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(Original Signature of Member)

115TH CONGRESS
2D SESSION

H. R. _____

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

Mr. SARBANES introduced the following bill; which was referred to the
Committee on _____

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.

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 “Biosimilars Competi-
5 tion Act of 2018”.

1 **SEC. 2. LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGI-**
2 **CAL PRODUCTS.**

3 Section 351(l) of the Public Health Service Act (42
4 U.S.C. 262(l)) is amended by adding at the end the fol-
5 lowing:

6 “(10) NOTIFICATION OF AGREEMENTS.—

7 “(A) REQUIREMENTS.—

8 “(i) AGREEMENT BETWEEN BIO-
9 SIMILAR PRODUCT APPLICANT AND REF-
10ERENCE PRODUCT SPONSOR.—If a sub-
11section (k) applicant and the reference
12product sponsor enter into an agreement
13described in subparagraph (B), the appli-
14cant and sponsor shall each file the agree-
15ment in accordance with subparagraph
16(C).

17 “(ii) AGREEMENT BETWEEN BIO-
18SIMILAR PRODUCT APPLICANTS.—If 2 or
19more subsection (k) applicants for bio-
20similar products with the same reference
21product enter into an agreement described
22in subparagraph (B), the applicants shall
23each file the agreement in accordance with
24subparagraph (C).

25 “(B) SUBJECT MATTER OF AGREEMENT.—

26 An agreement described in this subparagraph—

1 “(i) is an agreement between a sub-
2 section (k) applicant and the reference
3 product sponsor or between 2 or more sub-
4 section (k) applicants regarding the manu-
5 facture, marketing, or sale of—

6 “(I) the biosimilar product (or
7 biosimilar products) for which an ap-
8 plication was submitted under sub-
9 section (k); or

10 “(II) the reference product;

11 “(ii) includes any agreement between
12 a subsection (k) applicant and the ref-
13 erence product sponsor or between 2 or
14 more subsection (k) applicants that is con-
15 tingent upon, provides a contingent condi-
16 tion for, or otherwise relates to an agree-
17 ment described in clause (i); and

18 “(iii) excludes any agreement that
19 solely concerns—

20 “(I) purchase orders for raw ma-
21 terial supplies;

22 “(II) equipment and facility con-
23 tracts;

24 “(III) employment or consulting
25 contracts; or

1 “(IV) packaging and labeling
2 contracts.

3 “(C) FILING.—

4 “(i) IN GENERAL.—The text of an
5 agreement required to be filed by subpara-
6 graph (A) shall be filed with the Assistant
7 Attorney General in charge of the Anti-
8 trust Division of the Department of Jus-
9 tice (in this paragraph referred to as the
10 ‘Assistant Attorney General’) and the Fed-
11 eral Trade Commission not later than—

12 “(I) 10 business days after the
13 date on which the agreement is exe-
14 cuted; and

15 “(II) prior to the date of the first
16 commercial marketing of, for agree-
17 ments described in subparagraph
18 (A)(i), the biosimilar product that is
19 the subject of the application or, for
20 agreements described in subparagraph
21 (A)(ii), any biosimilar product that is
22 the subject of an application described
23 in such subparagraph.

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

1 filed by subparagraph (A) has not been re-
2 duced to text, the persons required to file
3 the agreement shall each file written de-
4 scriptions of the agreement that are suffi-
5 cient to disclose all the terms and condi-
6 tions of the agreement.

7 “(iii) CERTIFICATION.—The chief ex-
8 ecutive officer or the company official re-
9 sponsible for negotiating any agreement re-
10 quired to be filed by subparagraph (A)
11 shall include in any filing under this para-
12 graph a certification as follows: ‘I declare
13 under penalty of perjury that the following
14 is true and correct: The materials filed
15 with the Federal Trade Commission and
16 the Department of Justice under section
17 351(l)(10) of the Public Health Service
18 Act, with respect to the agreement ref-
19 erenced in this certification: (1) represent
20 the complete, final, and exclusive agree-
21 ment between the parties; (2) include any
22 ancillary agreements that are contingent
23 upon, provide a contingent condition for,
24 or are otherwise related to, the referenced
25 agreement; and (3) include written descrip-

1 tions of any oral agreements, representa-
2 tions, commitments, or promises between
3 the parties that are responsive to such sec-
4 tion and have not been reduced to writ-
5 ing.’.

6 “(D) DISCLOSURE EXEMPTION.—Any in-
7 formation or documentary material filed with
8 the Assistant Attorney General or the Federal
9 Trade Commission pursuant to this paragraph
10 shall be exempt from disclosure under section
11 552 of title 5, United States Code, and no such
12 information or documentary material may be
13 made public, except as may be relevant to any
14 administrative or judicial action or proceeding.
15 Nothing in this subparagraph prevents disclo-
16 sure of information or documentary material to
17 either body of the Congress or to any duly au-
18 thorized committee or subcommittee of the Con-
19 gress.

20 “(E) ENFORCEMENT.—

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

1 care Prescription Drug, Improvement, and
2 Modernization Act of 2003, as adjusted
3 pursuant to applicable law, for each day
4 during which such person is in violation of
5 this paragraph. Such penalty may be re-
6 covered in a civil action—

7 “(I) brought by the United
8 States; or

9 “(II) brought by the Federal
10 Trade Commission in accordance with
11 the procedures established in section
12 16(a)(1) of the Federal Trade Com-
13 mission Act.

14 “(ii) COMPLIANCE AND EQUITABLE
15 RELIEF.—If any person violates any provi-
16 sion of this paragraph, the United States
17 district court may order compliance, and
18 may grant such other equitable relief as
19 the court in its discretion determines nec-
20 essary or appropriate, upon application of
21 the Assistant Attorney General or the Fed-
22 eral Trade Commission.

23 “(F) RULEMAKING.—The Federal Trade
24 Commission, with the concurrence of the Assist-
25 ant Attorney General and by rule in accordance

1 with section 553 of title 5, United States Code,
2 consistent with the purposes of this para-
3 graph—

4 “(i) may define the terms used in this
5 paragraph;

6 “(ii) may exempt classes of persons or
7 agreements from the requirements of this
8 paragraph; and

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

12 “(G) SAVINGS CLAUSE.—Any action taken
13 by the Assistant Attorney General or the Fed-
14 eral Trade Commission, or any failure of the
15 Assistant Attorney General or the Commission
16 to take action, under this paragraph shall not
17 at any time bar any proceeding or any action
18 with respect to any agreement between a sub-
19 section (k) applicant and the reference product
20 sponsor, or any agreement between subsection
21 (k) applicants, under any other provision of
22 law, nor shall any filing under this paragraph
23 constitute or create a presumption of any viola-
24 tion of any competition laws.”.