

### 117TH CONGRESS 1ST SESSION

# H. R. 2883

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 heath concerns, and for other purposes.

### IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 2021

Mr. Jeffries (for himself, Mr. Buck, Mr. Nadler, Mr. Cicilline, and Mrs. Carolyn B. Maloney of New York) introduced the following bill; which was referred to the Committee on the Judiciary

## 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 heath 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 Stalling Access
- 5 to Affordable Medications".

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" means—
17	(A) an individual or entity;
18	(B) its directors, officers, employees,
19	agents, representatives, successors, and assigns;
20	and
21	(C) the joint ventures, subsidiaries, part-
22	nerships, divisions, groups, and affiliates it con-
23	trols, and the respective directors, officers, em-
24	ployees, agents, representatives, successors, and
25	assigns of each.

- 1 (5) Series of covered petitions.—The 2 term "series of covered petitions" means any group 3 of more than one covered petition.
  - (6) SHAM.—The term "sham" means a covered petition that is objectively baseless and that attempts to use a governmental process, as opposed to the outcome of that process, to interfere with the business of a competitor, or a series of covered petitions, that attempts to use a governmental process, as opposed to the outcome of that process, to interfere with the business of a competitor.

### 12 (b) VIOLATION.—

(1) IN GENERAL.—A person submitting or causing the submission of a covered petition or a series of covered petitions that is a sham shall be liable for engaging in an unfair method of competition under section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

### (c) CIVIL ACTION.—

(1) IN GENERAL.—If the Commission has reason to believe that the submission of a covered petition or a series of covered petitions constitutes a violation of section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)), the Commission may commence a civil action to recover a civil pen-

- alty and seek other appropriate relief in a district court of the United States against any person that submitted or caused to be submitted such covered petition or such series of covered petitions, including successors or assigns.
  - (2) Presumption.—In a civil action under paragraph (1), a covered petition shall be presumed to be part of a series of covered petitions that is a sham under subsection (b) of this section if the Secretary of Health and Human Services has determined that the covered petition was submitted with the primary purpose of delaying the approval of a covered application, was part of a series of covered petitions, and has referred such determination to the Federal Trade Commission in writing, with a reasoned basis for the determination.
    - (3) EXCEPTION.—The presumption in paragraph (2) shall not apply if the defendant establishes, by a preponderance of the evidence, that the series of covered petitions that includes the covered petition referred to the Commission by the Secretary of Health and Human Services is not a sham.
    - (4) CIVIL PENALTY.—In an action under paragraph (1), any person that has been found liable for a violation of section 5(a)(1) of the Federal Trade

- 1 Commission Act (15 U.S.C. 45(a)(1)) shall be sub-2 ject to a civil penalty for each violation of not more 3 than the greater of—
  - (A) any revenue earned from the sale by such person of any drug product, referenced in a covered application that was the subject of a covered petition or a series of covered petitions that is a sham, during the period in which the covered petition or series of covered petitions was under review by the Secretary of Health and Human Services; or
  - (B) \$50,000 for each calendar day that each covered petition that is a sham or that was part of a series of covered petitions that is a sham was under review by the Secretary of Health and Human Services.
  - (5) Antitrust laws.—Nothing in this section shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that it applies to unfair methods of competition.
  - (6) RULE OF CONSTRUCTION.—The civil penalty provided in this subsection is in addition to, and

- 1 not in lieu of, any other remedies provided by Fed-
- 2 eral law, including under section 16 of the Clayton
- Act (15 U.S.C. 26) or under section 13(b) of the
- 4 Federal Trade Commission Act (15 U.S.C. 53(b)).
- Nothing in this paragraph shall be construed to af-
- 6 fect any authority of the Commission under any
- 7 other provision of law.
- 8 (d) Applicability.—This section shall apply to any
- 9 covered petition submitted on or after the date of enact-
- 10 ment of this Act.

#### 11 SEC. 3. SEVERABILITY.

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

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