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115TH CONGRESS
2D SESSION

H. R. 6478

To enhance competition for prescription drugs by increasing the ability of the Department of Justice and Federal Trade Commission to enforce existing antitrust laws regarding biologic and biosimilar products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 23, 2018

Mr. SARBANES (for himself and Mr. JOHNSON of Ohio) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To enhance competition for prescription drugs by increasing the ability of the Department of Justice and Federal Trade Commission to enforce existing antitrust laws regarding biologic and biosimilar 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 ''Biosimilars Competition Act of 2018''.

SEC. 2. LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 351(l) of the Public Health Service Act (42 U.S.C. 262(l)) is amended by adding at the end the following:

''(10) NOTIFICATION OF AGREEMENTS.—

''(A) REQUIREMENTS.—

''(i) AGREEMENT BETWEEN BIOSIMILAR PRODUCT APPLICANT AND REFERENCE PRODUCT SPONSOR.—If a subsection (k) applicant and the reference product sponsor enter into an agreement described in subparagraph (B), the applicant and sponsor shall each file the agreement in accordance with subparagraph (C).

''(ii) AGREEMENT BETWEEN BIOSIMILAR PRODUCT APPLICANTS.—If 2 or more subsection (k) applicants for biosimilar products with the same reference product enter into an agreement described in subparagraph (B), the applicants shall each file the agreement in accordance with subparagraph (C).

''(B) SUBJECT MATTER OF AGREEMENT.—An agreement described in this subparagraph—

"(i) is an agreement between a subsection (k) applicant and the reference product sponsor or between 2 or more subsection (k) applicants regarding the manufacture, marketing, or sale of—

"(I) the biosimilar product (or biosimilar products) for which an application was submitted under subsection (k); or

"(II) the reference product;

"(ii) includes any agreement between a subsection (k) applicant and the reference product sponsor or between 2 or more subsection (k) applicants that is contingent upon, provides a contingent condition for, or otherwise relates to an agreement described in clause (i); and

"(iii) excludes any agreement that solely concerns—

"(I) purchase orders for raw material supplies;

"(II) equipment and facility contracts;

"(III) employment or consulting contracts; or

''(IV) packaging and labeling contracts.

''(C) FILING.—

''(i) IN GENERAL.—The text of an agreement required to be filed by subparagraph (A) shall be filed with the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice (in this paragraph referred to as the 'Assistant Attorney General') and the Federal Trade Commission not later than—

''(I) 10 business days after the date on which the agreement is executed; and

''(II) prior to the date of the first commercial marketing of, for agreements described in subparagraph (A)(i), the biosimilar product that is the subject of the application or, for agreements described in subparagraph (A)(ii), any biosimilar product that is the subject of an application described in such subparagraph.

''(ii) IF AGREEMENT NOT REDUCED TO TEXT.—If an agreement required to be

filed by subparagraph (A) has not been reduced to text, the persons required to file the agreement shall each file written descriptions of the agreement that are sufficient to disclose all the terms and conditions of the agreement.

''(iii) CERTIFICATION.—The chief executive officer or the company official responsible for negotiating any agreement required to be filed by subparagraph (A) shall include in any filing under this paragraph a certification as follows: 'I declare under penalty of perjury that the following is true and correct: The materials filed with the Federal Trade Commission and the Department of Justice under section 351(l)(10) of the Public Health Service Act, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descrip-

tions of any oral agreements, representations, commitments, or promises between the parties that are responsive to such section and have not been reduced to writing.'.

''(D) DISCLOSURE EXEMPTION.—Any information or documentary material filed with the Assistant Attorney General or the Federal Trade Commission pursuant to this paragraph shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this subparagraph prevents disclosure of information or documentary material to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.

''(E) ENFORCEMENT.—

''(i) CIVIL PENALTY.—Any person that violates a provision of this paragraph shall be liable for a civil penalty of not more than the maximum amount of a civil penalty under section 1115(a) of the Medi-

care Prescription Drug, Improvement, and Modernization Act of 2003, as adjusted pursuant to applicable law, for each day during which such person is in violation of this paragraph. Such penalty may be recovered in a civil action—

"(I) brought by the United States; or

"(II) brought by the Federal Trade Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act.

"(ii) COMPLIANCE AND EQUITABLE RELIEF.—If any person violates any provision of this paragraph, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Federal Trade Commission.

"(F) RULEMAKING.—The Federal Trade Commission, with the concurrence of the Assistant Attorney General and by rule in accordance

with section 553 of title 5, United States Code, consistent with the purposes of this paragraph—

"(i) may define the terms used in this paragraph;

"(ii) may exempt classes of persons or agreements from the requirements of this paragraph; and

"(iii) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this paragraph.

"(G) SAVINGS CLAUSE.—Any action taken by the Assistant Attorney General or the Federal Trade Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this paragraph shall not at any time bar any proceeding or any action with respect to any agreement between a subsection (k) applicant and the reference product sponsor, or any agreement between subsection (k) applicants, under any other provision of law, nor shall any filing under this paragraph constitute or create a presumption of any violation of any competition laws.".

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