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(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To protect an individuals ability to access medicines approved by the Food and Drug Administration to protect a health care providers ability to provide such medicines, and information related to such medicines.

IN THE HOUSE OF REPRESENTATIVES

Ms. ROSS introduced the following bill; which was referred to the Committee on _____

A BILL

To protect an individuals ability to access medicines approved by the Food and Drug Administration to protect a health care providers ability to provide such medicines, and information related to such medicines.

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 ''Right to FDA-Approved Medicines Act''.

SEC. 2. DEFINITIONS.

In this Act:

(1) FDA-APPROVED MEDICINE.—The term ''FDA-approved medicine'' means any drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) GOVERNMENT.—The term ''government'' includes each branch, department, agency, instrumentality, and official of the United States or a State.

(3) HEALTH CARE PROVIDER.—The term ''health care provider'' means any entity or individual (including any physician, certified nurse-midwife, nurse, nurse practitioner, physician assistant, and pharmacist) that is licensed or otherwise authorized by a State to prescribe FDA-approved medicines.

(4) STATE.—The term ''State'' includes each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, and each territory and possession of the United States, and any political subdivision of any of the foregoing, including any unit of local government, such as a county, city, town, village, or other general purpose political subdivision of a State.

SEC. 3. PURPOSES.

The purposes of this Act are—

(1) to provide a clear and comprehensive right to FDA-approved medicines; and

(2) to permit individuals to seek and obtain FDA-approved medicines and to permit health care providers to facilitate prescribing such medicines.

SEC. 4. PERMITTED SERVICES.

(a) IN GENERAL.—An individual has a statutory right under this Act to obtain FDA-approved medicines free from coercion, and a health care provider has a corresponding right to provide FDA-approved medicines, and information, referrals, and services related to such medicines.

(b) LIMITATIONS OR REQUIREMENTS.—The statutory rights specified in subsection (a) shall not be limited or otherwise infringed through any limitation or requirement that—

(1) expressly, effectively, implicitly, or as-implemented singles out—

(A) the provision of FDA-approved medicines, or information related to such medicines;

(B) health care providers who provide FDA-approved medicines or information related to such medicines; or

(C) facilities in which FDA-approved medicines or information related to such medicines; and

(2) impedes access to FDA-approved medicines or information related to such medicines.

(c) EXCEPTION.—To defend against a claim that a limitation or requirement violates a health care provider's or individual's statutory rights under subsection (b), a party must establish, by clear and convincing evidence, that—

(1) the limitation or requirement significantly advances access to FDA-approved medicines, and information related to such medicines; and

(2) access to FDA-approved medicines and information related to such medicines or the health of patients cannot be advanced by a less restrictive alternative measure or action.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to approve a drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or license a drug under section 351 of the Public Health Service Act (42 U.S.C. 262),

or for the Federal Government to enforce such approval or licensure.

SEC. 5. APPLICABILITY AND PREEMPTION.

(a) GENERAL APPLICATION.—

(1) IN GENERAL.—Except as provided in subsection (c), this Act supersedes and applies to the law of the Federal Government and each State, and the implementation of such law, whether statutory, common law, or otherwise, and whether adopted before or after the date of enactment of this Act.

(2) PROHIBITION.—Neither the Federal Government nor any State may administer, implement, or enforce any law, rule, regulation, standard, or other provision having the force and effect of law in a manner that—

(A) prohibits or restricts the sale, provision, or use of any FDA-approved medicines (as defined in section 2(2));

(B) prohibits or restricts any individual from aiding another individual in voluntarily obtaining or using any FDA-approved medicines; or

(C) exempts any FDA-approved medicines from any other generally applicable law in a

way that would make it more difficult to sell, provide, obtain, or use such medicines.

(3) RELATIONSHIP WITH OTHER LAWS.—This Act applies notwithstanding any other provision of Federal law, including the Religious Freedom Restoration Act of 1993 (42 U.S.C. 2000bb et seq.).

(b) SUBSEQUENTLY ENACTED FEDERAL LEGISLATION.—Federal law enacted after the date of enactment of this Act is subject to this Act, unless such law explicitly excludes such application by reference to this Act.

(c) LIMITATIONS.—The provisions of this Act shall not supersede or otherwise affect any provision of Federal law relating to coverage under (and shall not be construed as requiring the provision of specific benefits under) group health plans or group or individual health insurance coverage or coverage under a Federal health care program (as defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(f))), including coverage provided under section 1905(a)(4)(C) of the Social Security Act (42 U.S.C. 1396d(a)(4)(C)) and section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13).

(d) DEFENSE.—In any cause of action against an individual or entity who is subject to a limitation or requirement that violates this Act, in addition to the remedies

specified in section 7, this Act shall also apply to, and may be raised as a defense by, such an individual or entity.

(e) EFFECTIVE DATE.—This Act shall take effect immediately upon the date of enactment of this Act.

SEC. 6. RULES OF CONSTRUCTION.

(a) IN GENERAL.—In interpreting the provisions of this Act, a court shall liberally construe such provisions to effectuate the purposes described in section 3.

(b) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to authorize any government to interfere with a health care provider's ability to provide FDA-approved medicines or information related to such medicines or a patient's ability to obtain such medicines.

(c) OTHER INDIVIDUALS CONSIDERED AS GOVERNMENT OFFICIALS.—Any individual who, by operation of a provision of Federal or State law, is permitted to implement or enforce a limitation or requirement that violates section 4 shall be considered a government official for purposes of this Act.

SEC. 7. ENFORCEMENT.

(a) ATTORNEY GENERAL.—The Attorney General may commence a civil action on behalf of the United States against any State that violates, or against any government official (including an individual described in section 6(c)) that implements or enforces a limitation or re-

quirement that violates, section 4. The court shall hold unlawful and set aside the limitation or requirement if it is in violation of this Act.

(b) PRIVATE RIGHT OF ACTION.—

(1) IN GENERAL.—Any individual or entity, including any health care provider or patient, adversely affected by an alleged violation of this Act, may commence a civil action against any State that violates, or against any government official (including an individual described in section 6(c)) that implements or enforces a limitation or requirement that violates, section 4. The court shall hold unlawful and set aside the limitation or requirement if it is in violation of this Act.

(2) HEALTH CARE PROVIDER.—A health care provider may commence an action for relief on its own behalf, on behalf of the provider's staff, and on behalf of the provider's patients who are or may be adversely affected by an alleged violation of this Act.

(c) EQUITABLE RELIEF.—In any action under this section, the court may award appropriate equitable relief, including temporary, preliminary, and permanent injunctive relief.

(d) COSTS.—In any action under this section, the court shall award costs of litigation, as well as reasonable

attorney's fees, to any prevailing plaintiff. A plaintiff shall not be liable to a defendant for costs or attorney's fees in any nonfrivolous action under this section.

(e) JURISDICTION.—The district courts of the United States shall have jurisdiction over proceedings under this Act and shall exercise the same without regard to whether the party aggrieved shall have exhausted any administrative or other remedies that may be provided for by law.

(f) ABROGATION OF STATE IMMUNITY.—Neither a State that enforces or maintains, nor a government official (including an individual described in section 6(c)) who is permitted to implement or enforce any limitation or requirement that violates section 4 shall be immune under the Tenth Amendment to the Constitution of the United States, the Eleventh Amendment to the Constitution of the United States, or any other source of law, from an action in a Federal or State court of competent jurisdiction challenging that limitation or requirement.

SEC. 8. SEVERABILITY.

If any provision of this Act, or the application of such provision to any individual, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other individuals, entities, governments, or circumstances, shall not be affected thereby.