

119TH CONGRESS
1ST SESSION

H. R. 1262

AN ACT

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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Mikaela Naylor Give Kids a Chance Act”.

4 (b) TABLE OF CONTENTS.—The table of contents for
5 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 Ad-
ministration.

Sec. 10. Increasing transparency in generic drug applications.

Sec. 11. Medicare Improvement Fund.

6 **SEC. 2. RESEARCH INTO PEDIATRIC USES OF DRUGS; ADDI-**
7 **TIONAL AUTHORITIES OF FOOD AND DRUG**
8 **ADMINISTRATION REGARDING MOLECU-**
9 **LARLY TARGETED CANCER DRUGS.**

10 (a) IN GENERAL.—

11 (1) ADDITIONAL ACTIVE INGREDIENT FOR AP-
12 PPLICATION DRUG; LIMITATION REGARDING NOVEL-
13 COMBINATION APPLICATION DRUG.—Section
14 505B(a)(3) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 355c(a)(3)) is amended—

16 (A) by redesignating subparagraphs (B)
17 and (C) as subparagraphs (C) and (D), respec-
18 tively; and

1 (B) by striking subparagraph (A) and in-
2 serting the following:

3 “(A) IN GENERAL.—For purposes of para-
4 graph (1)(B), the investigation described in this
5 paragraph is a molecularly targeted pediatric
6 cancer investigation of—

7 “(i) the drug or biological product for
8 which the application referred to in such
9 paragraph is submitted; or

10 “(ii) such drug or biological product
11 used in combination with—

12 “(I) an active ingredient of a
13 drug or biological product—

14 “(aa) for which an approved
15 application under section 505(j)
16 under this Act or under section
17 351(k) of the Public Health
18 Service Act is in effect; and

19 “(bb) that is determined by
20 the Secretary, after consultation
21 with the applicant, to be part of
22 the standard of care for treating
23 a pediatric cancer; or

24 “(II) an active ingredient of a
25 drug or biological product—

1 “(aa) for which an approved
2 application under section 505(b)
3 of this Act or section 351(a) of
4 the Public Health Service Act to
5 treat an adult cancer is in effect
6 and is held by the same person
7 submitting the application under
8 paragraph (1)(B); and

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

14 “(B) ADDITIONAL REQUIREMENTS.—

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

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

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

8 “(II) more than one active ingre-
9 dient, if an application for the com-
10 bination of active ingredients has not
11 previously been approved but each ac-
12 tive ingredient is in a drug product
13 that has been previously approved to
14 treat an adult cancer.

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

1 “(iv) RULE OF CONSTRUCTION RE-
2 GARDING INACTIVE INGREDIENTS.—With
3 respect to a combination of active ingredi-
4 ents referred to in subparagraph (A)(ii),
5 such subparagraph shall not be construed
6 as addressing the use of inactive ingredi-
7 ents with such combination.”.

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

17 (3) CLARIFYING APPLICABILITY.—Section
18 505B(a)(1) of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 355c(a)(1)) is amended by
20 adding at the end the following:

21 “(C) RULE OF CONSTRUCTION.—No appli-
22 cation that is subject to the requirements of
23 subparagraph (B) shall be subject to the re-
24 quirements of subparagraph (A), and no appli-
25 cation (or supplement to an application) that is

1 subject to the requirements of subparagraph
2 (A) shall be subject to the requirements of sub-
3 paragraph (B).”.

4 (4) CONFORMING AMENDMENTS.—Section
5 505B(a) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 355c(a)) is amended—

7 (A) in paragraph (3)(C), as redesignated
8 by paragraph (1)(A) of this subsection, by
9 striking “investigations described in this para-
10 graph” and inserting “investigations referred to
11 in subparagraph (A)”;

12 (B) in paragraph (3)(D), as redesignated
13 by paragraph (1)(A) of this subsection, by
14 striking “the assessments under paragraph
15 (2)(B)” and inserting “the assessments re-
16 quired under paragraph (1)(A)”.

17 (b) GUIDANCE.—The Secretary of Health and
18 Human Services, acting through the Commissioner of
19 Food and Drugs, shall—

20 (1) not later than 12 months after the date of
21 enactment of this Act, issue draft guidance on the
22 implementation of the amendments made by sub-
23 section (a); and

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

4 (c) APPLICABILITY.—The amendments made by this
5 section apply with respect to any application under section
6 505(b) of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 355(b)) and any application under section 351(a)
8 of the Public Health Service Act (42 U.S.C. 262(a)), that
9 is submitted on or after the date that is 3 years after the
10 date of enactment of this Act.

11 (d) REPORTS TO CONGRESS.—

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

22 (2) GAO STUDY AND REPORT.—

23 (A) STUDY.—Not later than 8 years after
24 the date of enactment of this Act, the Comp-
25 troller General of the United States shall con-

duct a study of the effectiveness of requiring assessments and investigations described in section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c), as amended by subsection (a), in the development of drugs and biological products for pediatric cancer indications, including consideration of any benefits to, or burdens on, pediatric cancer drug development.

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

SEC. 3. ENSURING COMPLETION OF PEDIATRIC STUDY REQUIREMENTS.

(a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY REQUIREMENTS.—Section 505B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)) is amended—

1 (1) in paragraph (1), by striking “Beginning
2 270” and inserting “NONCOMPLIANCE LETTER.—
3 Beginning 270”;

4 (2) in paragraph (2)—

5 (A) by striking “The drug or” and insert-
6 ing “EFFECT OF NONCOMPLIANCE.—The drug
7 or”; and

8 (B) by striking “(except that the drug or
9 biological product shall not be subject to action
10 under section 303)” and inserting “(except that
11 the drug or biological product shall be subject
12 to action under section 303 only if such person
13 demonstrated a lack of due diligence in satis-
14 fying the applicable requirement)”; and

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

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

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

24 “(4) DUE DILIGENCE.—Before the Secretary
25 may conclude that a person failed to submit or oth-

1 erwise meet a requirement as described in the mat-
2 ter preceding paragraph (1), the Secretary shall—

3 “(A) issue a noncompliance letter pursuant
4 to paragraph (1);

5 “(B) provide such person with a 45-day
6 period beginning on the date of receipt of such
7 noncompliance letter to respond in writing as
8 set forth in such paragraph; and

9 “(C) after reviewing such written response,
10 determine whether the person demonstrated a
11 lack of due diligence in satisfying such require-
12 ment.”.

13 (c) CONFORMING AMENDMENTS.—Section
14 303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 333(f)(4)(A)) is amended by striking “or 505–
16 1” and inserting “505–1, or 505B”.

17 (d) TRANSITION RULE.—The Secretary of Health
18 and Human Services may take enforcement action under
19 section 303 of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 333) only for failures described in section
21 505B(d) of such Act (21 U.S.C. 355c(d)) that occur on
22 or after the date that is 180 days after the date of enact-
23 ment of this Act.

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

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

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

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

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

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

14 “(17) a listing of penalties, settlements, or pay-
15 ments under section 303 of the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 353) for failure to
17 comply with requirements under such section 505B,
18 including, for each penalty, settlement, or payment,
19 the name of the drug, the sponsor thereof, and the
20 amount of the penalty, settlement, or payment im-
21 posed.”.

22 **SEC. 5. EXTENSION OF AUTHORITY TO ISSUE PRIORITY RE-**
23 **VIEW VOUCHERS TO ENCOURAGE TREAT-**
24 **MENTS FOR RARE PEDIATRIC DISEASES.**

25 (a) EXTENSION.—Paragraph (5) of section 529(b) of
26 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 360ff(b)) is amended by striking “December 20, 2024, un-
2 less” and all that follows through the period at the end
3 and inserting “September 30, 2029.”.

4 (b) USER FEE PAYMENT.—Section 529(c)(4) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 360ff(c)(4)) is amended by striking subparagraph (A) and
7 inserting the following:

8 “(A) IN GENERAL.—The priority review
9 user fee required by this subsection shall be due
10 upon the submission of a human drug applica-
11 tion under section 505(b)(1) or section 351(a)
12 of the Public Health Service Act for which the
13 priority review voucher is used. All other user
14 fees associated with the human drug application
15 shall be due as required by the Secretary or
16 under applicable law.”.

17 (c) GAO REPORT ON EFFECTIVENESS OF RARE PE-
18 DIATRIC DISEASE PRIORITY VOUCHER AWARDS IN
19 INCENTIVIZING RARE PEDIATRIC DISEASE DRUG DEVEL-
20 OPMENT.—

21 (1) GAO STUDY.—

22 (A) STUDY.—The Comptroller General of
23 the United States shall conduct a study of the
24 effectiveness of awarding rare pediatric disease
25 priority vouchers under section 529 of the Fed-

1 eral Food, Drug, and Cosmetic Act (21 U.S.C.
2 360ff), as amended by subsection (a), in the de-
3 velopment of human drug products that treat or
4 prevent rare pediatric diseases (as defined in
5 such section 529).

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

9 (i) The indications for each drug or
10 biological product that—

11 (I) is the subject of a rare pedi-
12 atric disease product application (as
13 defined in section 529 of the Federal
14 Food, Drug, and Cosmetic Act (21
15 U.S.C. 360ff)) for which a priority re-
16 view voucher was awarded; and

17 (II) was approved under section
18 505 of the Federal Food, Drug, and
19 Cosmetic Act (42 U.S.C. 355) or li-
20 censed under section 351 of the Pub-
21 lic Health Service Act (42 U.S.C.
22 262).

23 (ii) Whether, and to what extent, an
24 unmet need related to the treatment or
25 prevention of a rare pediatric disease was

1 met through the approval or licensure of
2 such a drug or biological product.

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

8 (iv) The value of such priority review
9 voucher if transferred.

10 (v) Identification of each drug for
11 which a priority review voucher awarded
12 under such section 529 was used.

13 (vi) The size of the company using
14 each priority review voucher awarded
15 under such section 529.

16 (vii) The length of the period of time
17 between the date on which a priority re-
18 view voucher was awarded under such sec-
19 tion 529 and the date on which it was
20 used.

21 (viii) Whether, and to what extent, an
22 unmet need related to the treatment or
23 prevention of a rare pediatric disease was
24 met through the approval under section
25 505 of the Federal Food, Drug, and Cos-

1 metic Act (42 U.S.C. 355) or licensure
2 under section 351 of the Public Health
3 Service Act (42 U.S.C. 262) of a drug for
4 which a priority review voucher was used.

5 (ix) Whether, and to what extent,
6 companies were motivated by the avail-
7 ability of priority review vouchers under
8 section 529 of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 360ff) to at-
10 tempt to develop a drug for a rare pedi-
11 atric disease.

12 (x) Whether, and to what extent, pedi-
13 atric review vouchers awarded under such
14 section were successful in stimulating de-
15 velopment and expedited patient access to
16 drug products for treatment or prevention
17 of a rare pediatric disease that wouldn't
18 otherwise take place without the incentive
19 provided by such vouchers.

20 (xi) The impact of such priority re-
21 view vouchers on the workload, review
22 process, and public health prioritization ef-
23 forts of the Food and Drug Administra-
24 tion.

1 (xii) Any other incentives in Federal
2 law that exist for companies developing
3 drugs or biological products described in
4 clause (i).

5 (2) REPORT ON FINDINGS.—Not later than 5
6 years after the date of the enactment of this Act, the
7 Comptroller General of the United States shall sub-
8 mit to the Committee on Energy and Commerce of
9 the House of Representatives and the Committee on
10 Health, Education, Labor, and Pensions of the Sen-
11 ate a report containing the findings of the study
12 conducted under paragraph (1).

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

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

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

21 (2) in subsection (b)—

22 (A) in the matter preceding paragraph (1),
23 by striking “same rare disease or condition”
24 and inserting “same approved use or indication

1 for which such 7-year period applies to such al-
2 ready approved or licensed drug”; and

3 (B) in paragraph (1), by inserting “, relat-
4 ing to the approved use or indication,” after
5 “the needs”;

6 (3) in subsection (c)(1), by striking “same rare
7 disease or condition as the already approved drug”
8 and inserting “same use or indication for which the
9 already approved or licensed drug was approved or
10 licensed”; and

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

12 “(f) APPROVED USE OR INDICATION DEFINED.—In
13 this section, the term ‘approved use or indication’ means
14 the use or indication approved under section 505 of this
15 Act or licensed under section 351 of the Public Health
16 Service Act for a drug designated under section 526 for
17 a rare disease or condition.”.

18 (b) APPLICATION OF AMENDMENTS.—The amend-
19 ments made by subsection (a) shall apply with respect to
20 any drug designated under section 526 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-
22 less of the date on which the drug was so designated, and
23 regardless of the date on which the drug was approved
24 under section 505 of such Act (21 U.S.C. 355) or licensed

1 under section 351 of the Public Health Service Act (42
2 U.S.C. 262).

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

4 Section 409I(d)(1) of the Public Health Service Act
5 (42 U.S.C. 284m(d)(1)) is amended by striking “section,”
6 and all that follows through the period at the end and
7 inserting “section, \$25,000,000 for each of fiscal years
8 2026 through 2028.”.

9 **SEC. 8. ORGAN PROCUREMENT AND TRANSPLANTATION**
10 **NETWORK.**

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

13 (1) in subsection (b)(2)—

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

16 (B) in subparagraph (A)—

17 (i) in clause (i), by striking “, and”
18 and inserting “; and”; and

19 (ii) in clause (ii), by striking the
20 comma at the end and inserting a semi-
21 colon;

22 (C) in subparagraph (C), by striking
23 “twenty-four-hour telephone service” and in-
24 serting “24-hour telephone or information tech-
25 nology service”;

1 (D) in each of subparagraphs (B) through
2 (M), by striking the comma at the end and in-
3 serting a semicolon;

4 (E) in subparagraph (N), by striking
5 “transportation, and” and inserting “transporta-
6 tion;”;

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

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

10 “(P) encourage the integration of elec-
11 tronic health records systems through applica-
12 tion programming interfaces (or successor tech-
13 nologies) among hospitals, organ procurement
14 organizations, and transplant centers, including
15 the use of automated electronic hospital refer-
16 rals and the grant of remote, electronic access
17 to hospital electronic health records of potential
18 donors by organ procurement organizations, in
19 a manner that complies with the privacy regula-
20 tions promulgated under the Health Insurance
21 Portability and Accountability Act of 1996, at
22 part 160 of title 45, Code of Federal Regula-
23 tions, and subparts A, C, and E of part 164 of
24 such title (or any successor regulations); and

1 “(Q) consider establishing a dashboard to
2 display the number of transplants performed,
3 the types of transplants performed, the number
4 and types of organs that entered the Organ
5 Procurement and Transplantation Network sys-
6 tem and failed to be transplanted, and other
7 appropriate statistics, which should be updated
8 more frequently than annually.”; and

9 (2) by adding at the end the following:

10 “(d) REGISTRATION FEES.—

11 “(1) IN GENERAL.—The Secretary may collect
12 registration fees from any member of the Organ
13 Procurement and Transplantation Network for each
14 transplant candidate such member places on the list
15 described in subsection (b)(2)(A)(i). Such registra-
16 tion fees shall be collected and distributed only to
17 support the operation of the Organ Procurement
18 and Transplantation Network. Such registration fees
19 are authorized to remain available until expended.

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

23 “(3) DISTRIBUTION.—Any amounts collected
24 under this subsection shall—

1 “(A) be credited to the currently applicable
2 appropriation, account, or fund of the Depart-
3 ment of Health and Human Services as discre-
4 tionary offsetting collections; and

5 “(B) be available, only to the extent and in
6 the amounts provided in advance in appropria-
7 tions Acts, to distribute such fees among
8 awardees described in subsection (b)(1)(A).

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

10 “(A) promptly post on the website of the
11 Organ Procurement and Transplantation Net-
12 work—

13 “(i) the amount of registration fees
14 collected under this subsection from each
15 member of the Organ Procurement and
16 Transplantation Network; and

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

19 “(B) update the information posted pursu-
20 ant to subparagraph (A), as applicable for each
21 calendar quarter for which fees are collected
22 under paragraph (1).

23 “(5) GAO REVIEW.—Not later than 2 years
24 after the date of enactment of this subsection, the

1 Comptroller General of the United States shall, to
2 the extent data are available—

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

5 “(B) submit to the Committee on Health,
6 Education, Labor, and Pensions and the Com-
7 mittee on Finance of the Senate and the Com-
8 mittee on Energy and Commerce of the House
9 of Representatives, a report on such review, in-
10 cluding related recommendations, as applicable.

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

15 **SEC. 9. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE**

16 **WITHIN FOOD AND DRUG ADMINISTRATION.**

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

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

21 “(a) IN GENERAL.—The Secretary, acting through
22 the Commissioner of Food and Drugs, shall establish with-
23 in the Food and Drug Administration an office, to be
24 known as the Abraham Accords Office, to be headed by
25 a director.

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

3 “(1) in consultation with the governments of
4 Abraham Accords countries, as well as appropriate
5 United States Government diplomatic and security
6 personnel—

7 “(A) select the location of the Abraham
8 Accords Office in an Abraham Accords country;
9 and

10 “(B) establish such office; and

11 “(2) assign to such office such personnel of the
12 Food and Drug Administration as the Secretary de-
13 termines necessary to carry out the functions of
14 such office.

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

17 “(1) after the Abraham Accords Office is estab-
18 lished—

19 “(A) as part of the Food and Drug Admin-
20 istration’s work to strengthen the international
21 oversight of regulated commodities, provide
22 technical assistance to regulatory partners in
23 Abraham Accords countries on strengthening
24 regulatory oversight and converging regulatory
25 requirements for the oversight of regulated

1 products, including good manufacturing prac-
2 tices and other issues relevant to manufacturing
3 medical products that are regulated by the
4 Food and Drug Administration; and

5 “(B) facilitate interactions between the
6 Food and Drug Administration and interested
7 parties in Abraham Accords countries, including
8 by sharing relevant information regarding
9 United States regulatory pathways with such
10 parties, and facilitate feedback on the research,
11 development, and manufacturing of products
12 regulated in accordance with this Act; and

13 “(2) carry out other functions and activities as
14 the Secretary determines to be necessary to carry
15 out this section.

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

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

24 (b) REPORT TO CONGRESS.—

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

6 (A) an evaluation of how the Office has ad-
7 vanced progress toward conformance with Food
8 and Drug Administration regulatory require-
9 ments by manufacturers in the Abraham Ac-
10 cords countries;

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

16 (C) a summary of technical assistance pro-
17 vided to regulatory partners in Abraham Ac-
18 cords countries pursuant to subparagraph (A)
19 of such section 1015(c)(1); and

20 (D) recommendations for increasing and
21 improving coordination between the Food and
22 Drug Administration and entities in Abraham
23 Accords countries.

24 (2) ABRAHAM ACCORDS COUNTRY DEFINED.—

25 In this subsection, the term “Abraham Accords

1 country” has the meaning given such term in section
2 1015(d) of the Federal Food, Drug, and Cosmetic
3 Act (as added by subsection (a)).

4 **SEC. 10. INCREASING TRANSPARENCY IN GENERIC DRUG**
5 **APPLICATIONS.**

6 (a) IN GENERAL.—Section 505(j)(3) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is
8 amended by adding at the end the following:

9 “(H)(i) Upon request (in controlled correspondence
10 or an analogous process) by a person that has submitted
11 or intends to submit an abbreviated application under this
12 subsection for a drug that is required by regulation to con-
13 tain one or more of the same inactive ingredients in the
14 same concentrations as the listed drug referred to, or for
15 which the Secretary determines there is a scientific jus-
16 tification for an approach that is in vitro, in whole or in
17 part, to be used to demonstrate bioequivalence for a drug
18 if such a drug contains one or more of the same inactive
19 ingredients in the same concentrations as the listed drug
20 referred to, the Secretary shall inform the person whether
21 such drug is qualitatively and quantitatively the same as
22 the listed drug. The Secretary may also provide such infor-
23 mation to such a person on the Secretary’s own initiative
24 during the review of an abbreviated application under this
25 subsection for such drug.

1 “(ii) Notwithstanding section 301(j), if the Secretary
2 determines that such drug is not qualitatively or quan-
3 titatively the same as the listed drug, the Secretary shall
4 identify and disclose to the person—

5 “(I) the ingredient or ingredients that cause
6 such drug not to be qualitatively or quantitatively
7 the same as the listed drug; and

8 “(II) for any ingredient for which there is an
9 identified quantitative deviation, the amount of such
10 deviation.

11 “(iii) If the Secretary determines that such drug is
12 qualitatively and quantitatively the same as the listed
13 drug, the Secretary shall not change or rescind such deter-
14 mination after the submission of an abbreviated applica-
15 tion for such drug under this subsection unless—

16 “(I) the formulation of the listed drug has been
17 changed and the Secretary has determined that the
18 prior listed drug formulation was withdrawn for rea-
19 sons of safety or effectiveness; or

20 “(II) the Secretary makes a written determina-
21 tion that the prior determination must be changed
22 because an error has been identified.

23 “(iv) If the Secretary makes a written determination
24 described in clause (iii)(II), the Secretary shall provide no-

1 tice and a copy of the written determination to the person
2 making the request under clause (i).

3 “(v) The disclosures authorized under clauses (i) and
4 (ii) are disclosures authorized by law, including for pur-
5 poses of section 1905 of title 18, United States Code. This
6 subparagraph shall not otherwise be construed to author-
7 ize the disclosure of nonpublic qualitative or quantitative
8 information about the ingredients in a listed drug, or to
9 affect the status, if any, of such information as trade se-
10 cret or confidential commercial information for purposes
11 of section 301(j) of this Act, section 552 of title 5, United
12 States Code, or section 1905 of title 18, United States
13 Code.”.

14 (b) GUIDANCE.—

15 (1) IN GENERAL.—Not later than one year
16 after the date of enactment of this Act, the Sec-
17 retary of Health and Human Services shall issue
18 draft guidance, or update guidance, describing how
19 the Secretary will determine whether a drug is quali-
20 tatively and quantitatively the same as the listed
21 drug (as such terms are used in section
22 505(j)(3)(H) of the Federal Food, Drug, and Cos-
23 metic Act, as added by subsection (a)), including
24 with respect to assessing pH adjusters.

1 (2) PROCESS.—In issuing guidance under this
 2 subsection, the Secretary of Health and Human
 3 Services shall—

4 (A) publish draft guidance;

5 (B) provide a period of at least 60 days for
 6 comment on the draft guidance; and

7 (C) after considering any comments re-
 8 ceived and not later than one year after the
 9 close of the comment period on the draft guid-
 10 ance, publish final guidance.

11 (c) APPLICABILITY.—Section 505(j)(3)(H) of the
 12 Federal Food, Drug, and Cosmetic Act, as added by sub-
 13 section (a), applies beginning on the date of enactment
 14 of this Act, irrespective of the date on which the guidance
 15 required by subsection (b) is finalized.

16 **SEC. 11. MEDICARE IMPROVEMENT FUND.**

17 Section 1898(b)(1) of the Social Security Act (42
 18 U.S.C. 1395iii(b)(1)) is amended by striking
 19 “\$1,403,000,000” and inserting “\$2,622,000,000”.

 Passed the House of Representatives December 1,
 2025.

Attest:

Clerk.

119TH CONGRESS
1ST SESSION

H. R. 1262

AN ACT

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