

119TH CONGRESS
1ST SESSION

H. R. 1262

To amend the Federal Food, Drug, and Cosmetic Act with respect to molecularly targeted pediatric cancer investigations, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 12, 2025

Mr. McCAUL (for himself, Mr. BILIRAKIS, Mrs. DINGELL, Ms. SCHRIER, Mrs. HARSHBARGER, Ms. MATSUI, Mr. CRENSHAW, Ms. CASTOR of Florida, Mr. KELLY of Pennsylvania, Mrs. TRAHAN, and Mr. WEBER of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to molecularly targeted pediatric cancer investigations, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Give Kids a Chance Act of 2025”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

- Sec. 2. Research into pediatric uses of drugs; additional authorities of Food and Drug Administration regarding molecularly targeted cancer drugs.
- Sec. 3. Ensuring completion of pediatric study requirements.
- Sec. 4. FDA report on PREA enforcement.
- Sec. 5. Extension of authority to issue priority review vouchers to encourage treatments for rare pediatric diseases.
- Sec. 6. Limitations on exclusive approval or licensure of orphan drugs.
- Sec. 7. Program for pediatric studies of drugs.
- Sec. 8. Organ Procurement and Transplantation Network.
- Sec. 9. Establishment of Abraham Accords Office within Food and Drug Administration.

1 **SEC. 2. RESEARCH INTO PEDIATRIC USES OF DRUGS; ADDI-**
 2 **TIONAL AUTHORITIES OF FOOD AND DRUG**
 3 **ADMINISTRATION REGARDING MOLECU-**
 4 **LARLY TARGETED CANCER DRUGS.**

5 (a) IN GENERAL.—

6 (1) ADDITIONAL ACTIVE INGREDIENT FOR AP-
 7 PPLICATION DRUG; LIMITATION REGARDING NOVEL-
 8 COMBINATION APPLICATION DRUG.—Section
 9 505B(a)(3) of the Federal Food, Drug, and Cos-
 10 metic Act (21 U.S.C. 355c(a)(3)) is amended—

11 (A) by redesignating subparagraphs (B)
 12 and (C) as subparagraphs (C) and (D), respec-
 13 tively; and

14 (B) by striking subparagraph (A) and in-
 15 serting the following:

16 “(A) IN GENERAL.—For purposes of para-
 17 graph (1)(B), the investigation described in this
 18 paragraph is a molecularly targeted pediatric
 19 cancer investigation of—

1 “(i) the drug or biological product for
2 which the application referred to in such
3 paragraph is submitted; or

4 “(ii) such drug or biological product
5 used in combination with—

6 “(I) an active ingredient of a
7 drug or biological product—

8 “(aa) for which an approved
9 application under section 505(j)
10 under this Act or under section
11 351(k) of the Public Health
12 Service Act is in effect; and

13 “(bb) that is determined by
14 the Secretary, after consultation
15 with the applicant, to be part of
16 the standard of care for treating
17 a pediatric cancer; or

18 “(II) an active ingredient of a
19 drug or biological product—

20 “(aa) for which an approved
21 application under section 505(b)
22 of this Act or section 351(a) of
23 the Public Health Service Act to
24 treat an adult cancer is in effect
25 and is held by the same person

submitting the application under
paragraph (1)(B); and

“(bb) that is directed at a
molecular target that the Sec-
retary determines to be substan-
tially relevant to the growth or
progression of a pediatric cancer.

“(B) ADDITIONAL REQUIREMENTS.—

“(i) DESIGN OF INVESTIGATION.—A
molecularly targeted pediatric cancer inves-
tigation referred to in subparagraph (A)
shall be designed to yield clinically mean-
ingful pediatric study data that is gathered
using appropriate formulations for each
age group for which the study is required,
regarding dosing, safety, and preliminary
efficacy to inform potential pediatric label-
ing.

“(ii) LIMITATION.—An investigation
described in subparagraph (A)(ii) may be
required only if the drug or biological
product for which the application referred
to in paragraph (1)(B) contains either—

“(I) a single new active ingre-
dient; or

1 “(II) more than one active ingre-
2 dient, if an application for the com-
3 bination of active ingredients has not
4 previously been approved but each ac-
5 tive ingredient is in a drug product
6 that has been previously approved to
7 treat an adult cancer.

8 “(iii) RESULTS OF ALREADY-COM-
9 PLETED PRECLINICAL STUDIES OF APPLI-
10 CATION DRUG.—With respect to an inves-
11 tigation required pursuant to paragraph
12 (1)(B), the Secretary may require the re-
13 sults of any completed preclinical studies
14 relevant to the initial pediatric study plan
15 be submitted to the Secretary at the same
16 time that the initial pediatric study plan
17 required under subsection (e)(1) is sub-
18 mitted.

19 “(iv) RULE OF CONSTRUCTION RE-
20 GARDING INACTIVE INGREDIENTS.—With
21 respect to a combination of active ingredi-
22 ents referred to in subparagraph (A)(ii),
23 such subparagraph shall not be construed
24 as addressing the use of inactive ingredi-
25 ents with such combination.”.

1 (2) DETERMINATION OF APPLICABLE REQUIRE-
2 MENTS.—Section 505B(e)(1) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is
4 amended by adding at the end the following: “The
5 Secretary shall determine whether subparagraph (A)
6 or (B) of subsection (a)(1) applies with respect to an
7 application before the date on which the applicant is
8 required to submit the initial pediatric study plan
9 under paragraph (2)(A).”.

10 (3) CLARIFYING APPLICABILITY.—Section
11 505B(a)(1) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 355c(a)(1)) is amended by
13 adding at the end the following:

14 “(C) RULE OF CONSTRUCTION.—No appli-
15 cation that is subject to the requirements of
16 subparagraph (B) shall be subject to the re-
17 quirements of subparagraph (A), and no appli-
18 cation (or supplement to an application) that is
19 subject to the requirements of subparagraph
20 (A) shall be subject to the requirements of sub-
21 paragraph (B).”.

22 (4) CONFORMING AMENDMENTS.—Section
23 505B(a) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 355c(a)) is amended—

1 (A) in paragraph (3)(C), as redesignated
2 by paragraph (1)(A) of this subsection, by
3 striking “investigations described in this para-
4 graph” and inserting “investigations referred to
5 in subparagraph (A)”; and

6 (B) in paragraph (3)(D), as redesignated
7 by paragraph (1)(A) of this subsection, by
8 striking “the assessments under paragraph
9 (2)(B)” and inserting “the assessments re-
10 quired under paragraph (1)(A)”.

11 (b) GUIDANCE.—The Secretary of Health and
12 Human Services, acting through the Commissioner of
13 Food and Drugs, shall—

14 (1) not later than 12 months after the date of
15 enactment of this Act, issue draft guidance on the
16 implementation of the amendments made by sub-
17 section (a); and

18 (2) not later than 12 months after closing the
19 comment period on such draft guidance, finalize
20 such guidance.

21 (c) APPLICABILITY.—The amendments made by this
22 section apply with respect to any application under section
23 505(b) of the Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 355(b)) and any application under section 351(a)
25 of the Public Health Service Act (42 U.S.C. 262(a)), that

1 is submitted on or after the date that is 3 years after the
2 date of enactment of this Act.

3 (d) REPORTS TO CONGRESS.—

4 (1) SECRETARY OF HEALTH AND HUMAN SERV-
5 ICES.—Not later than 6 years after the date of en-
6 actment of this Act, the Secretary of Health and
7 Human Services shall submit to the Committee on
8 Energy and Commerce of the House of Representa-
9 tives and the Committee on Health, Education,
10 Labor, and Pensions of the Senate a report on the
11 Secretary's efforts, in coordination with industry, to
12 ensure implementation of the amendments made by
13 subsection (a).

14 (2) GAO STUDY AND REPORT.—

15 (A) STUDY.—Not later than 8 years after
16 the date of enactment of this Act, the Comp-
17 troller General of the United States shall con-
18 duct a study of the effectiveness of requiring
19 assessments and investigations described in sec-
20 tion 505B of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 355c), as amended by
22 subsection (a), in the development of drugs and
23 biological products for pediatric cancer indica-
24 tions, including consideration of any benefits to,

1 or burdens on, pediatric cancer drug develop-
 2 ment.

3 (B) FINDINGS.—Not later than 10 years
 4 after the date of enactment of this Act, the
 5 Comptroller General shall submit to the Com-
 6 mittee on Energy and Commerce of the House
 7 of Representatives and the Committee on
 8 Health, Education, Labor, and Pensions of the
 9 Senate a report containing the findings of the
 10 study conducted under subparagraph (A).

11 **SEC. 3. ENSURING COMPLETION OF PEDIATRIC STUDY RE-**
 12 **QUIREMENTS.**

13 (a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY
 14 REQUIREMENTS.—Section 505B(d) of the Federal Food,
 15 Drug, and Cosmetic Act (21 U.S.C. 355c(d)) is amend-
 16 ed—

17 (1) in paragraph (1), by striking “Beginning
 18 270” and inserting “NONCOMPLIANCE LETTER.—
 19 Beginning 270”;

20 (2) in paragraph (2)—

21 (A) by striking “The drug or” and insert-
 22 ing “EFFECT OF NONCOMPLIANCE.—The drug
 23 or”; and

24 (B) by striking “(except that the drug or
 25 biological product shall not be subject to action

1 under section 303)” and inserting “(except that
2 the drug or biological product shall be subject
3 to action under section 303 only if such person
4 demonstrated a lack of due diligence in satis-
5 fying the applicable requirement)”;

6 (3) by adding at the end the following:

7 “(3) LIMITATION.—The Secretary shall not
8 issue enforcement actions under section 303 for fail-
9 ures under this subsection in the case of a drug or
10 biological product that is no longer marketed.”.

11 (b) DUE DILIGENCE.—Section 505B(d) of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)),
13 as amended by subsection (a), is further amended by add-
14 ing at the end the following:

15 “(4) DUE DILIGENCE.—Before the Secretary
16 may conclude that a person failed to submit or oth-
17 erwise meet a requirement as described in the mat-
18 ter preceding paragraph (1), the Secretary shall—

19 “(A) issue a noncompliance letter pursuant
20 to paragraph (1);

21 “(B) provide such person with a 45-day
22 period beginning on the date of receipt of such
23 noncompliance letter to respond in writing as
24 set forth in such paragraph; and

1 “(C) after reviewing such written response,
2 determine whether the person demonstrated a
3 lack of due diligence in satisfying such require-
4 ment.”.

5 (c) CONFORMING AMENDMENTS.—Section
6 303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 333(f)(4)(A)) is amended by striking “or 505–
8 1” and inserting “505–1, or 505B”.

9 (d) TRANSITION RULE.—The Secretary of Health
10 and Human Services may take enforcement action under
11 section 303 of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 333) only for failures described in section
13 505B(d) of such Act (21 U.S.C. 355c(d)) that occur on
14 or after the date that is 180 days after the date of enact-
15 ment of this Act.

16 **SEC. 4. FDA REPORT ON PREA ENFORCEMENT.**

17 Section 508(b) of the Food and Drug Administration
18 Safety and Innovation Act (21 U.S.C. 355c–1(b)) is
19 amended—

20 (1) in paragraph (11), by striking the semicolon
21 at the end and inserting “, including an evaluation
22 of compliance with deadlines provided for in defer-
23 rals and deferral extensions;”;

24 (2) in paragraph (15), by striking “and” at the
25 end;

1 (3) in paragraph (16), by striking the period at
 2 the end and inserting “; and”; and

3 (4) by adding at the end the following:

4 “(17) a listing of penalties, settlements, or pay-
 5 ments under section 303 of the Federal Food, Drug,
 6 and Cosmetic Act (21 U.S.C. 353) for failure to
 7 comply with requirements under such section 505B,
 8 including, for each penalty, settlement, or payment,
 9 the name of the drug, the sponsor thereof, and the
 10 amount of the penalty, settlement, or payment im-
 11 posed; and”.

12 **SEC. 5. EXTENSION OF AUTHORITY TO ISSUE PRIORITY RE-**
 13 **VIEW VOUCHERS TO ENCOURAGE TREAT-**
 14 **MENTS FOR RARE PEDIATRIC DISEASES.**

15 (a) EXTENSION.—Paragraph (5) of section 529(b) of
 16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 17 360ff(b)) is amended by striking “December 20, 2024, un-
 18 less” and all that follows through the period at the end
 19 and inserting “September 30, 2029.”.

20 (b) USER FEE PAYMENT.—Section 529(c)(4) of the
 21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 22 360ff(c)(4)) is amended by striking subparagraph (A) and
 23 inserting the following:

24 “(A) IN GENERAL.—The priority review
 25 user fee required by this subsection shall be due

1 upon the submission of a human drug applica-
2 tion under section 505(b)(1) or section 351(a)
3 of the Public Health Service Act for which the
4 priority review voucher is used. All other user
5 fees associated with the human drug application
6 shall be due as required by the Secretary or
7 under applicable law.”.

8 (c) GAO REPORT ON EFFECTIVENESS OF RARE PE-
9 DIATRIC DISEASE PRIORITY VOUCHER AWARDS IN
10 INCENTIVIZING RARE PEDIATRIC DISEASE DRUG DEVEL-
11 OPMENT.—

12 (1) GAO STUDY.—

13 (A) STUDY.—The Comptroller General of
14 the United States shall conduct a study of the
15 effectiveness of awarding rare pediatric disease
16 priority vouchers under section 529 of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C.
18 360ff), as amended by subsection (a), in the de-
19 velopment of human drug products that treat or
20 prevent rare pediatric diseases (as defined in
21 such section 529).

22 (B) CONTENTS OF STUDY.—In conducting
23 the study under subparagraph (A), the Comp-
24 troller General shall examine the following:

1 (i) The indications for each drug or
2 biological product that—

3 (I) is the subject of a rare pedi-
4 atric disease product application (as
5 defined in section 529 of the Federal
6 Food, Drug, and Cosmetic Act (21
7 U.S.C. 360ff)) for which a priority re-
8 view voucher was awarded; and

9 (II) was approved under section
10 505 of the Federal Food, Drug, and
11 Cosmetic Act (42 U.S.C. 355) or li-
12 censed under section 351 of the Pub-
13 lic Health Service Act (42 U.S.C.
14 262).

15 (ii) Whether, and to what extent, an
16 unmet need related to the treatment or
17 prevention of a rare pediatric disease was
18 met through the approval or licensure of
19 such a drug or biological product.

20 (iii) The size of the company to which
21 a priority review voucher was awarded
22 under section 529 of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 360ff)
24 for such a drug or biological product.

1 (iv) The value of such priority review
2 voucher if transferred.

3 (v) Identification of each drug for
4 which a priority review voucher awarded
5 under such section 529 was used.

6 (vi) The size of the company using
7 each priority review voucher awarded
8 under such section 529.

9 (vii) The length of the period of time
10 between the date on which a priority re-
11 view voucher was awarded under such sec-
12 tion 529 and the date on which it was
13 used.

14 (viii) Whether, and to what extent, an
15 unmet need related to the treatment or
16 prevention of a rare pediatric disease was
17 met through the approval under section
18 505 of the Federal Food, Drug, and Cos-
19 metic Act (42 U.S.C. 355) or licensure
20 under section 351 of the Public Health
21 Service Act (42 U.S.C. 262) of a drug for
22 which a priority review voucher was used.

23 (ix) Whether, and to what extent,
24 companies were motivated by the avail-
25 ability of priority review vouchers under

1 section 529 of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 360ff) to at-
3 tempt to develop a drug for a rare pedi-
4 atric disease.

5 (x) Whether, and to what extent, pedi-
6 atric review vouchers awarded under such
7 section were successful in stimulating de-
8 velopment and expedited patient access to
9 drug products for treatment or prevention
10 of a rare pediatric disease that wouldn't
11 otherwise take place without the incentive
12 provided by such vouchers.

13 (xi) The impact of such priority re-
14 view vouchers on the workload, review
15 process, and public health prioritization ef-
16 forts of the Food and Drug Administra-
17 tion.

18 (xii) Any other incentives in Federal
19 law that exist for companies developing
20 drugs or biological products described in
21 clause (i).

22 (2) REPORT ON FINDINGS.—Not later than 5
23 years after the date of the enactment of this Act, the
24 Comptroller General of the United States shall sub-
25 mit to the Committee on Energy and Commerce of

1 the House of Representatives and the Committee on
 2 Health, Education, Labor, and Pensions of the Sen-
 3 ate a report containing the findings of the study
 4 conducted under paragraph (1).

5 **SEC. 6. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICEN-**
 6 **SURE OF ORPHAN DRUGS.**

7 (a) IN GENERAL.—Section 527 of the Federal Food,
 8 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

9 (1) in subsection (a), in the matter following
 10 paragraph (2), by striking “same disease or condi-
 11 tion” and inserting “same approved use or indica-
 12 tion within such rare disease or condition”;

13 (2) in subsection (b)—

14 (A) in the matter preceding paragraph (1),
 15 by striking “same rare disease or condition”
 16 and inserting “same approved use or indication
 17 for which such 7-year period applies to such al-
 18 ready approved or licensed drug”; and

19 (B) in paragraph (1), by inserting “, relat-
 20 ing to the approved use or indication,” after
 21 “the needs”;

22 (3) in subsection (c)(1), by striking “same rare
 23 disease or condition as the already approved drug”
 24 and inserting “same use or indication for which the

1 already approved or licensed drug was approved or
2 licensed”; and

3 (4) by adding at the end the following:

4 “(f) APPROVED USE OR INDICATION DEFINED.—In
5 this section, the term ‘approved use or indication’ means
6 the use or indication approved under section 505 of this
7 Act or licensed under section 351 of the Public Health
8 Service Act for a drug designated under section 526 for
9 a rare disease or condition.”.

10 (b) APPLICATION OF AMENDMENTS.—The amend-
11 ments made by subsection (a) shall apply with respect to
12 any drug designated under section 526 of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-
14 less of the date on which the drug was so designated, and
15 regardless of the date on which the drug was approved
16 under section 505 of such Act (21 U.S.C. 355) or licensed
17 under section 351 of the Public Health Service Act (42
18 U.S.C. 262).

19 **SEC. 7. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

20 Section 409I(d)(1) of the Public Health Service Act
21 (42 U.S.C. 284m(d)(1)) is amended by striking “section,”
22 and all that follows through the period at the end and
23 inserting “section, \$25,000,000 for each of fiscal years
24 2025 through 2027.”.

1 **SEC. 8. ORGAN PROCUREMENT AND TRANSPLANTATION**
2 **NETWORK.**

3 Section 372 of the Public Health Service Act (42
4 U.S.C. 274) is amended—

5 (1) in subsection (b)(2)—

6 (A) by moving the margins of subpara-
7 graphs (M) through (O) 2 ems to the left;

8 (B) in subparagraph (A)—

9 (i) in clause (i), by striking “, and”
10 and inserting “; and”; and

11 (ii) in clause (ii), by striking the
12 comma at the end and inserting a semi-
13 colon;

14 (C) in subparagraph (C), by striking
15 “twenty-four-hour telephone service” and in-
16 serting “24-hour telephone or information tech-
17 nology service”;

18 (D) in each of subparagraphs (B) through
19 (M), by striking the comma at the end and in-
20 serting a semicolon;

21 (E) in subparagraph (N), by striking
22 “transportation, and” and inserting “transpor-
23 tation;”;

24 (F) in subparagraph (O), by striking the
25 period and inserting a semicolon; and

26 (G) by adding at the end the following:

“(P) encourage the integration of electronic health records systems through application programming interfaces (or successor technologies) among hospitals, organ procurement organizations, and transplant centers, including the use of automated electronic hospital referrals and the grant of remote, electronic access to hospital electronic health records of potential donors by organ procurement organizations, in a manner that complies with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, at part 160 of title 45, Code of Federal Regulations, and subparts A, C, and E of part 164 of such title (or any successor regulations); and

“(Q) consider establishing a dashboard to display the number of transplants performed, the types of transplants performed, the number and types of organs that entered the Organ Procurement and Transplantation Network system and failed to be transplanted, and other appropriate statistics, which should be updated more frequently than annually.”; and

(2) by adding at the end the following:

“(d) REGISTRATION FEES.—

1 “(1) IN GENERAL.—The Secretary may collect
2 registration fees from any member of the Organ
3 Procurement and Transplantation Network for each
4 transplant candidate such member places on the list
5 described in subsection (b)(2)(A)(i). Such registra-
6 tion fees shall be collected and distributed only to
7 support the operation of the Organ Procurement
8 and Transplantation Network. Such registration fees
9 are authorized to remain available until expended.

10 “(2) COLLECTION.—The Secretary may collect
11 the registration fees under paragraph (1) directly or
12 through awards made under subsection (b)(1)(A).

13 “(3) DISTRIBUTION.—Any amounts collected
14 under this subsection shall—

15 “(A) be credited to the currently applicable
16 appropriation, account, or fund of the Depart-
17 ment of Health and Human Services as discre-
18 tionary offsetting collections; and

19 “(B) be available, only to the extent and in
20 the amounts provided in advance in appropria-
21 tions Acts, to distribute such fees among
22 awardees described in subsection (b)(1)(A).

23 “(4) TRANSPARENCY.—The Secretary shall—

1 “(A) promptly post on the website of the
2 Organ Procurement and Transplantation Net-
3 work—

4 “(i) the amount of registration fees
5 collected under this subsection from each
6 member of the Organ Procurement and
7 Transplantation Network; and

8 “(ii) a list of activities such fees are
9 used to support; and

10 “(B) update the information posted pursu-
11 ant to subparagraph (A), as applicable for each
12 calendar quarter for which fees are collected
13 under paragraph (1).

14 “(5) GAO REVIEW.—Not later than 2 years
15 after the date of enactment of this subsection, the
16 Comptroller General of the United States shall, to
17 the extent data are available—

18 “(A) conduct a review concerning the ac-
19 tivities under this subsection; and

20 “(B) submit to the Committee on Health,
21 Education, Labor, and Pensions and the Com-
22 mittee on Finance of the Senate and the Com-
23 mittee on Energy and Commerce of the House
24 of Representatives, a report on such review, in-
25 cluding related recommendations, as applicable.

1 “(6) SUNSET.—The authority to collect reg-
 2 istration fees under paragraph (1) shall expire on
 3 the date that is 3 years after the date of enactment
 4 of the Give Kids a Chance Act of 2025.”.

5 **SEC. 9. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE**
 6 **WITHIN FOOD AND DRUG ADMINISTRATION.**

7 (a) IN GENERAL.—Chapter X of the Federal Food,
 8 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
 9 ed by adding at the end the following:

10 **“SEC. 1015. ABRAHAM ACCORDS OFFICE.**

11 “(a) IN GENERAL.—The Secretary, acting through
 12 the Commissioner of Food and Drugs, shall establish with-
 13 in the Food and Drug Administration an office, to be
 14 known as the Abraham Accords Office, to be headed by
 15 a director.

16 “(b) OFFICE.—Not later than two years after the
 17 date of enactment of this section, the Secretary shall—

18 “(1) in consultation with the governments of
 19 Abraham Accords countries, as well as appropriate
 20 United States Government diplomatic and security
 21 personnel—

22 “(A) select the location of the Abraham
 23 Accords Office in an Abraham Accords country;
 24 and

25 “(B) establish such office; and

1 “(2) assign to such office such personnel of the
2 Food and Drug Administration as the Secretary de-
3 termines necessary to carry out the functions of
4 such office.

5 “(c) DUTIES.—The Secretary, acting through the Di-
6 rector of the Abraham Accords Office, shall—

7 “(1) after the Abraham Accords Office is estab-
8 lished—

9 “(A) as part of the Food and Drug Admin-
10 istration’s work to strengthen the international
11 oversight of regulated commodities, provide
12 technical assistance to regulatory partners in
13 Abraham Accords countries on strengthening
14 regulatory oversight and converging regulatory
15 requirements for the oversight of regulated
16 products, including good manufacturing prac-
17 tices and other issues relevant to manufacturing
18 medical products that are regulated by the
19 Food and Drug Administration; and

20 “(B) facilitate interactions between the
21 Food and Drug Administration and interested
22 parties in Abraham Accords countries, including
23 by sharing relevant information regarding
24 United States regulatory pathways with such
25 parties, and facilitate feedback on the research,

1 development, and manufacturing of products
2 regulated in accordance with this Act; and

3 “(2) carry out other functions and activities as
4 the Secretary determines to be necessary to carry
5 out this section.

6 “(d) ABRAHAM ACCORDS COUNTRY DEFINED.—In
7 this section, the term ‘Abraham Accords country’ means
8 a country identified by the Department of State as having
9 signed the Abraham Accords Declaration.

10 “(e) NATIONAL SECURITY.—Nothing in this section
11 shall be construed to require any action inconsistent with
12 a national security recommendation provided by the Fed-
13 eral Government.”.

14 (b) REPORT TO CONGRESS.—

15 (1) IN GENERAL.—Not later than 3 years after
16 the date of enactment of this Act, the Secretary of
17 Health and Human Services shall submit to the
18 Congress a report on the Abraham Accords Office,
19 including—

20 (A) an evaluation of how the Office has ad-
21 vanced progress toward conformance with Food
22 and Drug Administration regulatory require-
23 ments by manufacturers in the Abraham Ac-
24 cords countries;

1 (B) a numerical count of parties that the
2 Office has helped facilitate interactions or feed-
3 back pursuant to section 1015(c)(1)(B) of the
4 Federal Food, Drug, and Cosmetic Act (as
5 added by subsection (a));

6 (C) a summary of technical assistance pro-
7 vided to regulatory partners in Abraham Ac-
8 cords countries pursuant to subparagraph (A)
9 of such section 1015(c)(1); and

10 (D) recommendations for increasing and
11 improving coordination between the Food and
12 Drug Administration and entities in Abraham
13 Accords countries.

14 (2) ABRAHAM ACCORDS COUNTRY DEFINED.—
15 In this subsection, the term “Abraham Accords
16 country” has the meaning given such term in section
17 1015(d) of the Federal Food, Drug, and Cosmetic
18 Act (as added by subsection (a)).

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