Carolyn B. Maloney

(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

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.

IN THE HOUSE OF REPRESENTATIVES

Mrs. CAROLYN B. MALONEY of New York introduced the following bill; which was referred to the Committee on _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Generic Substitution Noninterference Act''.

SEC. 2. DECLARATION OF PURPOSES.

The purposes of this Act are—

(1) to enhance competition in the pharmaceutical market by stopping anticompetitive practices that limit or prevent competition from generic drugs and biosimilar biological products,

(2) to support the purposes and intent of antitrust law by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers, and

(3) to preserve physician autonomy.

SEC. 3. INTERFERENCE WITH PROVIDER SUBSTITUTION DECISIONS.

(a) PROHIBITION.—It shall be unlawful for a pharmaceutical manufacturer—

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

(2) to direct a health care provider to write ''dispense as written'', ''brand name only'', or another similar notation or direction on a prescription

when a generic drug or biosimilar biological product is available.

(b) LIMITATION.—Nothing in this section prevents a health care provider from exercising the provider's own medical judgment to prescribe any drug or biologic product.

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

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

(1) the nature, circumstances, extent, and gravity of the violation with respect to the pharmaceutical manufacturer,

(2) the degree of culpability,

(3) the history of violations,

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

(5) other matters that justice requires.

(d) UNFAIR METHOD OF COMPETITION.—A violation of this Act shall also constitute an unfair method of competition under section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

(e) ENFORCEMENT AUTHORITY.—Except as otherwise provided in subsection (c), the Commission shall enforce this Act in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this Act.

(f) ACTIONS BY STATES.—

(1) IN GENERAL.—In any case in which the attorney general of a State has reason to believe that an interest of the residents of that State has been or is threatened or adversely affected by the engagement of a pharmaceutical manufacturer in any conduct described in subsection (a), the State, as parens patriae, may bring a civil action on behalf of the residents of the State in a district court of the United States of appropriate jurisdiction to enjoin that practice, to obtain damages, restitution, or other compensation on behalf of residents of such State, or to obtain such further and other relief as the court may deem appropriate.

(2) NOTICE.—The State shall serve prior written notice of any civil action under this subsection upon the Commission and provide the Commission with a copy of its complaint, except that if it is not feasible for the State to provide such prior notice, the State shall serve such notice immediately upon instituting such action. Upon receiving a notice respecting a civil action, the Commission shall have the right to—

(A) intervene in such action,

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

(C) to file petitions for appeal.

(3) CONSTRUCTION.—For purposes of bringing a civil action under this subsection, nothing in this Act shall prevent an attorney general from exercising the powers conferred on the attorney general by the laws of such State to conduct investigations, or to administer oaths or affirmations, or to compel the attendance of witnesses or the production of documentary and other evidence.

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

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

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

(g) DEFINITIONS.—In this section:

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

(2) BIOSIMILAR BIOLOGICAL PRODUCT.—The term ''biosimilar biological product'' means a biological product licensed under section 351(k) of the Public Health Service Act.

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

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

(5) HEALTH CARE PROVIDER.—The term ''health care provider'' means any individual or entity, including any pharmacy, that participates in any Federal health care program (as defined in section 1128B(f)) of the Social Security Act.

(6) PHARMACEUTICAL MANUFACTURER.—The term ''pharmaceutical manufacturer'' means the holder of—

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

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

(h) RULE OF CONSTRUCTION.—Except to the extent this Act establishes an additional basis for liability enforced as provided herein, nothing in this Act shall modify, impair, limit, or supersede the applicability of the antitrust laws, as defined in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)), and of section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45(a)). Nothing in this Act shall be construed to limit the authority of the Federal Trade Commission under any other provision of law.

(i) SEVERABILITY.—If any provision of this Act, or the application of such provision, to any person or circumstance is held to be unconstitutional, the remainder of this Act, and the application of the remaining provisions of this Act, to any person or circumstance shall not be affected.