

113TH CONGRESS
2^D SESSION

H. R. 5657

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.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2014

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

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 2014” or the “FAST Generics
6 Act of 2014”.

1 **SEC. 2. FINDINGS.**

2 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) or
7 505(j) of the Food, Drug, and Cosmetic Act (21
8 U.S.C. 355(b)(2) and 355(j)) and under section 351
9 of the Public Health Service Act (42 U.S.C. 262).
10 These restrictions are deterring and delaying devel-
11 opment of generic drugs and biosimilars by extend-
12 ing lawful patent-based monopolies beyond their law-
13 ful 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 generic drugs and biosimilars.

21 (3) The opinion in Verizon Communications
22 Inc. v. Law Offices of Curtis V. Trinko, LLP, 540
23 U.S. 398 (2004) should not be construed to impair
24 or bar the application of the antitrust laws con-
25 sistent with the provisions of this Act.

1 (4) There is not a regulatory structure in place
2 that is sufficient to deter or remedy the anti-com-
3 petitive harm that results when access to reference
4 brand products is restricted to sponsors developing
5 drugs, generic drugs, and biosimilars in accordance
6 with section 505(b) or 505(j) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355(b)(2) and
8 355(j)), and section 351 of the Public Health Serv-
9 ice Act (42 U.S.C. 262), respectively.

10 (5) Requiring license holders to comply with re-
11 quirements for competitive access to their products,
12 and subjecting license holders to antitrust liability
13 for failing to do so, will not impose obligations on
14 the courts that they cannot adequately and reason-
15 ably adjudicate.

16 **SEC. 3. COMPETITIVE ACCESS TO COVERED PRODUCTS**
17 **FOR DEVELOPMENT PURPOSES.**

18 (a) IN GENERAL.—Chapter V of the Food Drug and
19 Cosmetic Act (21 U.S.C. 351 et seq.) is amended by in-
20 serting after section 505–1 of such Act (21 U.S.C. 355–
21 1) the following new section:

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

24 “(a) DEFINITIONS.—In this section:

1 “(1) COVERED PRODUCT.—The term ‘covered
2 product’ means any drug approved under section
3 505 or any biological product that is licensed under
4 section 351 of the Public Health Service Act, includ-
5 ing—

6 “(A) any combination thereof; and

7 “(B) when reasonably necessary to dem-
8 onstrate sameness, biosimilarity, or inter-
9 changeability for purposes of this section, sec-
10 tion 505, or section 351 of the Public Health
11 Service Act (as applicable), any product, includ-
12 ing any device, that is marketed or intended for
13 use with such drug or biological product.

14 “(2) ELIGIBLE PRODUCT DEVELOPER.—The
15 term ‘eligible product developer’ means a person that
16 seeks to develop an application for the approval of
17 a drug under section 505(b) or 505(j) or the licens-
18 ing of a biological product under section 351 of the
19 Public Health Service Act.

20 “(3) LICENSE HOLDER.—The term ‘license
21 holder’ means the holder of an application approved
22 under section 505(b) or section 505(j) or a license
23 under section 351 of the Public Health Service Act
24 for a covered product (including the holder’s agents,

1 wholesalers, distributors, assigns, and corporate af-
2 filiates).

3 “(4) REMS PRODUCT.—The term ‘REMS
4 product’ means a covered product that—

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

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

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 adopt, impose, or
19 enforce any condition relating to the sale, resale, or dis-
20 tribution of the covered product, including any condition
21 adopted, imposed, or enforced as an aspect of a risk eval-
22 uation and mitigation strategy approved by the Secretary,
23 that restricts or has the effect of restricting the supply
24 of such covered product to an eligible product developer
25 for development or testing purposes.

1 “(c) COMPETITIVE ACCESS TO COVERED PRODUCTS
2 OTHER THAN REMS PRODUCTS FOR DEVELOPMENT
3 PURPOSES.—No license holder shall adopt, impose, or en-
4 force any condition relating to the sale, resale, or distribu-
5 tion of a covered product that interferes with or restricts
6 access to reasonable quantities of a covered product by
7 an eligible product developer for development and testing
8 purposes, at commercially reasonable, market-based
9 prices, from the license holder or from any wholesaler or
10 specialty distributor authorized by the license holder to
11 commercially distribute or sell the covered product unless
12 the license holder generally adopts, imposes, or enforces
13 lawful conditions relating to the sale, resale, or distribu-
14 tion of a covered product, with respect to other buyers of
15 the covered product.

16 “(d) COMPETITIVE ACCESS TO REMS PRODUCTS
17 FOR DEVELOPMENT PURPOSES.—

18 “(1) PROHIBITED USE OF REMS TO RESTRICT
19 ACCESS.—With respect to a REMS product, no as-
20 pect of a risk evaluation and mitigation strategy
21 under section 505–1 shall prohibit or restrict, or be
22 construed or applied to prohibit or restrict, the sup-
23 ply of such REMS product to an eligible product de-
24 veloper for development and testing purposes, at
25 commercially reasonable, market-based prices, from

1 the REMS product’s license holder or from any
2 wholesaler or specialty distributor authorized by the
3 license holder to commercially distribute or sell the
4 REMS product.

5 “(2) SINGLE, SHARED SYSTEM OF ELEMENTS
6 TO ASSURE SAFE USE.—With respect to a REMS
7 product, no license holder shall take any step that
8 impedes—

9 “(A) the prompt development of a single,
10 shared system of elements to assure safe use
11 under section 505–1; or

12 “(B) the entry on commercially reasonable
13 terms of an eligible product developer into a
14 previously approved system of elements to as-
15 sure safe use.

16 “(e) PROCEDURES FOR OBTAINING ACCESS TO COV-
17 ERED PRODUCTS.—

18 “(1) COMPETITIVE ACCESS.—Notwithstanding
19 any other provision of law, in the case of an eligible
20 product developer that has an authorization to ob-
21 tain a covered product in effect under paragraph (2)
22 or (3), no license holder shall adopt, impose, or en-
23 force any other condition relating to the sale, resale,
24 or distribution of such covered product that inter-
25 feres with or restricts access to reasonable quantities

1 of the covered product by the eligible product devel-
2 oper for development and testing purposes, at com-
3 mercially reasonable, market-based prices, from the
4 license holder or from any wholesaler or specialty
5 distributor authorized by the license holder to com-
6 mercially distribute or sell the covered product, un-
7 less the license holder generally adopts, imposes, or
8 enforces lawful conditions relating to the sale, resale,
9 or distribution of a covered product, with respect to
10 other buyers of the covered product.

11 “(2) GENERAL COVERED PRODUCTS AUTHOR-
12 IZATION.—Any eligible product developer may seek a
13 general covered products authorization, authorizing
14 the eligible product developer to obtain any covered
15 product for the purposes of development and testing,
16 by making a written request to the Secretary. With-
17 in 60 days after receiving such a request, the Sec-
18 retary shall, by written notice, issue such authoriza-
19 tion if—

20 “(A) the eligible product developer holds
21 one or more approved applications or licenses
22 for a covered product or, in the absence of such
23 approvals or licensures, otherwise establishes
24 that the eligible product developer can comply
25 with the requirements of this Act and other ap-

1 applicable law for the development and testing of
2 covered products; and

3 “(B) the Secretary does not find that the
4 eligible product developer has materially failed
5 to comply with the requirements of this Act or
6 other applicable law for the development and
7 testing of covered products.

8 “(3) INDIVIDUAL COVERED PRODUCT AUTHOR-
9 IZATION.—Any eligible product developer may seek
10 an authorization to obtain an individual covered
11 product for development and testing purposes by
12 making a written request to the Secretary. Within
13 60 days of receiving such a request, the Secretary
14 shall, by written notice, issue such authorization for
15 purposes 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) testing that involves human clinical
22 trials if the eligible product developer has sub-
23 mitted a protocol for testing that includes pro-
24 tections that will provide an assurance of safety
25 comparable to the assurance of safety provided

1 by any distribution restrictions governing the
2 approval or licensure of the covered product or
3 the license holder’s distribution of the covered
4 product.

5 “(4) FAILURE BY SECRETARY TO TAKE FINAL
6 ACTION.—If the 60-day period referred to in para-
7 graph (2) or (3) expires without the Secretary hav-
8 ing taken final action on the request for authoriza-
9 tion, the Secretary shall be deemed to have issued,
10 by written notice, the requested authorization.

11 “(5)(A) PROCESS FOR OBTAINING PRODUCT
12 PURSUANT TO AN AUTHORIZATION.—If an eligible
13 product developer is unable, for purposes of develop-
14 ment and testing, to obtain reasonable quantities of
15 a covered product commercially, either from the li-
16 cense holder or from any wholesaler or specialty dis-
17 tributor authorized by the license holder to commer-
18 cially distribute or sell the covered product, any eli-
19 gible product developer that has obtained authoriza-
20 tion to do so, in accordance with paragraph (2) or
21 (3), shall be entitled to obtain such reasonable quan-
22 tities of such covered product at the same commer-
23 cially reasonable, market based price on which such
24 reasonable quantities of such covered product have
25 been previously sold by the license holder to third

1 parties in the open market. Such eligible product de-
2 veloper shall initiate its acquisition of such covered
3 product by providing a written request for specific
4 quantities of such covered product either—

5 “(i) to any wholesaler or specialty dis-
6 tributor authorized by the license holder to
7 commercially distribute or sell the covered prod-
8 uct; or

9 “(ii) in the event no such wholesaler or
10 specialty distributor has been designated for
11 such purpose by the license holder, to the Sec-
12 retary.

13 “(B) REQUEST CONTENTS.—Such request shall
14 include a statement regarding the quantity of cov-
15 ered product sought for development or testing pur-
16 poses, and state that either—

17 “(i) the eligible product developer has, or
18 is deemed to have, a general covered products
19 authorization under paragraph (2); or

20 “(ii) the eligible product developer has, or
21 is deemed to have, an authorization under para-
22 graph (3) to obtain the specific covered product.

23 “(C) DISCLOSURE OF INFORMATION BY
24 WHOLESALERS AND SPECIALTY DISTRIBUTORS.—In
25 the event that a request is made to a wholesaler or

1 specialty distributor under this paragraph, the
2 wholesaler or specialty distributor shall not disclose
3 to the license holder of the covered product involved
4 the identity of the eligible product developer, but
5 may disclose to such license holder, only if required
6 to do so by the holder—

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

8 “(ii) the dates on which the request was
9 made and fulfilled;

10 “(iii) the commercial terms on which the
11 request was fulfilled; and

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

15 “(D) DISCLOSURE PURSUANT TO MEANS SPECI-
16 FIED BY SECRETARY.—In the event that a request
17 is made to the Secretary under this subsection, then
18 the Secretary shall, within 5 business days of receipt
19 of the request, notify the license holder that a re-
20 quest for such covered product has been made, and
21 the quantity of the covered product requested, and
22 such license holder shall, within 30 days after receiv-
23 ing notice from the Secretary, provide the quantity
24 of the requested covered product, through means
25 specified by the Secretary, at a non-discriminatory,

1 commercially reasonable, market-based price for
2 which such covered product has been previously sold
3 by the license holder (or any wholesaler or specialty
4 distributor authorized by the license holder to com-
5 mercially distribute or sell the covered product) to
6 third parties in the open market. The means estab-
7 lished by the Secretary under this clause shall not
8 disclose to the license holder the identity of the eligi-
9 ble product developer that has requested quantities
10 of the covered product for development and testing
11 purposes.

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

23 “(f) PUBLIC AND PRIVATE ENFORCEMENT.—

24 “(1) APPLICATION OF CERTAIN PROVISIONS.—
25 For purposes of this Act and the Public Health

1 Service Act, a violation of a requirement or prohibi-
2 tion in subsection (b), (c), (d)(1), (d)(2), or (e)(1)
3 shall be treated in the case of a REMS product, as
4 a violation of the product’s risk evaluation and miti-
5 gation strategy.

6 “(2) REMEDIES.—An eligible product developer
7 that has authorization for access to a covered prod-
8 uct from the Secretary under subsection (e) and that
9 is aggrieved by a violation of subsection (b), (c),
10 (d)(1), (d)(2), or (e)(1) by a license holder or any
11 wholesaler or specialty distributor authorized by the
12 license holder to commercially distribute or sell the
13 covered product may sue such license holder for in-
14 junctive relief and treble damages (including costs
15 and interest of the kind described in section 4(a) of
16 the Clayton Act (15 U.S.C. 15(a))).

17 “(g) LIMITATION OF LIABILITY.—The holder of an
18 approved application or license for a covered product shall
19 not be liable for any claim arising out of an eligible prod-
20 uct developer’s development or testing activities conducted
21 under this section, including a claim arising out of a fail-
22 ure of the eligible drug developer to follow adequate safe-
23 guards to assure safe use of the covered product.

24 “(h) REPORTS.—

1 “(1) REPORT BY FDA.—Not later than 180
2 days after the enactment of the Fair Access for Safe
3 and Timely Generics Act of 2014, and annually
4 thereafter, the Secretary, acting through the Com-
5 missioner of Food and Drugs, shall submit to Con-
6 gress a report that—

7 “(A) identifies each instance of noncompli-
8 ance by any license holder with a requirement
9 or prohibition in subsection (b), (c), (d)(1),
10 (d)(2), or (e)(1); and

11 “(B) describes the actions taken by the
12 Secretary to remedy such noncompliance and to
13 enforce such requirements and prohibitions,
14 whether by assessment of a penalty or other-
15 wise.

16 “(2) REPORT BY FTC.—Not later than 270
17 days after the enactment of the Fair Access for Safe
18 and Timely Generics Act of 2014, and annually
19 thereafter, the Federal Trade Commission shall sub-
20 mit to Congress a report that—

21 “(A) describes the complaints received by
22 the Commission pertaining to the withholding
23 of competitive access to covered products, the
24 actions taken by the Commission with respect

1 to each such complaint, and the result of each
2 such Commission action; and

3 “(B) examines the impact on the market
4 entry of competing drug products, and the pric-
5 ing and availability of such products, in the
6 United States resulting from noncompliance by
7 license holders with a requirement or prohibi-
8 tion in subsection (b), (c), (d)(1), (d)(2), or
9 (e)(1).”.

10 (b) PROHIBITED ACT.—Section 301 of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
12 ed by adding at the end the following:

13 “(ddd) Any violation by the license holder of a cov-
14 ered product (as such terms are defined in section 505–
15 2(a) (including its contractors, assigns, or corporate affili-
16 ates)) of a requirement or prohibition in subsection (b),
17 (c), (d)(1), (d)(2), or (e)(1) of section 505–2 (relative to
18 competitive access to covered products for development
19 purposes).”.

20 (c) WAIVER OF SINGLE, SHARED SYSTEM REQUIRE-
21 MENT.—Section 505–1(i)(1)(B) of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 355–1(i)(1)(B)) is
23 amended—

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

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

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

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

16 (d) EFFECTIVE DATE.—This section and the amend-
17 ments made by this section shall take effect upon enact-
18 ment, and shall apply to all approved applications or li-
19 censes for a covered product (as defined in section 505-
20 2(a) of the Federal Food, Drug, and Cosmetic Act, as
21 added by this section) regardless of whether those applica-
22 tions or licenses were approved before, on, or after the
23 date of enactment of this Act.

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