  
5 Act of 2007 to have in effect an approved risk  
6 evaluation and mitigation strategy under sec-  
7 tion 505–1.

8           “(6) REMS IMPACTING PRODUCT DISTRIBUTION.—The term ‘REMS impacting product dis-  
9 tribution’ means a REMS that contains elements to  
10 assure safe use that impact the distribution of the  
11 product subject to the REMS.

12           “(b) COMPETITIVE ACCESS TO COVERED PRODUCTS  
13 AS A CONDITION ON APPROVAL OR LICENSING.—As a  
14 condition of approval or licensure, or continuation or re-  
15 newal of approval or licensure, of a covered product under  
16 section 505 of this Act or section 351 of the Public Health  
17 Service Act, respectively, the Secretary shall require that  
18 the covered product’s license holder not construe or apply  
19 any condition or restriction relating to the sale, resale, or  
20 distribution of the covered product, including any condi-  
21 tion or restriction adopted, imposed, or enforced as an as-  
22 pect of a risk evaluation and mitigation strategy, in a way  
23 that restricts or has the effect of restricting the supply  
24

1 of such covered product to an eligible product developer  
2 for development or testing purposes.

3       “(c) COMPETITIVE ACCESS FOR DEVELOPMENT PUR-  
4 POSES TO PRODUCTS WITH REMS IMPACTING PRODUCT  
5 DISTRIBUTION.—With respect to a product subject to a  
6 REMS impacting product distribution, no aspect of such  
7 a REMS shall be construed or applied by the REMS prod-  
8 uct’s license holder in a way that prohibits or restricts the  
9 supply, at commercially reasonable, market-based prices,  
10 of such REMS product from the REMS product’s license  
11 holder to an eligible product developer with an applicable  
12 individual covered product authorization obtained pursu-  
13 ant to subsection (e) for development and testing pur-  
14 poses.

15       “(d) SINGLE, SHARED SYSTEM OF ELEMENTS TO  
16 ASSURE SAFE USE.—Where an eligible product developer  
17 seeks approval of an application under 505(j) referencing  
18 a REMS product whose REMS includes elements to as-  
19 sure safe use—

20               “(1) no license holder shall take any step that  
21 impedes—

22                       “(A) the prompt development on commer-  
23 cially reasonable terms of a single, shared sys-  
24 tem of elements to assure safe use under sec-  
25 tion 505–1; or

1           “(B) the prompt entry on commercially  
2           reasonable terms of an eligible product devel-  
3           oper into a previously approved system of ele-  
4           ments to assure safe use; and

5           “(2) license holders shall negotiate in good faith  
6           towards the prompt development of (or entry into)  
7           a single, shared system of elements to assure safe  
8           use under section 505–1(i) on commercially reason-  
9           able terms.

10          “(e) PROCEDURES FOR OBTAINING ACCESS TO COV-  
11          ERED PRODUCTS.—

12           “(1) COMPETITIVE ACCESS TO PRODUCTS NOT  
13           SUBJECT TO REMS IMPACTING PRODUCT DISTRIBUTI-  
14           ON.—Notwithstanding any other provision of law,  
15           a license holder that receives a request from an eligi-  
16           ble product developer or its agent for sufficient sup-  
17           plies of a covered product (that is not subject to a  
18           REMS impacting product distribution) to conduct  
19           testing necessary to support an application under  
20           section 505(b)(2) or 505(j) or under section 351(k)  
21           of the Public Health Service Act (or otherwise meet  
22           the requirements for approval of such an applica-  
23           tion) shall provide to the eligible product developer  
24           or its agent the quantity requested within 30 days  
25           of receipt of the request at a nondiscriminatory,

1 commercially reasonable, market-based price for  
2 which such covered product has been previously sold  
3 by the license holder to third parties in the open  
4 market.

5 “(2) COMPETITIVE ACCESS TO PRODUCTS SUB-  
6 JECT TO REMS IMPACTING PRODUCT DISTRIBUTION:  
7 INDIVIDUAL COVERED PRODUCT AUTHORIZATION.—  
8 Any eligible product developer may seek an author-  
9 ization to obtain an individual covered product sub-  
10 ject to a REMS impacting product distribution for  
11 development and testing purposes by making a writ-  
12 ten request to the Secretary. Within 120 days of re-  
13 ceiving such a request, the Secretary shall, by writ-  
14 ten notice, issue such authorization for purposes  
15 of—

16 “(A) development and testing that does  
17 not involve human clinical trials, if the eligible  
18 product developer has agreed to comply with  
19 any conditions the Secretary determines nec-  
20 essary; or

21 “(B) development and testing that involves  
22 human clinical trials if the eligible product de-  
23 veloper has—

24 “(i) submitted a protocol for testing  
25 that includes protections that will provide

1 an assurance of safety comparable to the  
2 assurance of safety provided by any dis-  
3 tribution restrictions governing the ap-  
4 proval or licensure of the covered product;  
5 or

6 “(ii) otherwise satisfied the Secretary  
7 that such protections will be provided.

8 “(3)(A) PROCESS FOR OBTAINING PRODUCT  
9 PURSUANT TO AN AUTHORIZATION.—

10 “(i) An eligible product developer shall be  
11 entitled to obtain, from the license holder of a  
12 covered product subject to a REMS impacting  
13 distribution, sufficient quantities of the covered  
14 product for purposes of development and test-  
15 ing necessary to support an application under  
16 section 505(b)(2) or 505(j) or under section  
17 351(k) of the Public Health Service Act, or oth-  
18 erwise meet the requirements for approval of  
19 such application, if the eligible product devel-  
20 oper has obtained an applicable authorization  
21 under paragraph (2).

22 “(ii) Each license holder shall publicly des-  
23 ignate at least one wholesaler or specialty dis-  
24 tributor to receive and fulfill requests for cov-

1           ered products submitted pursuant to paragraph  
2           (1) or clause (i) of this paragraph.

3           “(iii) An eligible product developer shall  
4           initiate its acquisition of a covered product  
5           under clause (i) by providing or having its  
6           agent provide a written request for specific  
7           quantities of such covered product to the license  
8           holder.

9           “(B) REQUEST CONTENTS AND RESPONSE.—A  
10          request under subparagraph (A)(iii) shall include a  
11          statement regarding the quantity of covered product  
12          sought for development or testing purposes, and  
13          state that the eligible product developer has an au-  
14          thorization under paragraph (2) to obtain the spe-  
15          cific covered product. Within 30 days of receiving  
16          such a request, the wholesaler or specialty dis-  
17          tributor shall provide the requested quantity of the  
18          covered product at a nondiscriminatory, commer-  
19          cially reasonable, market-based price for which such  
20          covered product has been previously sold by the li-  
21          cense holder to third parties in the open market.

22          “(C) DISCLOSURE OF INFORMATION BY  
23          WHOLESALEERS AND SPECIALTY DISTRIBUTORS.—In  
24          the event that a request is made to a wholesaler or  
25          specialty distributor under this paragraph, the

1 wholesaler or specialty distributor shall not disclose  
2 to the license holder of the covered product involved  
3 the identity of the eligible product developer, but  
4 may disclose to such license holder—

5 “(i) the fact that a request has been made;

6 “(ii) the dates on which the request was  
7 made and fulfilled;

8 “(iii) the commercial terms on which the  
9 request was fulfilled; and

10 “(iv) the quantity of the covered product  
11 furnished by the wholesaler or specialty dis-  
12 tributor in compliance with the request.

13 “(D) IMMINENT HAZARD.—At any time, the  
14 Secretary may prohibit, limit, or otherwise suspend  
15 a transfer of a covered product to an eligible product  
16 developer if the Secretary determines that the trans-  
17 fer of such product to the eligible product developer  
18 would present an imminent hazard to the public  
19 health. In such cases, the Secretary shall specify the  
20 basis for the determination, including the specific in-  
21 formation available to the Secretary which served as  
22 the basis for such determination, and confirm such  
23 determination in writing.

24 “(f) ENFORCEMENT.—

1           “(1) REMEDIES.—An eligible product developer  
2 that is aggrieved by a violation of subsection (b), (c),  
3 (d), (e)(1) or (e)(3) by a license holder may sue such  
4 license holder in a court of competent jurisdiction  
5 for injunctive relief and treble damages (including  
6 costs and interest of the kind described in section  
7 4(a) of the Clayton Act (15 U.S.C. 15(a))).

8           “(2) RULE OF CONSTRUCTION.—

9           “(A) PRESERVATION OF ANTITRUST  
10 LAWS.—Nothing in this Act, or the amend-  
11 ments made by this Act, shall be construed to  
12 modify, supersede, or impair the operation of  
13 the antitrust laws.

14           “(B) DEFINITION.—For purposes of para-  
15 graph (1), the term ‘antitrust laws’ shall have  
16 the meaning given such term in subsection (a)  
17 of the 1st section of the Clayton Act (15 U.S.C.  
18 12), except that such term shall include section  
19 5 of the Federal Trade Commission Act (15  
20 U.S.C. 45) to the extent that such subsection  
21 applies to unfair methods of competition.

22           “(g) LIMITATION OF LIABILITY.—The holder of an  
23 approved application or license for a covered product shall  
24 not be liable for any claim arising out of an eligible prod-  
25 uct developer’s failure to follow adequate safeguards to as-

1 sure safe use of the covered product during development  
2 or testing activities conducted under this section.”.

3 (b) WAIVER OF SINGLE, SHARED SYSTEM REQUIRE-  
4 MENT.—Section 505–1(i)(1)(C) of the Federal Food,  
5 Drug, and Cosmetic Act (21 U.S.C. 355–1(i)(1)(C)) is  
6 amended—

7 (1) in clause (i), by striking “or” at the end;

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

10 (3) by inserting after clause (ii) the following:

11 “(iii) the applicant for an abbreviated  
12 new drug application certifies that it at-  
13 tempted in good faith to create or nego-  
14 tiate entry into a single, shared system,  
15 but was unable to finalize commercially  
16 reasonable terms with the holder of the  
17 listed drug within 120 days, and such cer-  
18 tification includes a description of the ef-  
19 forts made by the applicant for the abbrevi-  
20 ated new drug application to create or  
21 negotiate entry into a single, shared sys-  
22 tem.”.

23 (c) EFFECTIVE DATE.—This section and the amend-  
24 ments made by this section shall take effect upon enact-  
25 ment, and shall apply to all approved applications or li-

1 censes for a covered product (as defined in section 505–  
2 2(a) of the Federal Food, Drug, and Cosmetic Act, as  
3 added by this section) regardless of whether those applica-  
4 tions or licenses were approved before, on, or after the  
5 date of enactment of this Act.

○