

119TH CONGRESS
2D SESSION

H. R. 7953

To accelerate patient access to innovative medicines and clinical trials for life-threatening diseases by establishing a reciprocal approval mechanism with trusted international regulatory authorities.

IN THE HOUSE OF REPRESENTATIVES

MARCH 17, 2026

Mr. SESSIONS (for himself and Mr. PETERS) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To accelerate patient access to innovative medicines and clinical trials for life-threatening diseases by establishing a reciprocal approval mechanism with trusted international regulatory authorities.

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 “Fast-tracking Approval
5 for Innovative Rare disease therapies Act” or the “FAIR
6 ACT”.

7 **SEC. 2. FINDINGS.**

8 Congress finds the following:

1 (1) Patients in the United States often face sig-
2 nificant delays in accessing innovative medicines
3 compared to patients in other trusted nations.

4 (2) The lengthy regulatory process at the Food
5 and Drug Administration contributes to the move-
6 ment of clinical trials abroad, leading to fewer op-
7 portunities for United States patients to participate
8 in cutting-edge research.

9 (3) China and other nations are rapidly expand-
10 ing their clinical trial and biopharmaceutical devel-
11 opment capacity, threatening United States leader-
12 ship in biomedical innovation.

13 (4) A reciprocal approval mechanism with trust-
14 ed international regulatory authorities will accelerate
15 access for United States patients to life-saving
16 therapies and preserve the United States competitive
17 position in biomedical research and innovation.

18 **SEC. 3. RECIPROCAL MARKETING APPROVAL FOR CERTAIN**
19 **DRUGS.**

20 The Federal Food, Drug, and Cosmetic Act is amend-
21 ed by inserting after section 524B of such Act (21 U.S.C.
22 360n-2) the following:

1 **“SEC. 524C. RECIPROCAL MARKETING APPROVAL FOR CER-**
2 **TAIN DRUGS.**

3 “(a) IN GENERAL.—A covered product with recip-
4 rocal marketing approval in effect under this section is
5 deemed to be subject to an application or premarket notifi-
6 cation for which an approval is in effect under section
7 505(c) or 510(k) of this Act or section 351(a) of the Pub-
8 lic Health Service Act, as applicable.

9 “(b) ELIGIBILITY.—The Secretary shall, with respect
10 to a covered product, grant reciprocal marketing approval
11 if—

12 “(1) the sponsor of the covered product submits
13 a request for reciprocal marketing approval; and

14 “(2) the request demonstrates to the Sec-
15 retary’s satisfaction that—

16 “(A) the covered product is lawfully mar-
17 keted in a foreign country pursuant to an au-
18 thorization from a trusted international regu-
19 latory authority of that country;

20 “(B) absent reciprocal marketing approval,
21 the covered product is not approved for mar-
22 keting, as described in subsection (a);

23 “(C) the Secretary has not, because of any
24 concern relating to the safety or effectiveness of
25 the covered product, rescinded or withdrawn
26 any such approval;

1 “(D) the authorization to market the cov-
2 ered product in a foreign country pursuant to
3 an authorization from a trusted international
4 regulatory authority of that country has not,
5 because of any concern relating to the safety or
6 effectiveness of the covered product, been re-
7 scinded or withdrawn; and

8 “(E) the covered product is intended for
9 use in the diagnosis, treatment, or mitigation of
10 an immediately life-threatening disease or con-
11 dition.

12 “(c) REQUEST.—A request for reciprocal marketing
13 approval shall—

14 “(1) be in such form, be submitted in such
15 manner, and contain such information as the Sec-
16 retary determines necessary to determine whether
17 the criteria listed in subsection (b)(2) are met; and

18 “(2) include, with respect to each trusted inter-
19 national regulatory authority that authorized a cov-
20 ered product to be lawfully marketed in the foreign
21 country involved, as described in subsection
22 (b)(2)(A), an English translation (if necessary) of
23 the dossier issued by such regulatory authority to
24 authorize such marketing.

1 “(d) TIMING.—The Secretary shall issue an order
2 granting, or declining to grant, reciprocal marketing ap-
3 proval with respect to a covered product not later than
4 30 days after the Secretary’s receipt of a request under
5 subsection (b)(1) for the product.

6 “(e) LABELING; POST-MARKET REQUIREMENTS.—
7 During the 30-day period described in subsection (d), the
8 Secretary shall finalize—

9 “(1) the form and content of the labeling for a
10 covered product for which reciprocal marketing ap-
11 proval is to be granted; and

12 “(2) any postmarket studies the Secretary de-
13 termines necessary to ensure the safety and effec-
14 tiveness of such product.

15 “(f) APPLICABILITY OF RELEVANT PROVISIONS.—
16 The provisions of this Act shall apply with respect to a
17 covered product for which reciprocal marketing approval
18 is in effect to the same extent and in the same manner
19 as such provisions apply with respect to a product for
20 which approval of an application or premarket notification
21 under section 505(c) or 510(k) of this Act or section
22 351(a) of the Public Health Service Act, as applicable, is
23 in effect.

24 “(g) WITHDRAWAL OF RECIPROCAL MARKETING AP-
25 PROVAL.—

1 “(1) IN GENERAL.—The Secretary may, at any
2 time, withdraw or suspend reciprocal marketing ap-
3 proval with respect to a covered product granted
4 under this section if—

5 “(A) new clinical or real-world evidence
6 demonstrates that the product presents an un-
7 reasonable risk of serious adverse events or
8 mortality; or

9 “(B) the trusted international regulatory
10 authority that originally authorized the covered
11 product has rescinded or suspended its approval
12 in the applicable foreign country.

13 “(2) EFFECT OF WITHDRAWAL OR SUSPEN-
14 SION.—If the withdrawal or suspension under para-
15 graph (1) is based on adverse event reports occur-
16 ring within the first 30 days after reciprocal mar-
17 keting approval, the Secretary shall provide public
18 notice and may require immediate cessation of mar-
19 keting and distribution.

20 “(3) PHASE-OUT OPTION.—The Secretary may
21 implement a phase-out plan for withdrawal under
22 paragraph (1), including patient transition meas-
23 ures, to protect public health while minimizing dis-
24 ruption to ongoing treatment.

1 “(h) FEES FOR REQUEST.—For purposes of impos-
2 ing fees under chapter VII, a request for reciprocal mar-
3 keting approval under this section shall be treated as an
4 application or premarket notification for approval under
5 section 505(c) or 510(k) or section 351(a) of the Public
6 Health Service Act, as applicable.

7 “(i) REPORT.—Not later than 5 years after the date
8 of enactment of this section, the Secretary shall submit
9 to the Committee on Energy and Commerce and the Com-
10 mittee on Ways and Means of the House of Representa-
11 tives and the Committee on Finance and the Committee
12 on Health, Education, Labor, and Pensions of the Senate
13 a comprehensive report on—

14 “(1) the effectiveness of the reciprocal mar-
15 keting approval program under this section in accel-
16 erating access to innovative medicines in the United
17 States;

18 “(2) the number of reciprocal marketing ap-
19 provals of covered products granted or denied under
20 this section;

21 “(3) the impact of the reciprocal marketing ap-
22 proval program under this section on patient safety
23 and adverse event reporting; and

1 “(4) recommendations for the continuation,
2 modification, or termination of the reciprocal mar-
3 keting approval program under this section.

4 “(j) DEFINITIONS.—In this section:

5 “(1) COVERED PRODUCT.—The term ‘covered
6 product’ means a drug, including a biological prod-
7 uct (as defined in section 351(i) of the Public
8 Health Service Act (42 U.S.C. 262(i))).

9 “(2) IMMEDIATELY LIFE-THREATENING DIS-
10 EASE OR CONDITION.—The term ‘immediately life-
11 threatening disease or condition’ has the meaning
12 given such term in section 312.300(b)(1) of title 21,
13 Code of Federal Regulations (or successor regula-
14 tions).

15 “(3) TRUSTED INTERNATIONAL REGULATORY
16 AUTHORITY.—The term ‘trusted international regu-
17 latory authority’ means—

18 “(A) the European Medicines Agency;

19 “(B) the Medicines and Healthcare Prod-
20 ucts Regulatory Agency of the United Kingdom;

21 “(C) Health Canada; and

22 “(D) any other international regulatory
23 authority designated by the Secretary of Health
24 and Human Services.”.

1 **SEC. 4. RECIPROCAL ALLOWANCE OF CLINICAL INVESTIGA-**
2 **TIONS AUTHORIZED BY TRUSTED INTER-**
3 **NATIONAL REGULATORY AUTHORITIES.**

4 Chapter V of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 351 et seq.) is amended by inserting after
6 section 569B (21 U.S.C. 360bbb–8b) the following:

7 **“SEC. 569B–1. RECIPROCAL ALLOWANCE OF CLINICAL IN-**
8 **VESTIGATIONS AUTHORIZED BY TRUSTED**
9 **INTERNATIONAL REGULATORY AUTHORI-**
10 **TIES.**

11 “(a) IN GENERAL.—A manufacturer may seek recip-
12 rocal allowance to conduct a clinical trial under section
13 505(i) of this Act or section 351(a)(3) of the Public
14 Health Service Act with respect to a qualified product by
15 submitting an application for such allowance to the Sec-
16 retary.

17 “(b) APPLICATION.—A manufacturer seeking recip-
18 rocal allowance under subsection (a) to conduct a clinical
19 investigation as described in subsection (a) shall submit
20 to the Secretary an application containing—

21 “(1) the authorization by a trusted inter-
22 national regulatory authority to conduct the same
23 clinical investigation with respect to a qualified prod-
24 uct in the applicable foreign country; and

25 “(2) any supporting documentation for such au-
26 thorization.

1 “(c) TREATMENT.—The Secretary shall, for purposes
2 of applying section 505(i) of this Act or section 351(a)(3)
3 of the Public Health Service Act—

4 “(1) treat an application for reciprocal allow-
5 ance with respect to a qualified product under this
6 section as meeting the criteria applicable to a sub-
7 mission under section 505(i)(2) of this Act (or pur-
8 suant to section 351(a)(3) of the Public Health
9 Service Act) with respect to beginning a clinical in-
10 vestigation of a new drug (or biological product);
11 and

12 “(2) pursuant to that treatment, issue an order
13 allowing, or declining to allow, a reciprocal allowance
14 with respect to such qualified product not later than
15 30 days after the Secretary’s receipt of a request
16 under subsection (b) for the product.

17 “(d) APPLICABILITY OF PROVISIONS.—The provi-
18 sions of section 505(i) of this Act and section 351(a)(3)
19 shall apply with respect to an application for reciprocal
20 allowance under this section to the same extent and in
21 the same manner as such provisions apply to an investiga-
22 tional new drug application under section 505(i) of this
23 Act or section 351(a)(3) of the Public Health Service Act.

24 “(e) PROTOCOL MODIFICATIONS.—The Secretary
25 may request, before the end of the 30-day period specified

1 in subsection (c)(2), that the manufacturer requesting a
2 reciprocal allowance with respect to a clinical investigation
3 under this section modify the protocols for such clinical
4 investigation. The Secretary shall, notwithstanding a re-
5 quest for modification of protocols under this subsection,
6 grant, or decline to grant such reciprocal allowance within
7 such 30-day period.

8 “(f) QUALIFIED PRODUCT DEFINED.—In this sec-
9 tion, the term ‘qualified product’ means a covered product
10 (as defined in section 524B) that is intended for use in
11 the diagnosis, treatment, or mitigation of an immediately
12 life-threatening disease or condition.”.

○