

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
OFFERED BY MR. BILIRAKIS OF FLORIDA**

Strike all after the enacting clause and insert the
following:

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “Give Kids a Chance Act of 2024”.

4 (b) **TABLE OF CONTENTS.**—The table of contents for
5 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—GIVE KIDS A CHANCE

Sec. 101. Research into pediatric uses of drugs; additional authorities of Food
and Drug Administration regarding molecularly targeted cancer
drugs.

Sec. 102. Ensuring completion of pediatric study requirements.

Sec. 103. FDA report on PREA enforcement.

Sec. 104. Extension of authority to issue priority review vouchers to encourage
treatments for rare pediatric diseases.

Sec. 105. Limitations on exclusive approval or licensure of orphan drugs.

Sec. 106. Program for pediatric studies of drugs.

TITLE II—UNITED STATES-ABRAHAM ACCORDS COOPERATION
AND SECURITY

Sec. 201. Establishment of Abraham Accords Office within Food and Drug Ad-
ministration.

TITLE III—ORGAN PROCUREMENT AND TRANSPLANTATION
NETWORK

Sec. 301. Registration fees.

1 **TITLE I—GIVE KIDS A CHANCE**

2 **SEC. 101. RESEARCH INTO PEDIATRIC USES OF DRUGS; AD-**
3 **DITIONAL AUTHORITIES OF FOOD AND DRUG**
4 **ADMINISTRATION REGARDING MOLECU-**
5 **LARLY TARGETED CANCER DRUGS.**

6 (a) IN GENERAL.—

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

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

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

17 “(A) IN GENERAL.—For purposes of para-
18 graph (1)(B), the investigation described in this
19 paragraph is (as determined by the Secretary)
20 a molecularly targeted pediatric cancer inves-
21 tigation of—

22 “(i) the drug or biological product for
23 which the application referred to in such
24 paragraph is submitted; or

1 “(ii) such drug or biological product
2 in combination with—

3 “(I) an active ingredient of a
4 drug or biological product—

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

10 “(bb) that is determined by
11 the Secretary to be the standard
12 of care for treating a pediatric
13 cancer; or

14 “(II) an active ingredient of a
15 drug or biological product—

16 “(aa) for which an approved
17 application under section 505(b)
18 of this Act or section 351(a) of
19 the Public Health Service Act to
20 treat an adult cancer is in effect
21 and is held by the same person
22 submitting the application under
23 paragraph (1)(B); and

24 “(bb) that is directed at a
25 molecular target that the Sec-

1 retary determines to be substan-
2 tially relevant to the growth or
3 progression of a pediatric cancer.

4 “(B) ADDITIONAL REQUIREMENTS.—

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

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

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

22 “(II) more than one active ingre-
23 dient, if an application for the com-
24 bination of active ingredients has not
25 previously been approved but each ac-

1 tive ingredient has been previously ap-
2 proved to treat an adult cancer.

3 “(iii) RESULTS OF ALREADY-COM-
4 PLETED PRECLINICAL STUDIES OF APPLI-
5 CATION DRUG.—The Secretary may re-
6 quire that reports on an investigation re-
7 quired pursuant to paragraph (1)(B) in-
8 clude the results of all preclinical studies
9 on which the decision to conduct such in-
10 vestigation was based.

11 “(iv) RULE OF CONSTRUCTION RE-
12 GARDING INACTIVE INGREDIENTS.—With
13 respect to a combination of active ingredi-
14 ents referred to in subparagraph (A)(ii),
15 such subparagraph shall not be construed
16 as addressing the use of inactive ingredi-
17 ents with such combination.”.

18 (2) DETERMINATION OF APPLICABLE REQUIRE-
19 MENTS.—Section 505B(e)(1) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is
21 amended by adding at the end the following: “The
22 Secretary shall determine whether subparagraph (A)
23 or (B) of subsection (a)(1) shall apply with respect
24 to an application before the date on which the appli-

1 cant is required to submit the initial pediatric study
2 plan under paragraph (2)(A).”.

3 (3) CLARIFYING APPLICABILITY.—Section
4 505B(a)(1) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 355c(a)(1)) is amended by
6 adding at the end the following:

7 “(C) RULE OF CONSTRUCTION.—No appli-
8 cation that is subject to the requirements of
9 subparagraph (B) shall be subject to the re-
10 quirements of subparagraph (A), and no appli-
11 cation (or supplement to an application) that is
12 subject to the requirements of subparagraph
13 (A) shall be subject to the requirements of sub-
14 paragraph (B).”.

15 (4) CONFORMING AMENDMENTS.—Section
16 505B(a) of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 355c(a)) is amended—

18 (A) in paragraph (3)(C), as redesignated
19 by paragraph (1)(A) of this subsection, by
20 striking “investigations described in this para-
21 graph” and inserting “investigations referred to
22 in subparagraph (A)”; and

23 (B) in paragraph (3)(D), as redesignated
24 by paragraph (1)(A) of this subsection, by
25 striking “the assessments under paragraph

1 (2)(B)” and inserting “the assessments re-
2 quired under paragraph (1)(A)”.

3 (b) GUIDANCE.—The Secretary of Health and
4 Human Services, acting through the Commissioner of
5 Food and Drugs, shall—

6 (1) not later than 12 months after the date of
7 enactment of this Act, issue draft guidance on the
8 implementation of the amendments made by sub-
9 section (a); and

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

13 (c) APPLICABILITY.—The amendments made by this
14 section apply with respect to any application under section
15 505(b) of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 355(b)) and any application under section 351(a)
17 of the Public Health Service Act (42 U.S.C. 262(a)), that
18 is submitted on or after the date that is 3 years after the
19 date of enactment of this Act.

20 (d) REPORTS TO CONGRESS.—

21 (1) SECRETARY OF HEALTH AND HUMAN SERV-
22 ICES.—Not later than 2 years after the date of en-
23 actment of this Act, the Secretary of Health and
24 Human Services shall submit to the Committee on
25 Energy and Commerce of the House of Representa-

1 tives and the Committee on Health, Education,
2 Labor, and Pensions of the Senate a report on the
3 Secretary's efforts, in coordination with industry, to
4 ensure implementation of the amendments made by
5 subsection (a).

6 (2) GAO STUDY AND REPORT.—

7 (A) STUDY.—Not later than 3 years after
8 the date of enactment of this Act, the Comp-
9 troller General of the United States shall con-
10 duct a study of the effectiveness of requiring
11 assessments and investigations described in sec-
12 tion 505B of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C.355c), as amended by sub-
14 section (a), in the development of drugs and bi-
15 ological products for pediatric cancer indica-
16 tions.

17 (B) FINDINGS.—Not later than 7 years
18 after the date of enactment of this Act, the
19 Comptroller General shall submit to the Com-
20 mittee on Energy and Commerce of the House
21 of Representatives and the Committee on
22 Health, Education, Labor, and Pensions of the
23 Senate a report containing the findings of the
24 study conducted under subparagraph (A).

1 **SEC. 102. ENSURING COMPLETION OF PEDIATRIC STUDY**
2 **REQUIREMENTS.**

3 (a) **EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY**
4 **REQUIREMENTS.**—Section 505B(d) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 355e(d)) is amend-
6 ed—

7 (1) in paragraph (1), by striking “Beginning
8 270” and inserting “**NONCOMPLIANCE LETTER.**—
9 Beginning 270”;

10 (2) in paragraph (2)—

11 (A) by striking “The drug or” and insert-
12 ing “**EFFECT OF NONCOMPLIANCE.**—The drug
13 or”;

14 (B) by striking “(except that the drug or
15 biological product shall not be subject to action
16 under section 303)” and inserting “(except that
17 the drug or biological product shall be subject
18 to action under section 303 only if such person
19 demonstrated a lack of due diligence in satis-
20 fying the applicable requirement)”;

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

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

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

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

9 “(A) issue a noncompliance letter pursuant
10 to paragraph (1);

11 “(B) provide such person with a 45-day
12 period beginning on the date of receipt of such
13 noncompliance letter to respond in writing as
14 set forth in such paragraph; and

15 “(C) after reviewing such written response,
16 determine whether the person demonstrated a
17 lack of due diligence in satisfying such require-
18 ment.”.

19 (c) CONFORMING AMENDMENTS.—Section
20 303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 333(f)(4)(A)) is amended by striking “or 505-
22 1” and inserting “505-1, or 505B”.

23 (d) TRANSITION RULE.—The Secretary of Health
24 and Human Services may take enforcement action under
25 section 303 of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 333) only for failures described in section
2 505B(d) of such Act (21 U.S.C. 355c(d)) that occur on
3 or after the date that is 180 days after the date of enact-
4 ment of this Act.

5 **SEC. 103. FDA REPORT ON PREA ENFORCEMENT.**

6 Section 508(b) of the Food and Drug Administration
7 Safety and Innovation Act (21 U.S.C. 355c-1(b)) is
8 amended—

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

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

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

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

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

1 **SEC. 104. EXTENSION OF AUTHORITY TO ISSUE PRIORITY**
2 **REVIEW VOUCHERS TO ENCOURAGE TREAT-**
3 **MENTS FOR RARE PEDIATRIC DISEASES.**

4 (a) EXTENSION.—Paragraph (5) of section 529(b) of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 360ff(b)) is amended by striking “September 30, 2024,
7 unless” and all that follows through the period at the end
8 and inserting “September 30, 2029.”.

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

13 (1) GAO STUDY.—

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

23 (B) CONTENTS OF STUDY.—In conducting
24 the study under subparagraph (A), the Comp-
25 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. 105. LIMITATIONS ON EXCLUSIVE APPROVAL OR LI-**
6 **CENSURE 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. 106. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

20 Section 409I(d) of the Public Health Service Act (42
21 U.S.C. 284m(d)) is amended to read as follows:

22 “(d) FUNDING.—Of the amount made available for
23 pediatric research to each national research institute and
24 national center under this title for each of fiscal years
25 2025, 2026, and 2027, the Director of NIH is authorized

1 to make available up to one percent of such amount for
2 pediatric research under this section.”.

3 **TITLE II—UNITED STATES-ABRA-**
4 **HAM ACCORDS COOPERATION**
5 **AND SECURITY**

6 **SEC. 201. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE**
7 **WITHIN FOOD AND DRUG ADMINISTRATION.**

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

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

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

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

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

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

1 “(B) establish such office; and

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

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

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

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

21 “(B) facilitate interactions between the
22 Food and Drug Administration and interested
23 parties in Abraham Accords countries, including
24 by sharing relevant information regarding

1 United States regulatory pathways with such
2 parties; and

3 “(C) facilitate feedback between the Food
4 and Drug Administration and such parties lo-
5 cated within Abraham Accords countries prior
6 to submission of an application under section
7 505(b), 505(j), or 515 of this Act or section
8 351(a) or 351(k) of the Public Health Service
9 Act, or a notification under section 510(k) of
10 this Act, such as feedback on research, develop-
11 ment, and manufacturing of drugs, biologics,
12 and medical devices; 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 (b) REPORT TO CONGRESS.—

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

1 (A) an evaluation of how the Office has ad-
2 vanced progress toward conformance with Food
3 and Drug Administration regulatory require-
4 ments by manufacturers in the Abraham Ac-
5 cords countries;

6 (B) a numerical count of parties that the
7 Office has helped facilitate interactions or feed-
8 back pursuant to subparagraphs (B) and (C) of
9 section 1015(c)(1) of the Federal Food, Drug,
10 and Cosmetic Act (as added by subsection (a));

11 (C) a summary of technical assistance pro-
12 vided to regulatory partners in Abraham Ac-
13 cords countries pursuant to subparagraph (A)
14 of such section 1015(c)(1); and

15 (D) recommendations for increasing and
16 improving coordination between the Food and
17 Drug Administration and entities in Abraham
18 Accords countries.

19 (2) ABRAHAM ACCORDS COUNTRY DEFINED.—
20 In this subsection, the term “Abraham Accords
21 country” has the meaning given such term in section
22 1015(d) of the Federal Food, Drug, and Cosmetic
23 Act (as added by subsection (a)).

1 **TITLE III—ORGAN PROCUREMENT**
2 **AND TRANSPLANTATION NETWORK**
3

4 **SEC. 301. REGISTRATION FEES.**

5 Section 372 of the Public Health Service Act (42
6 U.S.C. 274) is amended by adding at the end the fol-
7 lowing:

8 “(d) REGISTRATION FEES.—

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

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

21 “(3) DISTRIBUTION.—The Secretary may dis-
22 tribute such fees among the awardees described in
23 subsection (b)(1)(A).

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

1 “(A) promptly post on the Internet website
2 of the Organ Procurement and Transplant 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-

1 cluding related recommendations, as applica-
2 ble.”.

