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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. _____

To enable the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To enable the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Stop Significant and
3 Time-wasting Abuse Limiting Legitimate Innovation of
4 New Generics Act” or the “Stop STALLING Act”.

5 **SEC. 2. FEDERAL TRADE COMMISSION ENFORCEMENT**
6 **AGAINST SHAM PETITIONS.**

7 (a) DEFINITIONS.—In this section:

8 (1) COMMISSION.—The term “Commission”
9 means the Federal Trade Commission.

10 (2) COVERED APPLICATION.—The term “cov-
11 ered application” means an application filed pursu-
12 ant to subsection (b)(2) or (j) of section 505 of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 355) or section 351(k) of the Public Health Service
15 Act (42 U.S.C. 262(k)).

16 (3) COVERED PETITION.—The term “covered
17 petition” means a petition, or a supplement to a pe-
18 tition, filed under section 505(q) of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)).

20 (4) PERSON.—The term “person” means—

21 (A) an individual or entity;

22 (B) its directors, officers, employees,
23 agents, representatives, successors, and assigns;
24 and

25 (C) the joint ventures, subsidiaries, part-
26 nerships, divisions, groups, and affiliates it con-

1 trolls, and the respective directors, officers, em-
2 ployees, agents, representatives, successors, and
3 assigns of each.

4 (5) SERIES OF COVERED PETITIONS.—The
5 term “series of covered petitions” means any group
6 of more than one covered petition.

7 (6) SHAM.—The term “sham” means a covered
8 petition that is objectively baseless and that at-
9 tempts to use a governmental process, as opposed to
10 the outcome of that process, to interfere with the
11 business of a competitor, or a series of covered peti-
12 tions, that attempts to use a governmental process,
13 as opposed to the outcome of that process, to inter-
14 fere with the business of a competitor.

15 (b) VIOLATION.—

16 (1) IN GENERAL.—A person submitting or
17 causing the submission of a covered petition or a se-
18 ries of covered petitions that is a sham shall be lia-
19 ble for engaging in an unfair method of competition
20 under section 5(a)(1) of the Federal Trade Commis-
21 sion Act (15 U.S.C. 45(a)(1)).

22 (c) CIVIL ACTION.—

23 (1) IN GENERAL.—If the Commission has rea-
24 son to believe that the submission of a covered peti-
25 tion or a series of covered petitions constitutes a vio-

1 lation of section 5(a)(1) of the Federal Trade Com-
2 mission Act (15 U.S.C. 45(a)(1)), the Commission
3 may commence a civil action to recover a civil pen-
4 alty and seek other appropriate relief in a district
5 court of the United States against any person that
6 submitted or caused to be submitted such covered
7 petition or such series of covered petitions, including
8 successors or assigns.

9 (2) PRESUMPTION.—In a civil action under
10 paragraph (1), a covered petition shall be presumed
11 to be part of a series of covered petitions that is a
12 sham under subsection (b) of this section if the Sec-
13 retary of Health and Human Services has deter-
14 mined that the covered petition was submitted with
15 the primary purpose of delaying the approval of a
16 covered application, was part of a series of covered
17 petitions, and has referred such determination to the
18 Federal Trade Commission in writing, with a rea-
19 soned basis for the determination.

20 (3) EXCEPTION.—The presumption in para-
21 graph (2) shall not apply if the defendant estab-
22 lishes, by a preponderance of the evidence, that the
23 series of covered petitions that includes the covered
24 petition referred to the Commission by the Secretary
25 of Health and Human Services is not a sham.

1 (4) CIVIL PENALTY.—In an action under para-
2 graph (1), any person that has been found liable for
3 a violation of section 5(a)(1) of the Federal Trade
4 Commission Act (15 U.S.C. 45(a)(1)) shall be sub-
5 ject to a civil penalty for each violation of not more
6 than the greater of—

7 (A) any revenue earned from the sale by
8 such person of any drug product, referenced in
9 a covered application that was the subject of a
10 covered petition or a series of covered petitions
11 that is a sham, during the period in which the
12 covered petition or series of covered petitions
13 was under review by the Secretary of Health
14 and Human Services; or

15 (B) \$50,000 for each calendar day that
16 each covered petition that is a sham or that was
17 part of a series of covered petitions that is a
18 sham was under review by the Secretary of
19 Health and Human Services.

20 (5) ANTITRUST LAWS.—Nothing in this section
21 shall modify, impair, limit, or supersede the applica-
22 bility of the antitrust laws as defined in subsection
23 (a) of the first section of the Clayton Act (15 U.S.C.
24 12(a)), and of section 5 of the Federal Trade Com-

1 mission Act (15 U.S.C. 45) to the extent that it ap-
2 plies to unfair methods of competition.

3 (6) RULE OF CONSTRUCTION.—The civil pen-
4 alty provided in this subsection is in addition to, and
5 not in lieu of, any other remedies provided by Fed-
6 eral law, including under section 16 of the Clayton
7 Act (15 U.S.C. 26) or under section 13(b) of the
8 Federal Trade Commission Act (15 U.S.C. 53(b)).
9 Nothing in this paragraph shall be construed to af-
10 fect any authority of the Commission under any
11 other provision of law.

12 (d) APPLICABILITY.—This section shall apply to any
13 covered petition submitted on or after the date of enact-
14 ment of this Act.

15 **SEC. 3. SEVERABILITY.**

16 If any provision of this Act, an amendment made by
17 this Act, or the application of such provision or amend-
18 ment to any person or circumstance is held to be unconsti-
19 tutional, the remainder of this Act, the amendments made
20 by this Act, and the application of the provisions of such
21 Act or amendments to any person or circumstance shall
22 not be affected.