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1ST SESSION

H. R. 4525

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

JULY 17, 2025

Ms. Ross (for herself, Ms. SCHRIER, Ms. CASTOR of Florida, Mrs. TRAHAN, and Mrs. FLETCHER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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.

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 “Right to FDA-App-
5 proved Medicines Act”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act:

1 (1) FDA-APPROVED MEDICINE.—The term
2 “FDA-approved medicine” means any drug ap-
3 proved under section 505 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355) or licensed
5 under section 351 of the Public Health Service Act
6 (42 U.S.C. 262).

7 (2) GOVERNMENT.—The term “government”
8 includes each branch, department, agency, instru-
9 mentality, and official of the United States or a
10 State.

11 (3) HEALTH CARE PROVIDER.—The term
12 “health care provider” means any entity or indi-
13 vidual (including any physician, certified nurse-mid-
14 wife, nurse, nurse practitioner, physician assistant,
15 and pharmacist) that is licensed or otherwise author-
16 ized by a State to prescribe FDA-approved medi-
17 cines.

18 (4) STATE.—The term “State” includes each of
19 the 50 States, the District of Columbia, the Com-
20 monwealth of Puerto Rico, and each territory and
21 possession of the United States, and any political
22 subdivision of any of the foregoing, including any
23 unit of local government, such as a county, city,
24 town, village, or other general purpose political sub-
25 division of a State.

1 **SEC. 3. PURPOSES.**

2 The purposes of this Act are—

3 (1) to provide a clear and comprehensive right

4 to FDA-approved medicines; and

5 (2) to permit individuals to seek and obtain

6 FDA-approved medicines and to permit health care

7 providers to facilitate prescribing such medicines.

8 **SEC. 4. PERMITTED SERVICES.**

9 (a) **IN GENERAL.**—An individual has a statutory
10 right under this Act to obtain FDA-approved medicines
11 free from coercion, and a health care provider has a cor-
12 responding right to provide FDA-approved medicines, and
13 information, referrals, and services related to such medi-
14 cines.

15 (b) **LIMITATIONS OR REQUIREMENTS.**—The statu-
16 tory rights specified in subsection (a) shall not be limited
17 or otherwise infringed through any limitation or require-
18 ment that—

19 (1) expressly, effectively, implicitly, or as-imple-
20 mented singles out—

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

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

1 (C) facilities in which FDA-approved medi-
2 cines or information related to such medicines;
3 and

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

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

11 (1) the limitation or requirement significantly
12 advances access to FDA-approved medicines, and in-
13 formation related to such medicines; and

14 (2) access to FDA-approved medicines and in-
15 formation related to such medicines or the health of
16 patients cannot be advanced by a less restrictive al-
17 ternative measure or action.

18 (d) RULE OF CONSTRUCTION.—Nothing in this sec-
19 tion shall be construed to limit the authority of the Sec-
20 retary of Health and Human Services, acting through the
21 Commissioner of Food and Drugs, to approve a drug
22 under section 505 of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 355) or license a drug under section
24 351 of the Public Health Service Act (42 U.S.C. 262),

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

3 **SEC. 5. APPLICABILITY AND PREEMPTION.**

4 (a) GENERAL APPLICATION.—

5 (1) IN GENERAL.—Except as provided in sub-
6 section (c), this Act supersedes and applies to the
7 law of the Federal Government and each State, and
8 the implementation of such law, whether statutory,
9 common law, or otherwise, and whether adopted be-
10 fore or after the date of enactment of this Act.

11 (2) PROHIBITION.—Neither the Federal Gov-
12 ernment nor any State may administer, implement,
13 or enforce any law, rule, regulation, standard, or
14 other provision having the force and effect of law in
15 a manner that—

16 (A) prohibits or restricts the sale, provi-
17 sion, or use of any FDA-approved medicines (as
18 defined in section 2(2));

19 (B) prohibits or restricts any individual
20 from aiding another individual in voluntarily
21 obtaining or using any FDA-approved medi-
22 cines; or

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

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

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

7 (b) SUBSEQUENTLY ENACTED FEDERAL LEGISLA-
8 TION.—Federal law enacted after the date of enactment
9 of this Act is subject to this Act, unless such law explicitly
10 excludes such application by reference to this Act.

11 (c) LIMITATIONS.—The provisions of this Act shall
12 not supersede or otherwise affect any provision of Federal
13 law relating to coverage under (and shall not be construed
14 as requiring the provision of specific benefits under) group
15 health plans or group or individual health insurance cov-
16 erage or coverage under a Federal health care program
17 (as defined in section 1128B(f) of the Social Security Act
18 (42 U.S.C. 1320a–7b(f))), including coverage provided
19 under section 1905(a)(4)(C) of the Social Security Act (42
20 U.S.C. 1396d(a)(4)(C)) and section 2713 of the Public
21 Health Service Act (42 U.S.C. 300gg–13).

22 (d) DEFENSE.—In any cause of action against an in-
23 dividual or entity who is subject to a limitation or require-
24 ment that violates this Act, in addition to the remedies

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

3 (e) EFFECTIVE DATE.—This Act shall take effect im-
4 mediately upon the date of enactment of this Act.

5 **SEC. 6. RULES OF CONSTRUCTION.**

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

9 (b) RULE OF CONSTRUCTION.—Nothing in this Act
10 shall be construed to authorize any government to inter-
11 fere with a health care provider's ability to provide FDA-
12 approved medicines or information related to such medi-
13 cines or a patient's ability to obtain such medicines.

14 (c) OTHER INDIVIDUALS CONSIDERED AS GOVERN-
15 MENT OFFICIALS.—Any individual who, by operation of
16 a provision of Federal or State law, is permitted to imple-
17 ment or enforce a limitation or requirement that violates
18 section 4 shall be considered a government official for pur-
19 poses of this Act.

20 **SEC. 7. ENFORCEMENT.**

21 (a) ATTORNEY GENERAL.—The Attorney General
22 may commence a civil action on behalf of the United
23 States against any State that violates, or against any gov-
24 ernment official (including an individual described in sec-
25 tion 6(c)) that implements or enforces a limitation or re-

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

4 (b) PRIVATE RIGHT OF ACTION.—

5 (1) IN GENERAL.—Any individual or entity, in-
6 cluding any health care provider or patient, ad-
7 versely affected by an alleged violation of this Act,
8 may commence a civil action against any State that
9 violates, or against any government official (includ-
10 ing an individual described in section 6(c)) that im-
11 plements or enforces a limitation or requirement
12 that violates, section 4. The court shall hold unlaw-
13 ful and set aside the limitation or requirement if it
14 is in violation of this Act.

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

20 (c) EQUITABLE RELIEF.—In any action under this
21 section, the court may award appropriate equitable relief,
22 including temporary, preliminary, and permanent injunc-
23 tive relief.

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

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

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

9 (f) ABROGATION OF STATE IMMUNITY.—Neither a
10 State that enforces or maintains, nor a government official
11 (including an individual described in section 6(c)) who is
12 permitted to implement or enforce any limitation or re-
13 quirement that violates section 4 shall be immune under
14 the Tenth Amendment to the Constitution of the United
15 States, the Eleventh Amendment to the Constitution of
16 the United States, or any other source of law, from an
17 action in a Federal or State court of competent jurisdic-
18 tion challenging that limitation or requirement.

19 **SEC. 8. SEVERABILITY.**

20 If any provision of this Act, or the application of such
21 provision to any individual, entity, government, or cir-
22 cumstance, is held to be unconstitutional, the remainder
23 of this Act, or the application of such provision to all other

- 1 individuals, entities, governments, or circumstances, shall
- 2 not be affected thereby.

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