

116TH CONGRESS  
1ST SESSION

# S. 1224

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.

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IN THE SENATE OF THE UNITED STATES

APRIL 29, 2019

Ms. KLOBUCHAR (for herself and Mr. GRASSLEY) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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## 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,*

3 **SECTION 1. SHORT TITLE.**

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

1 **SEC. 2. FEDERAL TRADE COMMISSION ENFORCEMENT**  
2 **AGAINST SHAM PETITIONS.**

3 (a) DEFINITIONS.—In this section:

4 (1) COMMISSION.—The term “Commission”  
5 means the Federal Trade Commission.

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

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

16 (4) PERSON.—The term “person”—

17 (A) means an individual or entity; and

18 (B) includes—

19 (i) a director, officer, employee, agent,  
20 representative, successor, and assign of an  
21 entity;

22 (ii) a joint venture, subsidiary, part-  
23 nership, division, group, and affiliate con-  
24 trolled by an entity; and

25 (iii) a director, officer, employee,  
26 agent, representative, successor, and assign

1 of a joint venture, subsidiary, partnership,  
2 division, group, and affiliate controlled by  
3 an entity.

4 (5) SERIES OF COVERED PETITIONS.—The  
5 term “series of covered petitions” means any group  
6 of more than 1 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.—A person submitting or causing the  
16 submission of a covered petition or a series of covered peti-  
17 tions that is a sham shall be liable for engaging in an  
18 unfair method of competition under section 5(a)(1) of the  
19 Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

20 (c) CIVIL ACTION.—

21 (1) IN GENERAL.—If the Commission has rea-  
22 son to believe that the submission of a covered peti-  
23 tion or a series of covered petitions constitutes a vio-  
24 lation of section 5(a)(1) of the Federal Trade Com-  
25 mission Act (15 U.S.C. 45(a)(1)), the Commission

1 may commence a civil action to recover a civil pen-  
2 alty and seek other appropriate relief in a district  
3 court of the United States against any person that  
4 submitted or caused to be submitted such covered  
5 petition or such series of covered petitions, including  
6 successors or assigns.

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

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

24 (4) CIVIL PENALTY.—In an action under para-  
25 graph (1), any person that has been found liable for

1 a violation of section 5(a)(1) of the Federal Trade  
2 Commission Act (15 U.S.C. 45(a)(1)) shall be sub-  
3 ject to a civil penalty for each violation of not more  
4 than the greater of—

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

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

18 (5) ANTITRUST LAWS.—Nothing in this section  
19 shall modify, impair, limit, or supersede the applica-  
20 bility of the antitrust laws as defined in subsection  
21 (a) of the first section of the Clayton Act (15 U.S.C.  
22 12(a)), and of section 5 of the Federal Trade Com-  
23 mission Act (15 U.S.C. 45) to the extent that it ap-  
24 plies to unfair methods of competition.

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

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

13 **SEC. 3. SEVERABILITY.**

14          If any provision of this Act or the application of such  
15 provision to any person or circumstance is held to be un-  
16 constitutional, the remainder of this Act and the applica-  
17 tion of the provisions of such Act to any person or cir-  
18 cumstance shall not be affected.

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