

117TH CONGRESS  
2D SESSION

# H. R. 7473

To prohibit pharmaceutical manufacturers from interfering with therapeutically equivalent or interchangeable substitution decisions by health care providers to limit competition from a generic drug or biosimilar biological product, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 7, 2022

Mrs. CAROLYN B. MALONEY of New York (for herself, Mr. CICILLINE, Mr. NADLER, Mr. WELCH, Ms. SCHAKOWSKY, Ms. PORTER, Mr. DESAULNIER, and Mr. RASKIN) introduced the following bill; which was referred to the Committee on the Judiciary

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## A BILL

To prohibit pharmaceutical manufacturers from interfering with therapeutically equivalent or interchangeable substitution decisions by health care providers to limit competition from a generic drug or biosimilar biological product, 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 “Generic Substitution  
5 Noninterference Act”.

1 **SEC. 2. DECLARATION OF PURPOSES.**

2 The purposes of this Act are—

3 (1) to enhance competition in the pharma-  
4 ceutical market by stopping anticompetitive practices  
5 that limit or prevent competition from generic drugs  
6 and biosimilar biological products,

7 (2) to support the purposes and intent of anti-  
8 trust law by prohibiting anticompetitive practices in  
9 the pharmaceutical industry that harm consumers,  
10 and

11 (3) to preserve physician autonomy.

12 **SEC. 3. INTERFERENCE WITH PROVIDER SUBSTITUTION**  
13 **DECISIONS.**

14 (a) PROHIBITION.—It shall be unlawful for a phar-  
15 maceutical manufacturer—

16 (1) to provide any item or service, or anything  
17 of value, for the purpose of aiding or assisting a  
18 health care provider to request or direct that a drug  
19 be dispensed “as written” or “brand name only”  
20 when a generic drug or biosimilar biological product  
21 is available, including any prescription notepad or  
22 prescription stamp, but not including any product  
23 sample, or

24 (2) to direct a health care provider to write  
25 “dispense as written”, “brand name only”, or an-  
26 other similar notation or direction on a prescription

1       when a generic drug or biosimilar biological product  
2       is available.

3       (b) LIMITATION.—Nothing in this section prevents a  
4 health care provider from exercising the provider’s own  
5 medical judgment to prescribe any drug or biologic prod-  
6 uct.

7       (c) CIVIL PENALTY ACTIONS.—If the Commission  
8 has reason to believe that a pharmaceutical manufacturer  
9 has violated or is violating this Act, the Federal Trade  
10 Commission may commence a civil action to recover a civil  
11 penalty and seek other appropriate relief in a district court  
12 of the United States against the pharmaceutical manufac-  
13 turer. Except as otherwise provided in section 16(a)(2) of  
14 the Federal Trade Commission Act (15 U.S.C. 56(a)(3)),  
15 the Commission shall have exclusive authority to com-  
16 mence or defend, and supervise the litigation of, any civil  
17 action under paragraph (1) and any appeal of such action  
18 in its own name by any of its attorneys designated by it  
19 for such purpose, unless the Commission authorizes the  
20 Attorney General to do so. The Commission shall inform  
21 the Attorney General of the exercise of such authority and  
22 such exercise shall not preclude the Attorney General from  
23 intervening on behalf of the United States in such action  
24 and any appeal of such action as may be otherwise pro-  
25 vided by law. The civil penalty shall be sufficient to deter

1 violations of this section, but in no event shall be greater  
2 than three times the gross revenues received for sales of  
3 the brand-name drug during the period in which the pro-  
4 hibited conduct occurred. In determining the amount of  
5 the civil penalty, the court shall take into account—

6 (1) the nature, circumstances, extent, and grav-  
7 ity of the violation with respect to the pharma-  
8 ceutical manufacturer,

9 (2) the degree of culpability,

10 (3) the history of violations,

11 (4) the ability to pay, and any effect on the  
12 ability to continue doing business, and

13 (5) other matters that justice requires.

14 (d) UNFAIR METHOD OF COMPETITION.—A violation  
15 of this Act shall also constitute an unfair method of com-  
16 petition under section 5(a)(1) of the Federal Trade Com-  
17 mission Act (15 U.S.C. 45(a)(1)).

18 (e) ENFORCEMENT AUTHORITY.—Except as other-  
19 wise provided in subsection (c), the Commission shall en-  
20 force this Act in the same manner, by the same means,  
21 and with the same jurisdiction, powers, and duties as  
22 though all applicable terms and provisions of the Federal  
23 Trade Commission Act (15 U.S.C. 41 et seq.) were incor-  
24 porated into and made a part of this Act.

25 (f) ACTIONS BY STATES.—

1           (1) IN GENERAL.—In any case in which the at-  
2           torney general of a State has reason to believe that  
3           an interest of the residents of that State has been  
4           or is threatened or adversely affected by the engage-  
5           ment of a pharmaceutical manufacturer in any con-  
6           duct described in subsection (a), the State, as  
7           *parens patriae*, may bring a civil action on behalf of  
8           the residents of the State in a district court of the  
9           United States of appropriate jurisdiction to enjoin  
10          that practice, to obtain damages, restitution, or  
11          other compensation on behalf of residents of such  
12          State, or to obtain such further and other relief as  
13          the court may deem appropriate.

14          (2) NOTICE.—The State shall serve prior writ-  
15          ten notice of any civil action under this subsection  
16          upon the Commission and provide the Commission  
17          with a copy of its complaint, except that if it is not  
18          feasible for the State to provide such prior notice,  
19          the State shall serve such notice immediately upon  
20          instituting such action. Upon receiving a notice re-  
21          specting a civil action, the Commission shall have  
22          the right to—

23                        (A) intervene in such action,

24                        (B) upon so intervening, to be heard on all  
25                        matters arising therein, and

1 (C) to file petitions for appeal.

2 (3) CONSTRUCTION.—For purposes of bringing  
3 a civil action under this subsection, nothing in this  
4 Act shall prevent an attorney general from exer-  
5 cising the powers conferred on the attorney general  
6 by the laws of such State to conduct investigations,  
7 or to administer oaths or affirmations, or to compel  
8 the attendance of witnesses or the production of doc-  
9 umentary and other evidence.

10 (4) ACTIONS BY COMMISSION.—Whenever a  
11 civil action has been instituted by or on behalf of the  
12 Commission for violation of this Act, no State may,  
13 during the pendency of such action instituted by or  
14 on behalf of the Commission, institute a civil action  
15 under this subsection against any defendant named  
16 in the complaint in such action for violation of this  
17 Act.

18 (5) VENUE; SERVICE OF PROCESS.—Any civil  
19 action brought under this subsection in a district  
20 court of the United States may be brought in the  
21 district in which the defendant is found, is an inhab-  
22 itant, or transacts business or wherever venue is  
23 proper under section 1391 of title 28. Process in  
24 such an action may be served in any district in

1       which the defendant is an inhabitant or in which the  
2       defendant may be found.

3       (g) DEFINITIONS.—In this section:

4           (1) ANTITRUST LAWS.—The term “antitrust  
5       laws” has the meaning given the term in subsection  
6       (a) of the 1st section of the Clayton Act (15 U.S.C.  
7       12(a)).

8           (2) BIOSIMILAR BIOLOGICAL PRODUCT.—The  
9       term “biosimilar biological product” means a biologi-  
10      cal product licensed under section 351(k) of the  
11      Public Health Service Act.

12          (3) BRAND NAME DRUG.—The term “brand  
13      name drug” means a drug approved or licensed  
14      under section 505(c) of the Federal Food, Drug, and  
15      Cosmetic Act or section 351(a) of the Public Health  
16      Service Act.

17          (4) GENERIC DRUG.—The term “generic drug”  
18      means a drug approved under section 505(j) of the  
19      Federal Food, Drug, and Cosmetic Act.

20          (5) HEALTH CARE PROVIDER.—The term  
21      “health care provider” means any individual or enti-  
22      ty, including any pharmacy, that participates in any  
23      Federal health care program (as defined in section  
24      1128B(f)) of the Social Security Act.

1           (6) PHARMACEUTICAL MANUFACTURER.—The  
2       term “pharmaceutical manufacturer” means the  
3       holder of—

4                   (A) an application approved under section  
5           505(c) or 505(j) of the Federal Food, Drug,  
6           and Cosmetic Act, or

7                   (B) a license under section 351(a) or  
8           351(k) of the Public Health Service Act.

9       (h) RULE OF CONSTRUCTION.—Except to the extent  
10   this Act establishes an additional basis for liability en-  
11   forced as provided herein, nothing in this Act shall modify,  
12   impair, limit, or supersede the applicability of the anti-  
13   trust laws, as defined in subsection (a) of the 1st section  
14   of the Clayton Act (15 U.S.C. 12(a)), and of section 5(a)  
15   of the Federal Trade Commission Act (15 U.S.C. 45(a)).  
16   Nothing in this Act shall be construed to limit the author-  
17   ity of the Federal Trade Commission under any other pro-  
18   vision of law.

19       (i) SEVERABILITY.—If any provision of this Act, or  
20   the application of such provision, to any person or cir-  
21   cumstance is held to be unconstitutional, the remainder  
22   of this Act, and the application of the remaining provisions  
23   of this Act, to any person or circumstance shall not be  
24   affected.

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