

118TH CONGRESS
2D SESSION

H. R. 3433

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 24, 2024

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with
respect to molecularly targeted pediatric cancer investiga-
tions, 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 “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.

6 **TITLE I—GIVE KIDS A CHANCE**

7 **SEC. 101. RESEARCH INTO PEDIATRIC USES OF DRUGS; AD-**
8 **DITIONAL AUTHORITIES OF FOOD AND DRUG**
9 **ADMINISTRATION REGARDING MOLECU-**
10 **LARLY TARGETED CANCER DRUGS.**

11 (a) IN GENERAL.—

12 (1) ADDITIONAL ACTIVE INGREDIENT FOR AP-
13 PPLICATION DRUG; LIMITATION REGARDING NOVEL-
14 COMBINATION APPLICATION DRUG.—Section

1 505B(a)(3) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 355c(a)(3)) is amended—

3 (A) by redesignating subparagraphs (B)
4 and (C) as subparagraphs (C) and (D), respec-
5 tively; and

6 (B) by striking subparagraph (A) and in-
7 serting the following:

8 “(A) IN GENERAL.—For purposes of para-
9 graph (1)(B), the investigation described in this
10 paragraph is (as determined by the Secretary)
11 a molecularly targeted pediatric cancer inves-
12 tigation of—

13 “(i) the drug or biological product for
14 which the application referred to in such
15 paragraph is submitted; or

16 “(ii) such drug or biological product
17 in combination with—

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

20 “(aa) for which an approved
21 application under section 505(j)
22 under this Act or under section
23 351(k) of the Public Health
24 Service Act is in effect; and

1 “(bb) that is determined by
2 the Secretary to be the standard
3 of care for treating a pediatric
4 cancer; or

5 “(II) an active ingredient of a
6 drug or biological product—

7 “(aa) for which an approved
8 application under section 505(b)
9 of this Act or section 351(a) of
10 the Public Health Service Act to
11 treat an adult cancer is in effect
12 and is held by the same person
13 submitting the application under
14 paragraph (1)(B); and

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

20 “(B) ADDITIONAL REQUIREMENTS.—

21 “(i) DESIGN OF INVESTIGATION.—A
22 molecularly targeted pediatric cancer inves-
23 tigation referred to in subparagraph (A)
24 shall be designed to yield clinically mean-
25 ingful pediatric study data that is gathered

1 using appropriate formulations for each
2 age group for which the study is required,
3 regarding dosing, safety, and preliminary
4 efficacy to inform potential pediatric label-
5 ing.

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

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

13 “(II) more than one active ingre-
14 dient, if an application for the com-
15 bination of active ingredients has not
16 previously been approved but each ac-
17 tive ingredient has been previously ap-
18 proved to treat an adult cancer.

19 “(iii) RESULTS OF ALREADY-COM-
20 PLETED PRECLINICAL STUDIES OF APPLI-
21 CATION DRUG.—The Secretary may re-
22 quire that reports on an investigation re-
23 quired pursuant to paragraph (1)(B) in-
24 clude the results of all preclinical studies

on which the decision to conduct such investigation was based.

“(iv) RULE OF CONSTRUCTION REGARDING INACTIVE INGREDIENTS.—With respect to a combination of active ingredients referred to in subparagraph (A)(ii), such subparagraph shall not be construed as addressing the use of inactive ingredients with such combination.”.

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

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

“(C) RULE OF CONSTRUCTION.—No application that is subject to the requirements of subparagraph (B) shall be subject to the re-

1 requirements of subparagraph (A), and no appli-
2 cation (or supplement to an application) that is
3 subject to the requirements of subparagraph
4 (A) shall be subject to the requirements of sub-
5 paragraph (B).”.

6 (4) CONFORMING AMENDMENTS.—Section
7 505B(a) of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 355c(a)) is amended—

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

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

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

22 (1) not later than 12 months after the date of
23 enactment of this Act, issue draft guidance on the
24 implementation of the amendments made by sub-
25 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 2 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 3 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.

(B) FINDINGS.—Not later than 7 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. 102. 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) in paragraph (1), by striking “Beginning 270” and inserting “NONCOMPLIANCE LETTER.—Beginning 270”;

(2) in paragraph (2)—

1 (A) by striking “The drug or” and insert-
2 ing “EFFECT OF NONCOMPLIANCE.—The drug
3 or”; and

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

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

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

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

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

24 “(A) issue a noncompliance letter pursuant
25 to paragraph (1);

1 “(B) provide such person with a 45-day
2 period beginning on the date of receipt of such
3 noncompliance letter to respond in writing as
4 set forth in such paragraph; and

5 “(C) after reviewing such written response,
6 determine whether the person demonstrated a
7 lack of due diligence in satisfying such require-
8 ment.”.

9 (c) CONFORMING AMENDMENTS.—Section
10 303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 333(f)(4)(A)) is amended by striking “or 505–
12 1” and inserting “505–1, or 505B”.

13 (d) TRANSITION RULE.—The Secretary of Health
14 and Human Services may take enforcement action under
15 section 303 of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 333) only for failures described in section
17 505B(d) of such Act (21 U.S.C. 355c(d)) that occur on
18 or after the date that is 180 days after the date of enact-
19 ment of this Act.

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

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

24 (1) in paragraph (11), by striking the semicolon
25 at the end and inserting “, including an evaluation

1 of compliance with deadlines provided for in defer-
2 rals and deferral extensions;”;

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

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

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

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

16 **SEC. 104. EXTENSION OF AUTHORITY TO ISSUE PRIORITY**
17 **REVIEW VOUCHERS TO ENCOURAGE TREAT-**
18 **MENTS FOR RARE PEDIATRIC DISEASES.**

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

24 (b) GAO REPORT ON EFFECTIVENESS OF RARE PE-
25 DIATRIC DISEASE PRIORITY VOUCHER AWARDS IN

1 INCENTIVIZING RARE PEDIATRIC DISEASE DRUG DEVEL-
2 OPMENT.—

3 (1) GAO STUDY.—

4 (A) STUDY.—The Comptroller General of
5 the United States shall conduct a study of the
6 effectiveness of awarding rare pediatric disease
7 priority vouchers under section 529 of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C.
9 360ff), as amended by subsection (a), in the de-
10 velopment of human drug products that treat or
11 prevent rare pediatric diseases (as defined in
12 such section 529).

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

16 (i) The indications for each drug or
17 biological product that—

18 (I) is the subject of a rare pedi-
19 atric disease product application (as
20 defined in section 529 of the Federal
21 Food, Drug, and Cosmetic Act (21
22 U.S.C. 360ff)) for which a priority re-
23 view voucher was awarded; and

24 (II) was approved under section
25 505 of the Federal Food, Drug, and

1 Cosmetic Act (42 U.S.C. 355) or li-
2 censed under section 351 of the Pub-
3 lic Health Service Act (42 U.S.C.
4 262).

5 (ii) Whether, and to what extent, an
6 unmet need related to the treatment or
7 prevention of a rare pediatric disease was
8 met through the approval or licensure of
9 such a drug or biological product.

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

15 (iv) The value of such priority review
16 voucher if transferred.

17 (v) Identification of each drug for
18 which a priority review voucher awarded
19 under such section 529 was used.

20 (vi) The size of the company using
21 each priority review voucher awarded
22 under such section 529.

23 (vii) The length of the period of time
24 between the date on which a priority re-
25 view voucher was awarded under such sec-

tion 529 and the date on which it was used.

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

(ix) Whether, and to what extent, companies were motivated by the availability of priority review vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) to attempt to develop a drug for a rare pediatric disease.

(x) Whether, and to what extent, pediatric review vouchers awarded under such section were successful in stimulating development and expedited patient access to drug products for treatment or prevention of a rare pediatric disease that wouldn't

otherwise take place without the incentive provided by such vouchers.

(xi) The impact of such priority review vouchers on the workload, review process, and public health prioritization efforts of the Food and Drug Administration.

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

(2) REPORT ON FINDINGS.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States 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 paragraph (1).

SEC. 105. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICENSURE OF ORPHAN DRUGS.

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

(1) in subsection (a), in the matter following paragraph (2), by striking “same disease or condi-

1 tion” and inserting “same approved use or indica-
2 tion within such rare disease or condition”;

3 (2) in subsection (b)—

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

9 (B) in paragraph (1), by inserting “, relat-
10 ing to the approved use or indication,” after
11 “the needs”;

12 (3) in subsection (c)(1), by striking “same rare
13 disease or condition as the already approved drug”
14 and inserting “same use or indication for which the
15 already approved or licensed drug was approved or
16 licensed”; and

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

18 “(f) APPROVED USE OR INDICATION DEFINED.—In
19 this section, the term ‘approved use or indication’ means
20 the use or indication approved under section 505 of this
21 Act or licensed under section 351 of the Public Health
22 Service Act for a drug designated under section 526 for
23 a rare disease or condition.”.

24 (b) APPLICATION OF AMENDMENTS.—The amend-
25 ments made by subsection (a) shall apply with respect to

1 any drug designated under section 526 of the Federal
 2 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-
 3 less of the date on which the drug was so designated, and
 4 regardless of the date on which the drug was approved
 5 under section 505 of such Act (21 U.S.C. 355) or licensed
 6 under section 351 of the Public Health Service Act (42
 7 U.S.C. 262).

8 **SEC. 106. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.**

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

11 “(d) FUNDING.—Of the amount made available for
 12 pediatric research to each national research institute and
 13 national center under this title for each of fiscal years
 14 2025, 2026, and 2027, the Director of NIH is authorized
 15 to make available up to one percent of such amount for
 16 pediatric research under this section.”.

17 **TITLE II—UNITED STATES-ABRA-**
 18 **HAM ACCORDS COOPERATION**
 19 **AND SECURITY**

20 **SEC. 201. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE**
 21 **WITHIN FOOD AND DRUG ADMINISTRATION.**

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

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

2 “(a) IN GENERAL.—The Secretary, acting through
3 the Commissioner of Food and Drugs, shall establish with-
4 in the Food and Drug Administration an office, to be
5 known as the Abraham Accords Office, to be headed by
6 a director.

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

9 “(1) in consultation with the governments of
10 Abraham Accords countries, as well as appropriate
11 United States Government diplomatic and security
12 personnel—

13 “(A) select the location of the Abraham
14 Accords Office in an Abraham Accords country;
15 and

16 “(B) establish such office; and

17 “(2) assign to such office such personnel of the
18 Food and Drug Administration as the Secretary de-
19 termines necessary to carry out the functions of
20 such office.

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

23 “(1) after the Abraham Accords Office is estab-
24 lished—

25 “(A) as part of the Food and Drug Admin-
26 istration’s work to strengthen the international

1 oversight of regulated commodities, provide
2 technical assistance to regulatory partners in
3 Abraham Accords countries on strengthening
4 regulatory oversight and converging regulatory
5 requirements for the oversight of regulated
6 products, including good manufacturing prac-
7 tices and other issues relevant to manufacturing
8 medical products that are regulated by the
9 Food and Drug Administration;

10 “(B) facilitate interactions between the
11 Food and Drug Administration and interested
12 parties in Abraham Accords countries, including
13 by sharing relevant information regarding
14 United States regulatory pathways with such
15 parties; and

16 “(C) facilitate feedback between the Food
17 and Drug Administration and such parties lo-
18 cated within Abraham Accords countries prior
19 to submission of an application under section
20 505(b), 505(j), or 515 of this Act or section
21 351(a) or 351(k) of the Public Health Service
22 Act, or a notification under section 510(k) of
23 this Act, such as feedback on research, develop-
24 ment, and manufacturing of drugs, biologics,
25 and medical devices; and

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

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

8 (b) REPORT TO CONGRESS.—

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

14 (A) an evaluation of how the Office has ad-
15 vanced progress toward conformance with Food
16 and Drug Administration regulatory require-
17 ments by manufacturers in the Abraham Ac-
18 cords countries;

19 (B) a numerical count of parties that the
20 Office has helped facilitate interactions or feed-
21 back pursuant to subparagraphs (B) and (C) of
22 section 1015(c)(1) of the Federal Food, Drug,
23 and Cosmetic Act (as added by subsection (a));

24 (C) a summary of technical assistance pro-
25 vided to regulatory partners in Abraham Ac-

1 cords countries pursuant to subparagraph (A)
 2 of such section 1015(c)(1); and

3 (D) recommendations for increasing and
 4 improving coordination between the Food and
 5 Drug Administration and entities in Abraham
 6 Accords countries.

7 (2) ABRAHAM ACCORDS COUNTRY DEFINED.—

8 In this subsection, the term “Abraham Accords
 9 country” has the meaning given such term in section
 10 1015(d) of the Federal Food, Drug, and Cosmetic
 11 Act (as added by subsection (a)).

12 **TITLE III—ORGAN PROCUREMENT**
 13 **AND TRANSPLANTATION**
 14 **NETWORK**

15 **SEC. 301. REGISTRATION FEES.**

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

19 “(d) REGISTRATION FEES.—

20 “(1) IN GENERAL.—The Secretary may collect
 21 registration fees from any member of the Organ
 22 Procurement and Transplantation Network for each
 23 transplant candidate such member places on the list
 24 described in subsection (b)(2)(A)(i). Such registra-
 25 tion fees shall only be collected and distributed to

1 support the operation of the Organ Procurement
2 and Transplantation Network. Such registration fees
3 are authorized to remain available until expended.

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

7 “(3) DISTRIBUTION.—Any amounts collected
8 under this subsection shall—

9 “(A) be credited to the currently applicable
10 appropriation, account, or fund of the Depart-
11 ment of Health and Human Services as discre-
12 tionary offsetting collections; and

13 “(B) be available, only to the extent and in
14 the amounts provided in advance in appropria-
15 tions Acts, to distribute such fees among the
16 awardees described in subsection (b)(1)(A).

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

18 “(A) promptly post on the Internet website
19 of the Organ Procurement and Transplant Net-
20 work—

21 “(i) the amount of registration fees
22 collected under this subsection from each
23 member of the Organ Procurement and
24 Transplantation Network; and

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

“(B) submit to the Committee on Health,
Education, Labor, and Pensions and the Com-
mittee on Finance of the Senate and the Com-
mittee on Energy and Commerce of the House
of Representatives, a report on such review, in-
cluding related recommendations, as applica-
ble.”.

Attest: KEVIN F. MCCUMBER,
Clerk.