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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.

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.

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 2019'' or the ''FAST Generics Act of 2019''.

SEC. 2. FINDINGS.

The 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)(2) or 505(j) of the Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2) and 355(j)) and under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)). These restrictions are deterring and delaying development of drugs, 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 drugs, generic drugs, and biosimilars.

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

(A) access to reference products is restricted to sponsors developing drugs, generic drugs, or biosimilars in accordance with section

505(b)(2) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2) or 355(j)), and section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), respectively; or

(B) license holders impede the prompt negotiation and development of a single, shared system of elements to assure safe use and supporting agreements under section 505–1(i)(1)(B) of such Act (21 U.S.C. 355–1(i)(1)(B)), on commercially reasonable terms.

(4) Requiring license holders to comply with requirements for competitive access to their products, and for the negotiation and development of single, shared systems of elements to assure safe use under section 505–1(i)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(i)(1)(B)), and subjecting license holders to 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-

ed 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'—

"(A) means—

"(i) any drug approved under section 505 or biological product licensed under section 351 of the Public Health Service Act;

"(ii) any combination thereof; or

"(iii) 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; and

"(B) excludes any drug or biological product which the Secretary has determined to be currently in shortage and that appears on the drug shortage list in effect under section 506E,

unless the shortage will not be promptly resolved—

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

"(ii) as otherwise determined by the Secretary.

"(2) ELIGIBLE PRODUCT DEVELOPER.—The term 'eligible product developer' means a person that seeks to develop a product for approval pursuant to an application under section 505(b)(2) or 505(j) or for licensing pursuant to an application under section 351(k) 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) of this Act or under section 351 of the Public Health Service Act for a covered product (including the holder's agents, wholesalers, distributors, assigns, corporate affiliates, and contractors).

"(4) REMS.—The term 'REMS' means a risk evaluation and mitigation strategy under section 505–1.

"(5) 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.

"(6) REMS IMPACTING PRODUCT DISTRIBUTION.—The term 'REMS impacting product distribution' means a REMS that contains elements to assure safe use that impact the distribution of the product subject to the REMS.

"(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 construe or apply any condition or restriction relating to the sale, resale, or distribution of the covered product, including any condition or restriction adopted, imposed, or enforced as an aspect of a risk evaluation and mitigation strategy, in a way 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 FOR DEVELOPMENT PURPOSES TO PRODUCTS WITH REMS IMPACTING PRODUCT DISTRIBUTION.—With respect to a product subject to a REMS impacting product distribution, no aspect of such a REMS shall be construed or applied by the REMS product's license holder in a way that prohibits or restricts the supply, at commercially reasonable, market-based prices, of such REMS product from the REMS product's license holder to an eligible product developer with an applicable individual covered product authorization obtained pursuant to subsection (e) for development and testing purposes.

''(d) SINGLE, SHARED SYSTEM OF ELEMENTS TO ASSURE SAFE USE.—Where an eligible product developer seeks approval of an application under 505(j) referencing a REMS product whose REMS includes elements to assure safe use—

''(1) no license holder shall take any step that impedes—

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

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

''(2) license holders shall negotiate in good faith towards the prompt development of (or entry into) a single, shared system of elements to assure safe use under section 505–1(i) on commercially reasonable terms.

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

''(1) COMPETITIVE ACCESS TO PRODUCTS NOT SUBJECT TO REMS IMPACTING PRODUCT DISTRIBUTION.—Notwithstanding any other provision of law, a license holder that receives a request from an eligible product developer or its agent for sufficient supplies of a covered product (that is not subject to a REMS impacting product distribution) to conduct testing necessary to support an application under section 505(b)(2) or 505(j) or under section 351(k) of the Public Health Service Act (or otherwise meet the requirements for approval of such an application) shall provide to the eligible product developer or its agent the quantity requested within 30 days of receipt of the request at a nondiscriminatory,

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

''(2) COMPETITIVE ACCESS TO PRODUCTS SUBJECT TO REMS IMPACTING PRODUCT DISTRIBUTION: INDIVIDUAL COVERED PRODUCT AUTHORIZATION.—Any eligible product developer may seek an authorization to obtain an individual covered product subject to a REMS impacting product distribution for development and testing purposes by making a written request to the Secretary. Within 120 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) development and testing that involves human clinical trials if the eligible product developer has—

''(i) 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

"(ii) otherwise satisfied the Secretary that such protections will be provided.

"(3)(A) PROCESS FOR OBTAINING PRODUCT PURSUANT TO AN AUTHORIZATION.—

"(i) An eligible product developer shall be entitled to obtain, from the license holder of a covered product subject to a REMS impacting distribution, sufficient quantities of the covered product for purposes of development and testing necessary to support an application under section 505(b)(2) or 505(j) or under section 351(k) of the Public Health Service Act, or otherwise meet the requirements for approval of such application, if the eligible product developer has obtained an applicable authorization under paragraph (2).

"(ii) Each license holder shall publicly designate at least one wholesaler or specialty distributor to receive and fulfill requests for cov-

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

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

"(B) REQUEST CONTENTS AND RESPONSE.—A request under subparagraph (A)(iii) shall include a statement regarding the quantity of covered product sought for development or testing purposes, and state that the eligible product developer has an authorization under paragraph (2) to obtain the specific covered product. Within 30 days of receiving such a request, the wholesaler or specialty distributor shall provide the requested quantity of the covered product at a nondiscriminatory, commercially reasonable, market-based price for which such covered product has been previously sold by the license holder to third parties in the open market.

"(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—

"(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) 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) ENFORCEMENT.—

''(1) REMEDIES.—An eligible product developer that is aggrieved by a violation of subsection (b), (c), (d), (e)(1) or (e)(3) by a license holder may sue such license holder in a court of competent jurisdiction 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))).

''(2) RULE OF CONSTRUCTION.—

''(A) PRESERVATION OF ANTITRUST LAWS.—Nothing in this Act, or the amendments made by this Act, shall be construed to modify, supersede, or impair the operation of the antitrust laws.

''(B) DEFINITION.—For purposes of paragraph (1), the term 'antitrust laws' shall have the meaning given such term in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12), except that such term shall include section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such subsection applies to unfair methods of competition.

''(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 failure to follow adequate safeguards to as-

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

(b) WAIVER OF SINGLE, SHARED SYSTEM REQUIREMENT.—Section 505–1(i)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(i)(1)(C)) 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 inserting after clause (ii) 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.''.

(c) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect upon enactment, and shall apply to all approved applications or li-

censes 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.

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