

119TH CONGRESS
1ST SESSION

S. _____

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 SENATE OF THE UNITED STATES

Ms. KLOBUCHAR (for herself, Mr. GRASSLEY, Mr. DURBIN, Mr. BLUMENTHAL, Mr. CRUZ, and Mr. WELCH) introduced the following bill; which was read twice and 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”—

21 (A) means an individual or entity; and

22 (B) includes—

23 (i) a successor or an assign of an enti-
24 ty;

1 (ii) a joint venture, subsidiary, part-
2 nership, division, group, or affiliate con-
3 trolled by an entity; and

4 (iii) a successor or an assign of a joint
5 venture, subsidiary, partnership, division,
6 group, or affiliate controlled by an entity.

7 (5) SERIES OF COVERED PETITIONS.—The
8 term “series of covered petitions” means any group
9 of more than 1 covered petition relating to the same
10 covered application.

11 (6) SHAM.—The term “sham” means—

12 (A) a covered petition that—

13 (i) is objectively baseless; and

14 (ii) attempts to use a governmental
15 process, as opposed to the outcome of that
16 process, to interfere with the business of a
17 competitor; or

18 (B) a series of covered petitions that at-
19 tempts to use a governmental process, as op-
20 posed to the outcome of that process, to inter-
21 fere with the business of a competitor.

22 (b) VIOLATION.—A person submitting or causing the
23 submission of a covered petition or a series of covered peti-
24 tions that is a sham shall be liable for engaging in an

1 unfair method of competition under section 5(a)(1) of the
2 Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

3 (c) CIVIL ACTION.—

4 (1) IN GENERAL.—If the Commission has rea-
5 son to believe that the submission of a covered peti-
6 tion or a series of covered petitions constitutes a vio-
7 lation of section 5(a)(1) of the Federal Trade Com-
8 mission Act (15 U.S.C. 45(a)(1)), the Commission
9 may commence a civil action to recover a civil pen-
10 alty and seek other appropriate relief in a district
11 court of the United States against any person that
12 submitted or caused to be submitted such covered
13 petition or such series of covered petitions.

14 (2) PRESUMPTION.—In a civil action under
15 paragraph (1), a covered petition shall be presumed
16 to be part of a series of covered petitions that is a
17 sham under subsection (b) of this section if—

18 (A) the Secretary of Health and Human
19 Services—

20 (i) has determined that the covered
21 petition was submitted with the primary
22 purpose of delaying the approval of a cov-
23 ered application; and

1 (ii) has referred such determination to
2 the Commission in writing, including a rea-
3 soned basis for the determination; and

4 (B) the covered petition was part of a se-
5 ries of covered petitions.

6 (3) EXCEPTION.—The presumption in para-
7 graph (2) shall not apply if the defendant estab-
8 lishes, by a preponderance of the evidence, that the
9 series of covered petitions that includes the covered
10 petition referred to the Commission by the Secretary
11 of Health and Human Services is not a sham.

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

18 (A) any revenue earned from the sale by
19 such person of any drug product, referenced in
20 a covered application that was the subject of a
21 covered petition or a series of covered petitions
22 that is a sham, during the period during which
23 the covered petition or series of covered peti-
24 tions was under review by the Secretary of
25 Health and Human Services; or

1 (B) \$50,000 for each calendar day that
2 each covered petition that is a sham or that was
3 part of a series of covered petitions that is a
4 sham was under review by the Secretary of
5 Health and Human Services.

6 (5) REVIEW OF REFERRAL.—No referral by the
7 Secretary of Health and Human Services under
8 paragraph (2)(A) shall be subject to judicial review,
9 except as a third-party claim asserted by the defend-
10 ant under section 706(2)(A) of title 5, United States
11 Code, against the Secretary of Health and Human
12 Services or the Department of Health and Human
13 Services, as part of a civil action commenced under
14 paragraph (1).

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

22 (7) RULE OF CONSTRUCTION.—The civil pen-
23 alty provided in this subsection is in addition to, and
24 not in lieu of, any other remedies provided by Fed-
25 eral law, including under section 16 of the Clayton

1 Act (15 U.S.C. 26) or under section 13(b) of the
2 Federal Trade Commission Act (15 U.S.C. 53(b)).

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

6 (e) RULE OF CONSTRUCTION.—Nothing in this Act
7 shall be construed to limit any authority of the Commis-
8 sion under any other provision of law.

9 **SEC. 3. SEVERABILITY.**

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