

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 2883  
OFFERED BY MR. NADLER OF NEW YORK**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Stop Stalling Access  
3 to Affordable Medications Act”.

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

6 (a) DEFINITIONS.—In this section:

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

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

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

1 (4) PERSON.—The term “person”—

2 (A) means an individual or entity; and

3 (B) includes—

4 (i) a successor and an assign of an  
5 entity;

6 (ii) a joint venture, subsidiary, part-  
7 nership, division, group, and affiliate con-  
8 trolled by an entity, and

9 (iii) a successor and an assign of a  
10 joint venture, subsidiary, partnership, divi-  
11 sion, group, and affiliate controlled by an  
12 entity.

13 (5) SERIES OF COVERED PETITIONS.—The  
14 term “series of covered petitions” means any group  
15 of more than 1 covered petition relating to the same  
16 covered application.

17 (6) SHAM.—The term “sham” means a covered  
18 petition that is objectively baseless and that at-  
19 tempts to use a governmental process, as opposed to  
20 the outcome of that process, to interfere with the  
21 business of a competitor, or a series of covered peti-  
22 tions that attempts to use a governmental process,  
23 as opposed to the outcome of that process, to inter-  
24 fere with the business of a competitor.

1 (b) VIOLATION.—A person submitting or causing the  
2 submission of a covered petition or a series of covered peti-  
3 tions that is a sham shall be liable for engaging in an  
4 unfair method of competition under section 5(a)(1) of the  
5 Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

6 (c) CIVIL ACTION.—

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

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

22 (A) the Secretary of Health and Human  
23 Services—

24 (i) has determined that the covered  
25 petition was submitted with the primary

1           purpose of delaying the approval of a cov-  
2           ered application; and

3                   (ii) has referred such determination to  
4           the Federal Trade Commission in writing,  
5           including a reasoned basis for the deter-  
6           mination; and

7           (B) the covered petition was part of a se-  
8           ries of covered petitions.

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

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

21                   (A) any revenue earned from the sale by  
22          such person of any drug product, referenced in  
23          a covered application that was the subject of a  
24          covered petition or a series of covered petitions  
25          that is a sham, during the period in which the

1 covered petition or series of covered petitions  
2 was under review by the Secretary of Health  
3 and Human Services; or

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

9 (5) ANTITRUST LAWS.—Nothing in this section  
10 shall modify, impair, limit, or supersede the applica-  
11 bility of the antitrust laws, as defined in subsection  
12 (a) of the first section of the Clayton Act (15 U.S.C.  
13 12(a)), and of section 5 of the Federal Trade Com-  
14 mission Act (15 U.S.C. 45) to the extent that it ap-  
15 plies to unfair methods of competition.

16 (6) RULE OF CONSTRUCTION.—The civil pen-  
17 alty provided in this subsection is in addition to, and  
18 not in lieu of, any other remedies provided by Fed-  
19 eral law, including under section 16 of the Clayton  
20 Act (15 U.S.C. 26) or under section 13(b) of the  
21 Federal Trade Commission Act (15 U.S.C. 53(b)).  
22 Nothing in this paragraph shall be construed to af-  
23 fect any authority of the Commission under any  
24 other provision of law.

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

4 **SEC. 3. SEVERABILITY.**

5 If any provision of this Act or the application of such  
6 provision to any person or circumstance is held to be un-  
7 constitutional, the remainder of this Act and the applica-  
8 tion of the provisions of such Act to any person or cir-  
9 cumstance shall not be affected.

Amend the title so as to read: “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.”.

