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(Original Signature of Member)

113TH CONGRESS
2D SESSION

# H. R. _____

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

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

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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.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Fair Access for Safe and Timely Generics Act of 2014'' or the ''FAST Generics Act of 2014''.

**SEC. 2. FINDINGS.**

Congress finds the following:

(1) Reference product license or approval holders are restricting competitive access to reference products by sponsors seeking to develop drugs, generic drugs, and biosimilars under section 505(b) or 505(j) of the Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2) and 355(j)) and under section 351 of the Public Health Service Act (42 U.S.C. 262). These restrictions are deterring and delaying development of generic drugs and biosimilars by extending lawful patent-based monopolies beyond their lawful patent life.

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

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

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

(5) Requiring license holders to comply with requirements for competitive access to their products, and subjecting license holders to antitrust liability for failing to do so, will not impose obligations on the courts that they cannot adequately and reasonably adjudicate.

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

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

**"SEC. 505–2. COMPETITIVE ACCESS TO COVERED PRODUCTS FOR DEVELOPMENT PURPOSES.**

''(a) DEFINITIONS.—In this section:

''(1) COVERED PRODUCT.—The term 'covered product' means any drug approved under section 505 or any biological product that is licensed under section 351 of the Public Health Service Act, including—

''(A) any combination thereof; and

''(B) when reasonably necessary to demonstrate sameness, biosimilarity, or interchangeability for purposes of this section, section 505, or section 351 of the Public Health Service Act (as applicable), any product, including any device, that is marketed or intended for use with such drug or biological product.

''(2) ELIGIBLE PRODUCT DEVELOPER.—The term 'eligible product developer' means a person that seeks to develop an application for the approval of a drug under section 505(b) or 505(j) or the licensing of a biological product under section 351 of the Public Health Service Act.

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

wholesalers, distributors, assigns, and corporate affiliates).

''(4) REMS PRODUCT.—The term 'REMS product' means a covered product that—

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

''(B) is deemed under section 909(b) of the Food and Drug Administration Amendments Act of 2007 to have in effect an approved risk evaluation and mitigation strategy under section 505–1.

''(b) COMPETITIVE ACCESS TO COVERED PRODUCTS AS A CONDITION ON APPROVAL OR LICENSING.—As a condition of approval or licensure, or continuation or renewal of approval or licensure, of a covered product under section 505 of this Act or section 351 of the Public Health Service Act, respectively, the Secretary shall require that the covered product's license holder not adopt, impose, or enforce any condition relating to the sale, resale, or distribution of the covered product, including any condition adopted, imposed, or enforced as an aspect of a risk evaluation and mitigation strategy approved by the Secretary, that restricts or has the effect of restricting the supply of such covered product to an eligible product developer for development or testing purposes.

''(c) COMPETITIVE ACCESS TO COVERED PRODUCTS OTHER THAN REMS PRODUCTS FOR DEVELOPMENT PURPOSES.—No license holder shall adopt, impose, or enforce any condition relating to the sale, resale, or distribution of a covered product that interferes with or restricts access to reasonable quantities of a covered product by an eligible product developer for development and testing purposes, at commercially reasonable, market-based prices, from the license holder or from any wholesaler or specialty distributor authorized by the license holder to commercially distribute or sell the covered product unless the license holder generally adopts, imposes, or enforces lawful conditions relating to the sale, resale, or distribution of a covered product, with respect to other buyers of the covered product.

''(d) COMPETITIVE ACCESS TO REMS PRODUCTS FOR DEVELOPMENT PURPOSES.—

''(1) PROHIBITED USE OF REMS TO RESTRICT ACCESS.—With respect to a REMS product, no aspect of a risk evaluation and mitigation strategy under section 505–1 shall prohibit or restrict, or be construed or applied to prohibit or restrict, the supply of such REMS product to an eligible product developer for development and testing purposes, at commercially reasonable, market-based prices, from

the REMS product's license holder or from any wholesaler or specialty distributor authorized by the license holder to commercially distribute or sell the REMS product.

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

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

''(B) the entry on commercially reasonable terms of an eligible product developer into a previously approved system of elements to assure safe use.

''(e) PROCEDURES FOR OBTAINING ACCESS TO COVERED PRODUCTS.—

''(1) COMPETITIVE ACCESS.—Notwithstanding any other provision of law, in the case of an eligible product developer that has an authorization to obtain a covered product in effect under paragraph (2) or (3), no license holder shall adopt, impose, or enforce any other condition relating to the sale, resale, or distribution of such covered product that interferes with or restricts access to reasonable quantities

of the covered product by the eligible product developer for development and testing purposes, at commercially reasonable, market-based prices, from the license holder or from any wholesaler or specialty distributor authorized by the license holder to commercially distribute or sell the covered product, unless the license holder generally adopts, imposes, or enforces lawful conditions relating to the sale, resale, or distribution of a covered product, with respect to other buyers of the covered product.

''(2) GENERAL COVERED PRODUCTS AUTHORIZATION.—Any eligible product developer may seek a general covered products authorization, authorizing the eligible product developer to obtain any covered product for the purposes of development and testing, by making a written request to the Secretary. Within 60 days after receiving such a request, the Secretary shall, by written notice, issue such authorization if—

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

plicable law for the development and testing of covered products; and

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

''(3) INDIVIDUAL COVERED PRODUCT AUTHORIZATION.—Any eligible product developer may seek an authorization to obtain an individual covered product for development and testing purposes by making a written request to the Secretary. Within 60 days of receiving such a request, the Secretary shall, by written notice, issue such authorization for purposes of—

''(A) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

''(B) testing that involves human clinical trials if the eligible product developer has submitted a protocol for testing that includes protections that will provide an assurance of safety comparable to the assurance of safety provided

by any distribution restrictions governing the approval or licensure of the covered product or the license holder's distribution of the covered product.

''(4) FAILURE BY SECRETARY TO TAKE FINAL ACTION.—If the 60-day period referred to in paragraph (2) or (3) expires without the Secretary having taken final action on the request for authorization, the Secretary shall be deemed to have issued, by written notice, the requested authorization.

''(5)(A) PROCESS FOR OBTAINING PRODUCT PURSUANT TO AN AUTHORIZATION.—If an eligible product developer is unable, for purposes of development and testing, to obtain reasonable quantities of a covered product commercially, either from the license holder or from any wholesaler or specialty distributor authorized by the license holder to commercially distribute or sell the covered product, any eligible product developer that has obtained authorization to do so, in accordance with paragraph (2) or (3), shall be entitled to obtain such reasonable quantities of such covered product at the same commercially reasonable, market based price on which such reasonable quantities of such covered product have been previously sold by the license holder to third

parties in the open market. Such eligible product developer shall initiate its acquisition of such covered product by providing a written request for specific quantities of such covered product either—

''(i) to any wholesaler or specialty distributor authorized by the license holder to commercially distribute or sell the covered product; or

''(ii) in the event no such wholesaler or specialty distributor has been designated for such purpose by the license holder, to the Secretary.

''(B) REQUEST CONTENTS.—Such request shall include a statement regarding the quantity of covered product sought for development or testing purposes, and state that either—

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

''(ii) the eligible product developer has, or is deemed to have, an authorization under paragraph (3) to obtain the specific covered product.

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

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

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

''(ii) the dates on which the request was made and fulfilled;

''(iii) the commercial terms on which the request was fulfilled; and

''(iv) the quantity of the covered product furnished by the wholesaler or specialty distributor in compliance with the request.

''(D) DISCLOSURE PURSUANT TO MEANS SPECIFIED BY SECRETARY.—In the event that a request is made to the Secretary under this subsection, then the Secretary shall, within 5 business days of receipt of the request, notify the license holder that a request for such covered product has been made, and the quantity of the covered product requested, and such license holder shall, within 30 days after receiving notice from the Secretary, provide the quantity of the requested covered product, through means specified by the Secretary, at a non-discriminatory,

commercially reasonable, market-based price for which such covered product has been previously sold by the license holder (or any wholesaler or specialty distributor authorized by the license holder to commercially distribute or sell the covered product) to third parties in the open market. The means established by the Secretary under this clause shall not disclose to the license holder the identity of the eligible product developer that has requested quantities of the covered product for development and testing purposes.

''(E) IMMINENT HAZARD.—At any time, the Secretary may prohibit, limit, or otherwise suspend a transfer of a covered product to an eligible product developer if the Secretary determines that the transfer of such product to the eligible product developer would present an imminent hazard to the public health. In such cases, the Secretary shall specify the basis for the determination, including the specific information available to the Secretary which served as the basis for such determination, and confirm such determination in writing.

''(f) PUBLIC AND PRIVATE ENFORCEMENT.—

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

Service Act, a violation of a requirement or prohibition in subsection (b), (c), (d)(1), (d)(2), or (e)(1) shall be treated in the case of a REMS product, as a violation of the product's risk evaluation and mitigation strategy.

''(2) REMEDIES.—An eligible product developer that has authorization for access to a covered product from the Secretary under subsection (e) and that is aggrieved by a violation of subsection (b), (c), (d)(1), (d)(2), or (e)(1) by a license holder or any wholesaler or specialty distributor authorized by the license holder to commercially distribute or sell the covered product) may sue such license holder for injunctive relief and treble damages (including costs and interest of the kind described in section 4(a) of the Clayton Act (15 U.S.C. 15(a)).

''(g) LIMITATION OF LIABILITY.—The holder of an approved application or license for a covered product shall not be liable for any claim arising out of an eligible product developer's development or testing activities conducted under this section, including a claim arising out of a failure of the eligible drug developer to follow adequate safeguards to assure safe use of the covered product.

''(h) REPORTS.—

''(1) REPORT BY FDA.—Not later than 180 days after the enactment of the Fair Access for Safe and Timely Generics Act of 2014, and annually thereafter, the Secretary, acting through the Commissioner of Food and Drugs, shall submit to Congress a report that—

''(A) identifies each instance of noncompliance by any license holder with a requirement or prohibition in subsection (b), (c), (d)(1), (d)(2), or (e)(1); and

''(B) describes the actions taken by the Secretary to remedy such noncompliance and to enforce such requirements and prohibitions, whether by assessment of a penalty or otherwise.

''(2) REPORT BY FTC.—Not later than 270 days enactment of the Fair Access for Safe and Timely Generics Act of 2014, and annually thereafter, the Federal Trade Commission shall submit to Congress a report that—

''(A) describes the complaints received by the Commission pertaining to the withholding of competitive access to covered products, the actions taken by the Commission with respect

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

''(B) examines the impact on the market entry of competing drug products, and the pricing and availability of such products, in the United States resulting from noncompliance by license holders with a requirement or prohibition in subsection (b), (c), (d)(1), (d)(2), or (e)(1).''.

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

''(ddd) Any violation by the license holder of a covered product (as such terms are defined in section 505–2(a) (including its contractors, assigns, or corporate affiliates)) of a requirement or prohibition in subsection (b), (c), (d)(1), (d)(2), or (e)(1) of section 505–2 (relative to competitive access to covered products for development purposes).''.

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

(1) in clause (i), by striking ''or'' at the end;

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

(3) by adding at the end the following:

''(iii) the applicant for an abbreviated new drug application certifies that it attempted in good faith to create or negotiate entry into a single, shared system, but was unable to finalize commercially reasonable terms with the holder of the listed drug within 120 days, and such certification includes a description of the efforts made by the applicant for the abbreviated new drug application to create or negotiate entry into a single, shared system.''.

(d) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect upon enactment, and shall apply to all approved applications or licenses for a covered product (as defined in section 505–2(a) of the Federal Food, Drug, and Cosmetic Act, as added by this section) regardless of whether those applications or licenses were approved before, on, or after the date of enactment of this Act.