118TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
118–700

GIVE KIDS A CHANCE ACT OF 2024

SEPTEMBER 20, 2024.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mrs. RODGERS of Washington, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 3433]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3433) to amend the Federal Food, Drug, and Cosmetic Act with respect to molecularly targeted pediatric cancer investigations, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Give Kids a Chance Act of 2024".

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

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.

(a) IN GENERAL.—

(1) ADDITIONAL ACTIVE INGREDIENT FOR APPLICATION DRUG; LIMITATION REGARDING NOVEL-COMBINATION APPLICATION DRUG.—Section 505B(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(3)) is amended—

(A) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively; and

(B) by striking subparagraph (A) and inserting the following:

"(A) IN GENERAL.—For purposes of paragraph (1)(B), the investigation described in this paragraph is (as determined by the Secretary) a molecularly targeted pediatric cancer investigation of—

"(i) the drug or biological product for which the application referred to in such paragraph is submitted; or

"(ii) such drug or biological product in combination with—

"(I) an active ingredient of a drug or biological product—

"(aa) for which an approved application under section 505(j) under this Act or under section 351(k) of the Public Health Service Act is in effect; and

"(bb) that is determined by the Secretary to be the standard of care for treating a pediatric cancer; or

"(II) an active ingredient of a drug or biological product—

"(aa) for which an approved application under section 505(b) of this Act or section 351(a) of the Public Health Service Act to treat an adult cancer is in effect 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 Secretary determines to be substantially relevant to the growth or progression of a pediatric cancer.

"(B) ADDITIONAL REQUIREMENTS.—

"(i) DESIGN OF INVESTIGATION.—A molecularly targeted pediatric cancer investigation referred to in subparagraph (A) shall be designed to yield clinically meaningful 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 labeling.

"(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 ingredient; or

"(II) more than one active ingredient, if an application for the combination of active ingredients has not previously been approved but each active ingredient has been previously approved to treat an adult cancer.

"(iii) RESULTS OF ALREADY-COMPLETED PRECLINICAL STUDIES OF APPLICATION DRUG.—The Secretary may require that reports on an investiga-

tion required pursuant to paragraph (1)(B) include 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 requirements of subparagraph (A), and no application (or supplement to an application) that is subject to the requirements of subparagraph (A) shall be subject to the requirements of subparagraph (B).".

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

(A) in paragraph (3)(C), as redesignated by paragraph (1)(A) of this subsection, by striking "investigations described in this paragraph" and inserting "investigations referred to in subparagraph (A)"; and

(B) in paragraph (3)(D), as redesignated by paragraph (1)(A) of this subsection, by striking "the assessments under paragraph (2)(B)" and inserting "the assessments required under paragraph (1)(A)".

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

(1) not later than 12 months after the date of enactment of this Act, issue draft guidance on the implementation of the amendments made by subsection (a); and

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

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

(d) REPORTS TO CONGRESS.—

(1) SECRETARY OF HEALTH AND HUMAN SERVICES.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services 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 on the Secretary's efforts, in coordination with industry, to ensure implementation of the amendments made by subsection (a).

(2) GAO STUDY AND REPORT.—

(A) STUDY.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct 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)—

(A) by striking "The drug or" and inserting "EFFECT OF NONCOMPLIANCE.—The drug or"; and

(B) by striking "(except that the drug or biological product shall not be subject to action under section 303)" and inserting "(except that the drug or biological product shall be subject to action under section 303 only if such person demonstrated a lack of due diligence in satisfying the applicable requirement)"; and

(3) by adding at the end the following:

"(3) LIMITATION.—The Secretary shall not issue enforcement actions under section 303 for failures under this subsection in the case of a drug or biological product that is no longer marketed.".

(b) DUE DILIGENCE.—Section 505B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)), as amended by subsection (a), is further amended by adding at the end the following:

"(4) DUE DILIGENCE.—Before the Secretary may conclude that a person failed to submit or otherwise meet a requirement as described in the matter preceding paragraph (1), the Secretary shall—

"(A) issue a noncompliance letter pursuant to paragraph (1);

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

"(C) after reviewing such written response, determine whether the person demonstrated a lack of due diligence in satisfying such requirement.".

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

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

SEC. 103. FDA REPORT ON PREA ENFORCEMENT.

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

(1) in paragraph (11), by striking the semicolon at the end and inserting ", including an evaluation of compliance with deadlines provided for in deferrals and deferral extensions;";

(2) in paragraph (15), by striking "and" at the end;

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

(4) by adding at the end the following:

"(17) a listing of penalties, settlements, or payments under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353) for failure to comply with requirements under such section 505B, including, for each penalty, settlement, or payment, the name of the drug, the sponsor thereof, and the amount of the penalty, settlement, or payment imposed; and".

SEC. 104. EXTENSION OF AUTHORITY TO ISSUE PRIORITY REVIEW VOUCHERS TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

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

(b) GAO REPORT ON EFFECTIVENESS OF RARE PEDIATRIC DISEASE PRIORITY VOUCHER AWARDS IN INCENTIVIZING RARE PEDIATRIC DISEASE DRUG DEVELOPMENT.—

(1) GAO STUDY.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study of the effectiveness of awarding rare pediatric disease priority vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff), as amended by subsection (a), in the development of human drug products that treat or prevent rare pediatric diseases (as defined in such section 529).

(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

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

(I) is the subject of a rare pediatric disease product application (as defined in section 529 of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 360ff)) for which a priority review voucher was awarded; and

(II) was approved under section 505 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

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

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

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

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

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

(vii) The length of the period of time between the date on which a priority review voucher was awarded under such section 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 condition" and inserting "same approved use or indication within such rare disease or condition";

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "same rare disease or condition" and inserting "same approved use or indication for which such 7-year period applies to such already approved or licensed drug"; and

(B) in paragraph (1), by inserting ", relating to the approved use or indication," after "the needs";

(3) in subsection (c)(1), by striking "same rare disease or condition as the already approved drug" and inserting "same use or indication for which the already approved or licensed drug was approved or licensed"; and

(4) by adding at the end the following:

"(f) APPROVED USE OR INDICATION DEFINED.—In this section, the term 'approved use or indication' means the use or indication approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act for a drug designated under section 526 for a rare disease or condition.".

(b) APPLICATION OF AMENDMENTS.—The amendments made by subsection (a) shall apply with respect to any drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regardless of the date on which the drug was so designated, and regardless of the date on which the drug was approved

under section 505 of such Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 106. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

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

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

TITLE II—UNITED STATES-ABRAHAM ACCORDS COOPERATION AND SECURITY

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

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

"SEC. 1015. ABRAHAM ACCORDS OFFICE.

"(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration an office, to be known as the Abraham Accords Office, to be headed by a director.

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

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

"(A) select the location of the Abraham Accords Office in an Abraham Accords country; and

"(B) establish such office; and

"(2) assign to such office such personnel of the Food and Drug Administration as the Secretary determines necessary to carry out the functions of such office.

"(c) DUTIES.—The Secretary, acting through the Director of the Abraham Accords Office, shall—

"(1) after the Abraham Accords Office is established—

"(A) as part of the Food and Drug Administration's work to strengthen the international oversight of regulated commodities, provide technical assistance to regulatory partners in Abraham Accords countries on strengthening regulatory oversight and converging regulatory requirements for the oversight of regulated products, including good manufacturing practices and other issues relevant to manufacturing medical products that are regulated by the Food and Drug Administration;

"(B) facilitate interactions between the Food and Drug Administration and interested parties in Abraham Accords countries, including by sharing relevant information regarding United States regulatory pathways with such parties; and

"(C) facilitate feedback between the Food and Drug Administration and such parties located within Abraham Accords countries prior to submission of an application under section 505(b), 505(j), or 515 of this Act or section 351(a) or 351(k) of the Public Health Service Act, or a notification under section 510(k) of this Act, such as feedback on research, development, and manufacturing of drugs, biologics, and medical devices; and

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

"(d) ABRAHAM ACCORDS COUNTRY DEFINED.—In this section, the term 'Abraham Accords country' means a country identified by the Department of State as having signed the Abraham Accords Declaration.".

(b) REPORT TO CONGRESS.—

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

(A) an evaluation of how the Office has advanced progress toward conformance with Food and Drug Administration regulatory requirements by manufacturers in the Abraham Accords countries;

(B) a numerical count of parties that the Office has helped facilitate interactions or feedback pursuant to subparagraphs (B) and (C) of section

1015(c)(1) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a));

(C) a summary of technical assistance provided to regulatory partners in Abraham Accords countries pursuant to subparagraph (A) of such section 1015(c)(1); and

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

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

TITLE III—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

SEC. 301. REGISTRATION FEES.

Section 372 of the Public Health Service Act (42 U.S.C. 274) is amended by adding at the end the following:

"(d) REGISTRATION FEES.—

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

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

"(3) DISTRIBUTION.—The Secretary may distribute such fees among the awardees described in subsection (b)(1)(A).

"(4) TRANSPARENCY.—The Secretary shall—

"(A) promptly post on the Internet website of the Organ Procurement and Transplant Network—

"(i) the amount of registration fees collected under this subsection from each member of the Organ Procurement and Transplantation Network; and

"(ii) a list of activities such fees are used to support; and

"(B) update the information posted pursuant to subparagraph (A), as applicable for each calendar quarter for which fees are collected under paragraph (1).

"(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—

"(A) conduct a review concerning the activities under this subsection; and

"(B) submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on such review, including related recommendations, as applicable.".

PURPOSE AND SUMMARY

H.R. 3433 provides the Food and Drug Administration (FDA) with additional authority to require pediatric cancer trials for combination therapies. The bill also authorizes the FDA to take enforcement action against companies that do not conduct required pediatric trials under the Pediatric Research Equity Act (PREA) and requires the FDA to report on enforcement of PREA. Additionally, the bill reauthorizes the FDA rare pediatric disease priority review voucher (PRV) program through fiscal year 2029, and limits orphan drug exclusivity to the approved indication, rather than the potentially broader designation. Lastly, the bill requires the FDA to establish an office in an Abraham Accord country and allows the Secretary of Health and Human Services to collect registration fees and distribute these fees to support the operation of OPTN.

BACKGROUND AND NEED FOR LEGISLATION

Today, it is estimated that over 80 percent of children diagnosed with cancer will be cured.[1] However, the rate of improvement in survival has more recently slowed and more than one-half of pediatric cancer survivors experience serious long-term effects of their cancer and its therapy.[2] Combination therapy, a treatment method that utilizes two or more therapeutic agents, is considered a cornerstone of cancer therapy.[3] Combination therapies are often more effective than single agent therapy and demonstrate lower levels of toxicity during long-term treatment.[4] Currently, the FDA is only authorized to require pediatric trials of single drug cancer treatments. By extending this FDA authority to include studies of combination therapies, as well as clarifying that Orphan Drug Exclusivity allows approvals for other uses of a drug for a disease or condition to permit pediatric indications, reauthorizing the rare pediatric disease priority review voucher (PRV) program and establishing an FDA office in an Abraham Accords country to spur innovation, the Give Kids a Chance Act of 2024 seeks to accelerate the development of novel, safe, and effective treatments and improve outcomes for pediatric cancer and rare pediatric diseases. Further, allowing the Department of Health and Human Services (HHS) to collect and distribute registration fees to support the OPTN operations will continue our shared mission to increase organ transplant rates and ultimately improve health outcomes.

COMMITTEE ACTION

On February 29, 2024, the Subcommittee on Health held a hearing on several bills, including H.R. 3433, as well as H.R. 7384 and H.R. 7383, which are included with slight modification in the amended text of H.R. 3433. The title of the hearing was "Legislative Proposals to Support Patients with Rare Diseases." The Subcommittee received testimony from:

- Terence Flotte, MD, Provost and Dean of UMass Chan Medical School, Vice President of American Society of Gene and Cell Therapy;
- Alexander Bassuk, MD, PhD, Physician-in-Chief, University of Iowa Stead Family Children's Hospital; Chair and Professor, Stead Family Department of Pediatrics;
- Aaron Kesselheim, MD, JD, MPH, Professor of Medicine, Harvard Medical School; Director, Program On Regulation, Therapeutics, And Law (PORTAL) at Brigham and Women's Hospital;
- Jeromie Ballreich, PhD, Associate Research Professor, Johns Hopkins Bloomberg School of Public Health;

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[1] Erin Butler et al., "Recent progress in the treatment of cancer in children," *American Cancer Society Journals*, 2021, https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21665.

[2] *Id.*

[3] Rexa Bayat Mokhtari et al., "Combination therapy in combating cancer," *Oncotarget*, 2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5514969/.

[4] Wang, Yiling and Audrey Minden, "Current Molecular Combination Therapies Used for the Treatment of Breast Cancer," *International Journal of Molecular Sciences*, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9569555/#:~:text=Recently%2C%20combination%20therapies%20%28in%20which%20two%20or%20more,demonstrate%20lower%20levels%20of%20toxicity%20during%20long-term%20treatment.

- Alice Chen, PhD, Senior Fellow, USC Schaeffer Center for Health Policy and Economics; Associate Professor and Vice Dean for Research, USC Sol Price School of Public Policy; and,
- Khrystal Davis, JD, Founding President, Texas Rare Alliance.

On May 16, 2024, the Subcommittee on Health met in open markup session and forwarded H.R. 3433, as amended, to the full Committee by a vote of 16 yeas and 11 nays.

On September 18, 2024, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 3433, as amended, favorably reported to the House by a recorded vote of 43 yeas and 0 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

COMMITTEE ON ENERGY AND COMMERCE
118TH CONGRESS
ROLL CALL VOTE # 5

BILL: H.R. 3433, Give Kids a Chance Act of 2024

AMENDMENT: A motion by Chair Rodgers to order H.R. 3433, Give Kids a Chance Act of 2024, favorably reported to the House, as Amended (Final Passage).

DISPOSITION: AGREED TO, by a recorded vote of 43 Yeas and 0 Nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Rep. Rodgers	X			Rep. Pallone	X		
Rep. Burgess	X			Rep. Eshoo	X		
Rep. Latta	X			Rep. DeGette	X		
Rep. Guthrie	X			Rep. Schakowsky			
Rep. Griffith	X			Rep. Matsui	X		
Rep. Bilirakis	X			Rep. Castor	X		
Rep. Bucshon	X			Rep. Sarbanes	X		
Rep. Hudson				Rep. Tonko	X		
Rep. Walberg				Rep. Clarke			
Rep. Carter	X			Rep. Cárdenas	X		
Rep. Duncan	X			Rep. Ruiz	X		
Rep. Palmer	X			Rep. Peters	X		
Rep. Dunn				Rep. Dingell			
Rep. Curtis	X			Rep. Veasey	X		
Rep. Lesko	X			Rep. Kuster	X		
Rep. Pence	X			Rep. Kelly	X		
Rep. Crenshaw	X			Rep. Barragán			
Rep. Joyce	X			Rep. Blunt Rochester			
Rep. Armstrong				Rep. Soto	X		
Rep. Weber	X			Rep. Craig	X		
Rep. Allen	X			Rep. Schrier	X		
Rep. Balderson	X			Rep. Trahan	X		
Rep. Fulcher	X			Rep. Fletcher	X		
Rep. Pfluger	X						
Rep. Harshbarger	X						
Rep. Miller-Meeks	X						
Rep. Cammack	X						
Rep. Obernolte	X						
Rep. James	X						

09/18/2024

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 3433 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to promote the development of new and effective treatments for pediatric cancer and rare pediatric diseases.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 3433 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

RELATED COMMITTEE AND SUBCOMMITTEE HEARINGS

Pursuant to clause 3(c)(6) of rule XIII, the following related hearing was used to develop or consider H.R. 3433:

- On February 29, 2024, the Subcommittee on Health held a hearing on H.R. 3433, as well as H.R. 7384 and H.R. 7383, which are included with slight modification in the amended text of H.R. 3433. The title of the hearing was "Legislative Proposals to Support Patients with Rare diseases." The Subcommittee received testimony from:
  - Terence Flotte, MD, Provost and Dean of UMass Chan Medical School, Vice President of American Society of Gene and Cell Therapy;
  - Alexander Bassuk, MD, PhD, Physician-in-Chief, University of Iowa Stead Family Children's Hospital; Chair and Professor, Stead Family Department of Pediatrics;
  - Aaron Kesselheim, MD, JD, MPH, Professor of Medicine, Harvard Medical School; Director, Program On Regulation,

Therapeutics, And Law (PORTAL) at Brigham and Women's Hospital;

○ Jeromie Ballreich, PhD, Associate Research Professor, Johns Hopkins Bloomberg School of Public Health;

○ Alice Chen, PhD, Senior Fellow, USC Schaeffer Center for Health Policy and Economics; Associate Professor and Vice Dean for Research, USC Sol Price School of Public Policy; and,

○ Khrystal Davis, JD, Founding President, Texas Rare Alliance.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 3433 contains no earmarks, limited tax benefits, or limited tariff benefits.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides that the Act may be cited as the "Give Kids a Chance Act of 2024".

TITLE I—GIVE KIDS A CHANCE

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

Section 101 provides the Food and Drug Administration (FDA) the authority to require pediatric cancer trials for new drugs that are used in combination with active ingredients that meet the standard of care for targeting pediatric cancer or have been approved to treat adult cancer and are directed at molecular targets for pediatric cancer. It would also require the Government Accountability Office to conduct a study and report to Congress on the effectiveness of the requirements outlined in this section in the development of drugs and biological products for pediatric cancer indications.

Section 102. Ensuring completion of pediatric study requirements

Section 102 provides the FDA the authority to enforce against companies that fail to meet pediatric study requirements. The Secretary of the Department of Health and Human Services shall perform due diligence before concluding failure to meet requirements.

Section 103. FDA report on PREA enforcement

Section 103 requires the FDA to report on enforcement of the Pediatric Research Equity Act (PREA).

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

Section 104 extends the FDA priority review voucher program from fiscal year 2024 through fiscal year 2029, to incentivize the development of drugs for rare pediatric diseases. It also requires a study from the Government Accountability Office on the effectiveness of the pediatric PRV program.

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

Section 105 introduced as H.R. 7383, the "Retaining Access and Restoring Exclusivity (RARE) Act," by Rep. Doris Matsui (D–CA), clarifies that orphan drug exclusivity applies to the approved indication, rather than the potentially broader designation, in alignment with the FDA's interpretation.

Section 106. Program for pediatric studies of drugs

Section 106 updates authority for the National Institutes of Health (NIH) to fund studies of drugs in children, to better reflect how it is currently funded.

TITLE II—UNITED STATES-ABRAHAM ACCORDS COOPERATION AND SECURITY

Section 201. Establishment of Abraham Accords office within Food and Drug Administration

Section 201 would require the Food and Drug Administration to establish an office in an Abraham Accords country to enhance facilitation with the agency and require the Secretary of Health and Human Services to submit a report to Congress 3 years after the date of enactment of this Act to evaluate the office's progress.

TITLE III—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Section 301. Registration fees

Section 301 allows the Secretary of Health and Human Services to collect registration fees from any member of the Organ Procurement Transplantation Network (OPTN) for each transplant candidate such member places on the list and distribute these fees to support the operation of OPTN.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omit-

ted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

* * * * * * *

PENALTIES

SEC. 303. (a)(1) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both.

(b)(1) Notwithstanding subsection (a), any person who violates section 301(t) by—

(A) knowingly importing a drug in violation of section 801(d)(1),

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 503(c)(1),

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 503(c)(2), or

(D) knowingly distributing drugs in violation of section 503(e)(1),

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 301(t) because of a violation of section 503(c)(1) or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 503(b) or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a re-

lated series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 301(t) because of a failure to make a report required by section 503(d)(3)(E) shall be subject to a civil penalty of not more than $100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 301(t) because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 503(c)(1) or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 301(t) because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 503(c)(1), such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than $125,000.

(6) Notwithstanding subsection (a), any person who is a manufacturer or importer of a prescription drug under section 804(b) and knowingly fails to comply with a requirement of section 804(e) that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and has a reasonable probability of causing serious adverse health con-

sequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than $1,000,000, or both.

(8) Notwithstanding subsection (a), any person who violates section 301(i)(3) by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit drug, or who violates section 301(fff)(3) by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit device, shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.

(c) No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301(a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301(d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301(a), where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act; or (4) for having violated section 301 (b), (c), or (k) by failure to comply with section 502(f) in respect to an article received in interstate commerce to which neither section 503(a) nor section 503(b)(1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 301(i)(2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug; or (6) for having violated section 301(fff)(2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a device being a counterfeit device, or for having violated section 301(fff)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the device was a counterfeit device.

(d) No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a)(2) because of its advertising.

(e)(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 505 and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, United States Code, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, United States Code, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act for the purposes of forfeiture under section 413 of such Act.

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(f)(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a person accredited under paragraph (2) of section 704(g) who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this Act that relates to devices.

(B) Subparagraph (A) shall not apply—

(i) to any person who violates the requirements of section 519(a) or 520(f) unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 519(e) or 519(g) (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 501(a)(2)(A) which involve one or more devices which are not defective.

(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) or any person who does not comply with a recall order under section 423 shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of

any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 304 or the injunction authorities of section 302 with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 408(g)(2)(B). The third sentence of paragraph (5)(A) shall not apply to any investigation under this paragraph.

(3)(A) Any person who violates section 301(jj) shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding.

(B) If a violation of section 301(jj) is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii), the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected.

(4)(A) Any responsible person (as such term is used in section 505–1) that violates a requirement of section 505(o), 505(p), [or 505–1] *505–1, or 505B* shall be subject to a civil monetary penalty of—

(i) not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(ii) in the case of a violation that continues after the Secretary provides written notice to the responsible person, the responsible person shall be subject to a civil monetary penalty of $250,000 for the first 30-day period (or any portion thereof) that the responsible person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(B) In determining the amount of a civil penalty under subparagraph (A)(ii), the Secretary shall take into consideration whether the responsible person is making efforts toward correcting the violation of the requirement of section 505(o), 505(p), or 505–1 for which the responsible person is subject to such civil penalty.

(5)(A) A civil penalty under paragraph (1), (2), (3), (4), or (9) shall be assessed, or a no-tobacco-sale order may be imposed, by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty, or upon whom a no-tobacco-sale order is to be im-

posed, under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, or the period to be covered by a no-tobacco-sale order, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1), (2), (3), (4), or (9). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.

(6) Any person who requested, in accordance with paragraph (5)(A), a hearing respecting the assessment of a civil penalty or the imposition of a no-tobacco-sale order and who is aggrieved by an order assessing a civil penalty or the imposition of a no-tobacco-sale order may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued, or on which the no-tobacco-sale order was imposed, as the case may be.

(7) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(8) If the Secretary finds that a person has committed repeated violations of section 906(d)(5) or of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the

entry of a no-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone, or at the nearest regional or field office of the Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

(9) CIVIL MONETARY PENALTIES FOR VIOLATION OF TOBACCO PRODUCT REQUIREMENTS.—

(A) IN GENERAL.—Subject to subparagraph (B), any person who violates a requirement of this Act which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

(B) ENHANCED PENALTIES.—

(i) Any person who intentionally violates a requirement of section 902(5), 902(6), 904, 908(c), or 911(a), shall be subject to a civil monetary penalty of—

(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(ii) Any person who violates a requirement of section 911(g)(2)(C)(ii) or 911(i)(1), shall be subject to a civil monetary penalty of—

(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to such person, $250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(iii) In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is making efforts toward correcting the violation of the requirements of the section for which such person is subject to such civil penalty.

(g)(1) With respect to a person who is a holder of an approved application under section 505 for a drug subject to section 503(b) or under section 351 of the Public Health Service Act, any such

person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $250,000 for the first such violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this Act (including the civil penalty in section 303(f)(4)) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this paragraph: (A) Repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered one violation. (B) On and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered one violation. With respect to advertisements that appear in magazines or other publications that are published less frequently than daily, each issue date (whether weekly or monthly) shall be treated as a single day for the purpose of calculating the number of violations under this paragraph.

(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the person to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

(3) The Secretary, in determining the amount of the civil penalty under paragraph (1), shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

(A) Whether the person submitted the advertisement or a similar advertisement for review under section 736A.

(B) Whether the person submitted the advertisement for review if required under section 503B.

(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the person disseminated or caused another party to disseminate the advertisement before the end of the 45-day comment period.

(D) Whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination.

(E) Whether the person ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

(F) Whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

(G) Whether the violations were material.

(H) Whether the person who created the advertisement or caused the advertisement to be created acted in good faith.

(I) Whether the person who created the advertisement or caused the advertisement to be created has been assessed a

civil penalty under this provision within the previous 1-year period.

(J) The scope and extent of any voluntary, subsequent remedial action by the person.

(K) Such other matters, as justice may require.

(4)(A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated or caused another party to disseminate such advertisement after incorporating each comment received from the Secretary.

(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the person of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

(5) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owed by the United States to the person charged.

(6) Any person who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessments was issued.

(7) If any person fails to pay an assessment of a civil penalty under paragraph (1)—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General of the United States shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

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SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—

(A) GENERAL REQUIREMENTS.—Except with respect to an application for which subparagraph (B) applies, a person that submits, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, an application (or supplement to an application) for a drug—

(i) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

(ii) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration,

shall submit with the application the assessments described in paragraph (2).

(B) CERTAIN MOLECULARLY TARGETED CANCER INDICATIONS.—A person that submits, on or after the date that is 3 years after the date of enactment of the FDA Reauthorization Act of 2017, an original application for a new active ingredient under section 505 of this Act or section 351 of the Public Health Service Act, shall submit with the application reports on the investigation described in paragraph (3) if the drug or biological product that is the subject of the application is—

(i) intended for the treatment of an adult cancer; and

(ii) directed at a molecular target that the Secretary determines to be substantially relevant to the growth or progression of a pediatric cancer.

(C) RULE OF CONSTRUCTION.—No application that is subject to the requirements of subparagraph (B) shall be subject to the requirements of subparagraph (A), and no application (or supplement to an application) that is subject to the requirements of subparagraph (A) shall be subject to the requirements of subparagraph (B).

(2) ASSESSMENTS.—

(A) IN GENERAL.—The assessments referred to in paragraph (1)(A) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from

adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.

(iii) INFORMATION ON EXTRAPOLATION.—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under section 505 of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262).

(3) MOLECULARLY TARGETED PEDIATRIC CANCER INVESTIGATION.—

[(A) IN GENERAL.—With respect to a drug or biological product described in paragraph (1)(B), the investigation described in this paragraph is a molecularly targeted pediatric cancer investigation, which shall be designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling.]

(A) IN GENERAL.—For purposes of paragraph (1)(B), the investigation described in this paragraph is (as determined by the Secretary) a molecularly targeted pediatric cancer investigation of—

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

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

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

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

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

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

(aa) for which an approved application under section 505(b) of this Act or section 351(a) of the Public Health Service Act to treat an adult cancer is in effect 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 Secretary determines to be substantially relevant to the growth or progression of a pediatric cancer.

(B) ADDITIONAL REQUIREMENTS.—

(i) DESIGN OF INVESTIGATION.—A molecularly targeted pediatric cancer investigation referred to in sub-

paragraph (A) shall be designed to yield clinically meaningful 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 labeling.

(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 ingredient; or

(II) more than one active ingredient, if an application for the combination of active ingredients has not previously been approved but each active ingredient has been previously approved to treat an adult cancer.

(iii) RESULTS OF ALREADY-COMPLETED PRECLINICAL STUDIES OF APPLICATION DRUG.—The Secretary may require that reports on an investigation required pursuant to paragraph (1)(B) include 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.

[(B)**]** *(C)* EXTRAPOLATION OF DATA.—Paragraph (2)(B) shall apply to **[**investigations described in this paragraph**]** *investigations referred to in subparagraph (A)* to the same extent and in the same manner as paragraph (2)(B) applies with respect to the assessments required under paragraph (1)(A).

[(C)**]** *(D)* DEFERRALS AND WAIVERS.—Deferrals and waivers under paragraphs (4) and (5) shall apply to investigations described in this paragraph to the same extent and in the same manner as such deferrals and waivers apply with respect to **[**the assessments under paragraph (2)(B)**]** *the assessments required under paragraph (1)(A).*

(4) DEFERRAL.—

(A) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1)(A) or reports on the investigation required under paragraph (1)(B) until a specified date after approval of the drug or issuance of the license for a biological product if—

(i) the Secretary finds that—

(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

(III) there is another appropriate reason for deferral; and

(ii) the applicant submits to the Secretary—

(I) certification of the grounds for deferring the assessments or reports on the investigation;

(II) a pediatric study plan as described in subsection (e);

(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and

(IV) a timeline for the completion of such studies.

(B) DEFERRAL EXTENSION.—

(i) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may grant an extension of a deferral approved under subparagraph (A) for submission of some or all assessments required under paragraph (1)(A) or reports on the investigation required under paragraph (1)(B) if—

(I) the Secretary determines that the conditions described in subclause (II) or (III) of subparagraph (A)(i) continue to be met; and

(II) the applicant submits a new timeline under subparagraph (A)(ii)(IV) and any significant updates to the information required under subparagraph (A)(ii).

(ii) TIMING AND INFORMATION.—If the deferral extension under this subparagraph is requested by the applicant, the applicant shall submit the deferral extension request containing the information described in this subparagraph not less than 90 days prior to the date that the deferral would expire. The Secretary shall respond to such request not later than 45 days after the receipt of such letter. If the Secretary grants such an extension, the specified date shall be the extended date. The sponsor of the required assessment under paragraph (1)(A) or reports on the investigation under paragraph (1)(B) shall not be issued a letter described in subsection (d) unless the specified or extended date of submission for such required studies has passed or if the request for an extension is pending. For a deferral that has expired prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act or that will expire prior to 270 days after the date of enactment of such Act, a deferral extension shall be requested by an applicant not later than 180 days after the date of enactment of such Act. The Secretary shall respond to any such request as soon as practicable, but not later than 1 year after the date of enactment of such Act. Nothing in this clause shall prevent the Secretary from updating the status of a study or studies publicly if components of such study or studies are late or delayed.

(C) ANNUAL REVIEW.—

(i) IN GENERAL.—On an annual basis following the approval of a deferral under subparagraph (A), the applicant shall submit to the Secretary the following information:

(I) Information detailing the progress made in conducting pediatric studies.

(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time.

(III) Projected completion date for pediatric studies.

(IV) The reason or reasons why a deferral or deferral extension continues to be necessary.

(ii) PUBLIC AVAILABILITY.—Not later than 90 days after the submission to the Secretary of the information submitted through the annual review under clause (i), the Secretary shall make available to the public in an easily accessible manner, including through the Internet Web site of the Food and Drug Administration—

(I) such information;

(II) the name of the applicant for the product subject to the assessment or investigation;

(III) the date on which the product was approved; and

(IV) the date of each deferral or deferral extension under this paragraph for the product.

(5) WAIVERS.—

(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments or reports on the investigation for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

(iii) the drug or biological product—

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments or reports on the investigation for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

(iii) the drug or biological product—

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a partial waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking such a partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.

(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—The Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act to submit by a specified date the assessments described in subsection (a)(2), if the Secretary finds that—

(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

(ii) adequate pediatric labeling could confer a benefit on pediatric patients;

(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.

(2) WAIVERS.—

(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.

(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

(iii)(I) the drug or biological product—

(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.

(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

(c) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful thera-

peutic benefit over existing therapies if the Secretary determines that—

(1) if approved, the drug or biological product could represent an improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

(d) SUBMISSION OF ASSESSMENTS AND REPORTS ON THE INVESTIGATION.—If a person fails to submit a required assessment described in subsection (a)(2) or the investigation described in subsection (a)(3), fails to meet the applicable requirements in subsection (a)(4), or fails to submit a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b), the following shall apply:

(1) [Beginning 270] *NONCOMPLIANCE LETTER.—Beginning 270* days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall issue a non-compliance letter to such person informing them of such failure to submit or meet the requirements of the applicable subsection. Such letter shall require the person to respond in writing within 45 calendar days of issuance of such letter. Such response may include the person's request for a deferral extension if applicable. Such letter and the person's written response to such letter shall be made publicly available on the Internet Web site of the Food and Drug Administration 60 calendar days after issuance, with redactions for any trade secrets and confidential commercial information. If the Secretary determines that the letter was issued in error, the requirements of this paragraph shall not apply. The Secretary shall inform the Pediatric Advisory Committee of letters issued under this paragraph and responses to such letters.

(2) [The drug or] *EFFECT OF NONCOMPLIANCE.—The drug or* biological product that is the subject of an assessment described in subsection (a)(2) or the investigation described in subsection (a)(3), applicable requirements in subsection (a)(4), or request for approval of a pediatric formulation, may be considered misbranded solely because of that failure and subject to relevant enforcement action [(except that the drug or biological product shall not be subject to action under section 303)] *(except that the drug or biological product shall be subject to action under section 303 only if such person demonstrated a lack of due diligence in satisfying the applicable requirement)*, but such failure shall not be the basis for a proceeding—

(A) to withdraw approval for a drug under section 505(e); or

(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.

(3) LIMITATION.—The Secretary shall not issue enforcement actions under section 303 for failures under this subsection in the case of a drug or biological product that is no longer marketed.

(4) DUE DILIGENCE.—Before the Secretary may conclude that a person failed to submit or otherwise meet a requirement as described in the matter preceding paragraph (1), the Secretary shall—

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

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

(C) after reviewing such written response, determine whether the person demonstrated a lack of due diligence in satisfying such requirement.

(e) PEDIATRIC STUDY PLANS.—

(1) IN GENERAL.—An applicant subject to subsection (a) shall submit to the Secretary an initial pediatric study plan prior to the submission of the assessments described under subsection (a)(2) or the investigation described in subsection (a)(3). *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).*

(2) TIMING; CONTENT; MEETINGS.—

(A) TIMING.—An applicant shall submit the initial pediatric study plan under paragraph (1)—

(i) before the date on which the applicant submits the assessments under subsection (a)(2) or the investigation described in subsection (a)(3); and

(ii) not later than—

(I) 60 calendar days after the date of the end-of-Phase 2 meeting (as such term is used in section 312.47 of title 21, Code of Federal Regulations, or successor regulations); or

(II) such other time as may be agreed upon between the Secretary and the applicant.

Nothing in this section shall preclude the Secretary from accepting the submission of an initial pediatric study plan earlier than the date otherwise applicable under this subparagraph.

(B) CONTENT OF INITIAL PEDIATRIC STUDY PLAN.—The initial pediatric study plan shall include—

(i) an outline of the pediatric study or studies that the applicant plans to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach);

(ii) any request for a deferral, partial waiver, or waiver under this section, if applicable, along with any supporting information; and

(iii) other information specified in the regulations promulgated under paragraph (7).

(C) MEETINGS.—The Secretary—

(i) shall meet with the applicant—

(I) if requested by the applicant with respect to a drug or biological product that is intended to treat a serious or life-threatening disease or condition, to discuss preparation of the initial pediatric

study plan, not later than the end-of-Phase 1 meeting (as such term is used in section 312.82(b) of title 21, Code of Federal Regulations, or successor regulations) or within 30 calendar days of receipt of such request, whichever is later;

(II) to discuss the initial pediatric study plan as soon as practicable, but not later than 90 calendar days after the receipt of such plan under subparagraph (A); and

(III) to discuss the bases for the deferral under subsection (a)(4) or a full or partial waiver under subsection (a)(5);

(ii) may determine that a written response to the initial pediatric study plan is sufficient to communicate comments on the initial pediatric study plan, and that no meeting under clause (i)(II) is necessary; and

(iii) if the Secretary determines that no meeting under clause (i)(II) is necessary, shall so notify the applicant and provide written comments of the Secretary as soon as practicable, but not later than 90 calendar days after the receipt of the initial pediatric study plan.

(3) AGREED INITIAL PEDIATRIC STUDY PLAN.—Not later than 90 calendar days following the meeting under paragraph (2)(C)(i)(II) or the receipt of a written response from the Secretary under paragraph (2)(C)(iii), the applicant shall document agreement on the initial pediatric study plan in a submission to the Secretary marked "Agreed Initial Pediatric Study Plan", and the Secretary shall confirm such agreement to the applicant in writing not later than 30 calendar days of receipt of such agreed initial pediatric study plan.

(4) DEFERRAL AND WAIVER.—If the agreed initial pediatric study plan contains a request from the applicant for a deferral, partial waiver, or waiver under this section, the written confirmation under paragraph (3) shall include a recommendation from the Secretary as to whether such request meets the standards under paragraphs (3) or (4) of subsection (a).

(5) AMENDMENTS TO THE AGREED INITIAL PEDIATRIC STUDY PLAN.—At the initiative of the Secretary or the applicant, the agreed initial pediatric study plan may be amended at any time. The requirements of paragraph (2)(C) shall apply to any such proposed amendment in the same manner and to the same extent as such requirements apply to an initial pediatric study plan under paragraph (1). The requirements of paragraphs (3) and (4) shall apply to any agreement resulting from such proposed amendment in the same manner and to the same extent as such requirements apply to an agreed initial pediatric study plan.

(6) INTERNAL COMMITTEE.—The Secretary shall consult the internal committee under section 505C on the review of the initial pediatric study plan, agreed initial pediatric study plan, and any significant amendments to such plans.

(7) REQUIRED RULEMAKING.—Not later than 1 year after the date of enactment of the Food and Drug Administration Safety

and Innovation Act, the Secretary shall promulgate proposed regulations and issue guidance to implement the provisions of this subsection.

(f) REVIEW OF PEDIATRIC STUDY PLANS,ASSESSMENTS, DEFERRALS, DEFERRAL EXTENSIONS, AND WAIVERS.—

(1) REVIEW.—Beginning not later than 30 days after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall utilize the internal committee established under section 505C to provide consultation to reviewing divisions on initial pediatric study plans, agreed initial pediatric study plans, and any significant amendments to such plans, and assessments prior to approval of an application or supplement for which a pediatric assessment is required under this section and all deferral, deferral extension, and waiver requests granted pursuant to this section.

(2) ACTIVITY BY COMMITTEE.—The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.

(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (4) or (5), which members of the committee participated in such activity.

(4) REVIEW OF PEDIATRIC STUDY PLANS, ASSESSMENTS, DEFERRALS, DEFERRAL EXTENSIONS, AND WAIVERS.—Consultation on initial pediatric study plans, agreed initial pediatric study plans, and assessments by the committee referred to in paragraph (1) pursuant to this section shall occur prior to approval of an application or supplement for which a pediatric assessment is required under this section. The committee shall review all requests for deferrals, deferral extensions, and waivers from the requirement to submit a pediatric assessment granted under this section and shall provide recommendations as needed to reviewing divisions, including with respect to whether such a supplement, when submitted, shall be considered for priority review.

(5) RETROSPECTIVE REVIEW OF PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—Not later than 1 year after the date of the enactment of the Pediatric Research Equity Act of 2007, the committee referred to in paragraph (1) shall conduct a retrospective review and analysis of a representative sample of assessments submitted and deferrals and waivers approved under this section since the enactment of the Pediatric Research Equity Act of 2003. Such review shall include an analysis of the quality and consistency of pediatric information in pediatric assessments and the appropriateness of waivers and deferrals granted. Based on such review, the Secretary shall issue recommendations to the review divisions for improvements and initiate guidance to industry related to the scope of pediatric studies required under this section.

(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—

(A) the number of assessments conducted under this section;

(B) the specific drugs and biological products and their uses assessed under this section;

(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

(D) aggregated on an annual basis—

(i) the total number of deferrals and deferral extensions requested and granted under this section and, if granted, the reasons for each such deferral or deferral extension;

(ii) the timeline for completion of the assessments;

(iii) the number of assessments completed and pending; and

(iv) the number of postmarket non-compliance letters issued pursuant to subsection (d), and the recipients of such letters;

(E) the number of waivers requested and granted under this section and, if granted, the reasons for the waivers;

(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulation was not developed;

(G) the labeling changes made as a result of assessments conducted under this section;

(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (h)(2);

(I) an annual summary of information submitted pursuant to subsection (a)(4)(C); and

(J) the number of times the committee referred to in paragraph (1) made a recommendation to the Secretary under paragraph (4) regarding priority review, the number of times the Secretary followed or did not follow such a recommendation, and, if not followed, the reasons why such a recommendation was not followed.

(g) LABELING CHANGES.—

(1) DISPUTE RESOLUTION.—

(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Commissioner determines that a sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review—

(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

(ii) if the sponsor does not agree within 30 days after the Commissioner's request to make a labeling

change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

(i) review the pediatric study reports; and

(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate.

(D) MISBRANDING.—If the sponsor of the application or supplement, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application or supplement to be misbranded.

(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(2) OTHER LABELING CHANGES.—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of such assessment is safe and effective in pediatric populations or subpopulations, including whether such assessment results are inconclusive, the Secretary shall order the labeling of such product to include information about the results of the assessment and a statement of the Secretary's determination.

(h) DISSEMINATION OF PEDIATRIC INFORMATION.—

(1) IN GENERAL.—Not later than 210 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a priority review, or not later than 330 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a standard review, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments, and shall post such assessments on the Web site of the Food and Drug Administration.

(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall require that the sponsors of the assessments that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(6)(H) distribute such information to physicians and other health care providers.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall alter or amend section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

(i) ADVERSE EVENT REPORTING.—

(1) REPORTING IN FIRST 18-MONTH PERIOD.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, during the 18-month period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to such reports.

(2) REPORTING IN SUBSEQUENT PERIODS.—Following the 18-month period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.

(4) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

(j) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

(k) RELATION TO ORPHAN DRUGS.—

(1) IN GENERAL; EXEMPTION FOR ORPHAN INDICATIONS.—Unless the Secretary requires otherwise by regulation and except as provided in paragraph (2), this section does not apply to any drug or biological product for an indication for which orphan designation has been granted under section 526.

(2) APPLICABILITY DESPITE ORPHAN DESIGNATION OF CERTAIN INDICATIONS.—This section shall apply with respect to a drug

or biological product for which an indication has been granted orphan designation under 526 if the investigation described in subsection (a)(3) applies to the drug or biological product as described in subsection (a)(1)(B).

(l) NEW ACTIVE INGREDIENT.—

(1) NON-INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is biosimilar to a reference product under section 351 of the Public Health Service Act, and that the Secretary has not determined to meet the standards described in subsection (k)(4) of such section for interchangeability with the reference product, shall be considered to have a new active ingredient under this section.

(2) INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is interchangeable with a reference product under section 351 of the Public Health Service Act shall not be considered to have a new active ingredient under this section.

(m) LIST OF PRIMARY MOLECULAR TARGETS.—

(1) IN GENERAL.—Within one year of the date of enactment of the FDA Reauthorization Act of 2017, the Secretary shall establish and update regularly, and shall publish on the internet website of the Food and Drug Administration—

(A) a list of molecular targets considered, on the basis of data the Secretary determines to be adequate, to be substantially relevant to the growth and progression of a pediatric cancer, and that may trigger the requirements under this section; and

(B) a list of molecular targets of new cancer drugs and biological products in development for which pediatric cancer study requirements under this section will be automatically waived.

(2) CONSULTATION.—In establishing the lists described in paragraph (1), the Secretary shall consult the National Cancer Institute, members of the internal committee under section 505C, and the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee, and shall take into account comments from the meeting under subsection (c).

(3) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to require the inclusion of a molecular target on the list published under such paragraph as a condition for triggering the requirements under subsection (a)(1)(B) with respect to a drug or biological product directed at such molecular target; or

(B) to authorize the disclosure of confidential commercial information, as prohibited under section 301(j) of this Act or section 1905 of title 18, United States Code.

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SUBCHAPTER B—DRUGS FOR RARE DISEASES OR CONDITIONS

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PROTECTION FOR DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 527. (a) Except as provided in subsection (b), if the Secretary—

(1) approves an application filed pursuant to section 505, or

(2) issues a license under section 351 of the Public Health Service Act

for a drug designated under section 526 for a rare disease or condition, the Secretary may not approve another application under section 505 or issue another license under section 351 of the Public Health Service Act for the same drug for the [same disease or condition] *same approved use or indication within such rare disease or condition* for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license. Section 505(c)(2) does not apply to the refusal to approve an application under the preceding sentence.

(b) During the 7-year period described in subsection (a) for an approved application under section 505 or license under section 351 of the Public Health Service Act, the Secretary may approve an application or issue a license for a drug that is otherwise the same, as determined by the Secretary, as the already approved drug for the [same rare disease or condition] *same approved use or indication for which such 7-year period applies to such already approved or licensed drug* if—

(1) the Secretary finds, after providing the holder of exclusive approval or licensure notice and opportunity for the submission of views, that during such period the holder of the exclusive approval or licensure cannot ensure the availability of sufficient quantities of the drug to meet the needs*, relating to the approved use or indication,* of persons with the disease or condition for which the drug was designated; or

(2) the holder provides the Secretary in writing the consent of such holder for the approval of other applications or the issuance of other licenses before the expiration of such seven-year period.

(c) CONDITION OF CLINICAL SUPERIORITY.—

(1) IN GENERAL.—If a sponsor of a drug that is designated under section 526 and is otherwise the same, as determined by the Secretary, as an already approved or licensed drug is seeking exclusive approval or exclusive licensure described in subsection (a) for the [same rare disease or condition as the already approved drug] *same use or indication for which the already approved or licensed drug was approved or licensed*, the Secretary shall require such sponsor, as a condition of such exclusive approval or licensure, to demonstrate that such drug is clinically superior to any already approved or licensed drug that is the same drug.

(2) DEFINITION.—For purposes of paragraph (1), the term "clinically superior" with respect to a drug means that the drug provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care.

(3) APPLICABILITY.—This subsection applies to any drug designated under section 526 for which an application was approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act after the date of enactment of the FDA Reauthorization Act of 2017, regardless of the date on which such drug was designated under section 526.

(d) REGULATIONS.—The Secretary may promulgate regulations for the implementation of subsection (c). Beginning on the date of enactment of the FDA Reauthorization Act of 2017, until such time as the Secretary promulgates regulations in accordance with this subsection, the Secretary may apply any definitions set forth in regulations that were promulgated prior to such date of enactment, to the extent such definitions are not inconsistent with the terms of this section, as amended by such Act.

(e) DEMONSTRATION OF CLINICAL SUPERIORITY STANDARD.—To assist sponsors in demonstrating clinical superiority as described in subsection (c), the Secretary—

(1) upon the designation of any drug under section 526, shall notify the sponsor of such drug in writing of the basis for the designation, including, as applicable, any plausible hypothesis offered by the sponsor and relied upon by the Secretary that the drug is clinically superior to a previously approved drug; and

(2) upon granting exclusive approval or licensure under subsection (a) on the basis of a demonstration of clinical superiority as described in subsection (c), shall publish a summary of the clinical superiority findings.

(f) APPROVED USE OR INDICATION DEFINED.—In this section, the term "approved use or indication" means the use or indication approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act for a drug designated under section 526 for a rare disease or condition.

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SEC. 529. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) DEFINITIONS.—In this section:

(1) PRIORITY REVIEW.—The term "priority review", with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

(2) PRIORITY REVIEW VOUCHER.—The term "priority review voucher" means a voucher issued by the Secretary to the sponsor of a rare pediatric disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the rare pediatric disease product application.

(3) RARE PEDIATRIC DISEASE.—The term "rare pediatric disease" means a disease that meets each of the following criteria:

(A) The disease is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents.

(B) The disease is a rare disease or condition, within the meaning of section 526.

(4) RARE PEDIATRIC DISEASE PRODUCT APPLICATION.—The term "rare pediatric disease product application" means a human drug application, as defined in section 735(1), that—

(A) is for a drug or biological product that is for the prevention or treatment of a rare pediatric disease;

(B)(i) is for such a drug—

(I) that contains no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 505; and

(II) that is the subject of an application submitted under section 505(b)(1); or

(ii) is for such a biological product—

(I) that contains no active ingredient that has been previously approved in any other application under section 351(a) or 351(k) of the Public Health Service Act; and

(II) that is the subject of an application submitted under section 351(a) of the Public Health Service Act;

(C) the Secretary deems eligible for priority review;

(D) that relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population;

(E) that does not seek approval for an adult indication in the original rare pediatric disease product application; and

(F) is approved after the date of the enactment of the Advancing Hope Act of 2016.

(b) PRIORITY REVIEW VOUCHER.—

(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a rare pediatric disease product application upon approval by the Secretary of such rare pediatric disease product application.

(2) TRANSFERABILITY.—

(A) IN GENERAL.—The sponsor of a rare pediatric disease product application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

(B) NOTIFICATION OF TRANSFER.—Each person to whom a voucher is transferred shall notify the Secretary of such change in ownership of the voucher not later than 30 days after such transfer.

(3) LIMITATION.—A sponsor of a rare pediatric disease product application may not receive a priority review voucher under this section if the rare pediatric disease product applica-

tion was submitted to the Secretary prior to the date that is 90 days after the date of enactment of the Prescription Drug User Fee Amendments of 2012.

(4) NOTIFICATION.—

(A) SPONSOR OF A RARE PEDIATRIC DISEASE PRODUCT.—

(i) IN GENERAL.—Beginning on the date that is 90 days after the date of enactment of the Advancing Hope Act of 2016, the sponsor of a rare pediatric disease product application that intends to request a priority review voucher under this section shall notify the Secretary of such intent upon submission of the rare pediatric disease product application that is the basis of the request for a priority review voucher.

(ii) APPLICATIONS SUBMITTED BUT NOT YET APPROVED.—The sponsor of a rare pediatric disease product application that was submitted and that has not been approved as of the date of enactment of the Advancing Hope Act of 2016 shall be considered eligible for a priority review voucher, if—

(I) such sponsor has submitted such rare pediatric disease product application—

(aa) on or after the date that is 90 days after the date of enactment of the Prescription Drug User Fee Amendments of 2012; and

(bb) on or before the date of enactment of the Advancing Hope Act of 2016; and

(II) such application otherwise meets the criteria for a priority review voucher under this section.

(B) SPONSOR OF A DRUG APPLICATION USING A PRIORITY REVIEW VOUCHER.—

(i) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay the user fee to be assessed in accordance with this section.

(ii) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under clause (i) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after [September 30, 2024, unless the rare pediatric disease product application—] *September 30, 2029.*

[(A) is for a drug that, not later than September 30, 2024, is designated under subsection (d) as a drug for a rare pediatric disease; and

[(B) is, not later than September 30, 2026, approved under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.]

(c) PRIORITY REVIEW USER FEE.—

(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary, based on the difference between—

(A) the average cost incurred by the Food and Drug Administration in the review of a human drug application subject to priority review in the previous fiscal year; and

(B) the average cost incurred by the Food and Drug Administration in the review of a human drug application that is not subject to priority review in the previous fiscal year.

(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2012, the amount of the priority review user fee for that fiscal year.

(4) PAYMENT.—

(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the notification by a sponsor of the intent of such sponsor to use the voucher, as specified in subsection (b)(4)(A). All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.

(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriations Acts.

(d) DESIGNATION PROCESS.—

(1) IN GENERAL.—Upon the request of the manufacturer or the sponsor of a new drug, the Secretary may designate—

(A) the new drug as a drug for a rare pediatric disease; and

(B) the application for the new drug as a rare pediatric disease product application.

(2) REQUEST FOR DESIGNATION.—The request for a designation under paragraph (1) shall be made at the same time a request for designation of orphan disease status under section 526 or fast-track designation under section 506 is made. Requesting designation under this subsection is not a prerequisite to receiving a priority review voucher under this section.

(3) DETERMINATION BY SECRETARY.—Not later than 60 days after a request is submitted under paragraph (1), the Secretary shall determine whether—

(A) the disease or condition that is the subject of such request is a rare pediatric disease; and

(B) the application for the new drug is a rare pediatric disease product application.

(e) MARKETING OF RARE PEDIATRIC DISEASE PRODUCTS.—

(1) REVOCATION.—The Secretary may revoke any priority review voucher awarded under subsection (b) if the rare pediatric disease product for which such voucher was awarded is not marketed in the United States within the 365-day period beginning on the date of the approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act.

(2) POSTAPPROVAL PRODUCTION REPORT.—The sponsor of an approved rare pediatric disease product shall submit a report to the Secretary not later than 5 years after the approval of the applicable rare pediatric disease product application. Such report shall provide the following information, with respect to each of the first 4 years after approval of such product:

(A) The estimated population in the United States suffering from the rare pediatric disease.

(B) The estimated demand in the United States for such rare pediatric disease product.

(C) The actual amount of such rare pediatric disease product distributed in the United States.

(f) NOTICE AND REPORT.—

(1) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Internet Web site of the Food and Drug Administration not later than 30 days after the occurrence of each of the following:

(A) The Secretary issues a priority review voucher under this section.

(B) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor of the application used a priority review voucher under this section.

(2) NOTIFICATION.—If, after the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, a sponsor of an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for a drug uses a priority review voucher under this section for such application, the Secretary 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 document—

(A) notifying such Committees of the use of such voucher; and

(B) identifying the drug for which such priority review voucher is used.

(g) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act, except that no sponsor of a rare pediatric disease product application may receive more than one priority review voucher issued under any section of this Act with respect to the drug for which the application is made..

(h) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of drugs for tropical diseases and rare pediatric diseases.

(i) GAO STUDY AND REPORT.—

(1) STUDY.—

(A) IN GENERAL.—Beginning on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, the Comptroller General of the United States shall conduct a study of the effectiveness of awarding rare pediatric disease priority vouchers under this section in the development of human drug products that treat or prevent such diseases.

(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

(i) The indications for which each rare disease product for which a priority review voucher was awarded was approved under section 505 or section 351 of the Public Health Service Act.

(ii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was met through the approval of such a rare disease product.

(iii) The value of the priority review voucher if transferred.

(iv) Identification of each drug for which a priority review voucher was used.

(v) The length of the period of time between the date on which a priority review voucher was awarded and the date on which it was used.

(2) REPORT.—Not later than 1 year after the date under paragraph (1)(A), 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 results of the study under paragraph (1).

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CHAPTER X—MISCELLANEOUS

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SEC. 1015. ABRAHAM ACCORDS OFFICE.

(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration an office, to be known as the Abraham Accords Office, to be headed by a director.

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

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

(A) select the location of the Abraham Accords Office in an Abraham Accords country; and

(B) establish such office; and

(2) assign to such office such personnel of the Food and Drug Administration as the Secretary determines necessary to carry out the functions of such office.

(c) DUTIES.—The Secretary, acting through the Director of the Abraham Accords Office, shall—

(1) after the Abraham Accords Office is established—

(A) as part of the Food and Drug Administration's work to strengthen the international oversight of regulated commodities, provide technical assistance to regulatory partners in Abraham Accords countries on strengthening regulatory oversight and converging regulatory requirements for the oversight of regulated products, including good manufacturing practices and other issues relevant to manufacturing medical products that are regulated by the Food and Drug Administration;

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

(C) facilitate feedback between the Food and Drug Administration and such parties located within Abraham Accords countries prior to submission of an application under section 505(b), 505(j), or 515 of this Act or section 351(a) or 351(k) of the Public Health Service Act, or a notification under section 510(k) of this Act, such as feedback on research, development, and manufacturing of drugs, biologics, and medical devices; and

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

(d) ABRAHAM ACCORDS COUNTRY DEFINED.—In this section, the term "Abraham Accords country" means a country identified by the Department of State as having signed the Abraham Accords Declaration.

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT

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TITLE V—PEDIATRIC DRUGS AND DEVICES

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SEC. 508. REPORT.

(a) IN GENERAL.—Not later than four years after the date of enactment of this Act and every five years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, including through posting on the Internet Web site of the Food and Drug Administration, a report on the implementation of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c).

(b) CONTENTS.—Each report under subsection (a) shall include—

(1) an assessment of the effectiveness of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act in improving information about pediatric uses for approved drugs and biological products, including the number and type of labeling changes made since the date of enactment of this Act and the importance of such uses in the improvement of the health of children;

(2) the number of required studies under such section 505B that have not met the initial deadline provided under such section 505B, including—

(A) the number of deferrals and deferral extensions granted and the reasons such extensions were granted;

(B) the number of waivers and partial waivers granted; and

(C) the number of letters issued under subsection (d) of such section 505B;

(3) an assessment of the timeliness and effectiveness of pediatric study planning since the date of enactment of this Act, including the number of initial pediatric study plans not submitted in accordance with the requirements of subsection (e) of such section 505B and any resulting rulemaking;

(4) the number of written requests issued, accepted, and declined under such section 505A since the date of enactment of this Act, and a listing of any important gaps in pediatric information as a result of such declined requests;

(5) a description and current status of referrals made under subsection (n) of such section 505A;

(6) an assessment of the effectiveness of studying biological products in pediatric populations under such sections 505A and 505B and section 409I of the Public Health Service Act (42 U.S.C. 284m);

(7)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonatal population (including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe); and

(B) the results of such efforts;

(8)(A) the number and importance of drugs and biological products for children with cancer that are being tested as a result of the programs under such sections 505A and 505B and under section 409I of the Public Health Service Act; and

(B) any recommendations for modifications to such programs that would lead to new and better therapies for children with cancer, including a detailed rationale for each recommendation;

(9) any recommendations for modification to such programs that would improve pediatric drug research and increase pediatric labeling of drugs and biological products;

(10) an assessment of the successes of and limitations to studying drugs for rare diseases under such sections 505A and 505B;

(11) an assessment of the impact of the amendments to such section 505B made by the FDA Reauthorization Act of 2017 on pediatric research and labeling of drugs and biological products and pediatric labeling of molecularly targeted drugs and biological products for the treatment of cancer**[**;**]**, *including an evaluation of compliance with deadlines provided for in deferrals and deferral extensions;*

(12) an assessment of the efforts of the Secretary to implement the plan developed under section 505C–1 of the Federal Food, Drug, and Cosmetic Act, regarding earlier submission of pediatric studies under sections 505A and 505B of such Act and section 351(m) of the Public Health Service Act, including—

(A) the average length of time after the approval of an application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) before studies conducted pursuant to such section 505A, 505B, or section 351(m) are completed, submitted, and incorporated into labeling;

(B) the average length of time after the receipt of a proposed pediatric study request before the Secretary responds to such request;

(C) the average length of time after the submission of a proposed pediatric study request before the Secretary issues a written request for such studies;

(D) the number of written requests issued for each investigational new drug or biological product prior to the submission of an application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act; and

(E) the average number, and range of numbers, of amendments to written requests issued, and the time the Secretary requires to review and act on proposed amendments to written requests;

(13) a list of sponsors of applications or holders of approved applications who received exclusivity under such section 505A or such section 351(m) after receiving a letter issued under such section 505B(d)(1) for any drug or biological product before the studies referred to in such letter were completed and submitted;

(14) a list of assessments and investigations required under such section 505B;

(15) how many requests under such section 505A for molecular targeted cancer drugs, as defined by subsection (a)(1)(B) of such section 505B, approved prior to 3 years after the date of enactment of the FDA Reauthorization Act of 2017, have been issued by the Food and Drug Administration, and how many such requests have been completed; [and]

(16) the Secretary's assessment of the overall impact of the amendments made by section 504 of the FDA Reauthorization Act of 2017 on the conduct and effectiveness of pediatric cancer research and the orphan drug program, as well any subsequent recommendations[.]*; and*

(17) a listing of penalties, settlements, or payments under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353) for failure to comply with requirements under such section 505B, including, for each penalty, settlement, or payment, the name of the drug, the sponsor thereof, and the amount of the penalty, settlement, or payment imposed; and

(c) STAKEHOLDER COMMENT.—At least 180 days prior to the submission of each report under subsection (a), the Secretary shall consult with representatives of patient groups (including pediatric patient groups), consumer groups, regulated industry, academia, and other interested parties to obtain any recommendations or information relevant to the report including suggestions for modifications that would improve pediatric drug research and pediatric labeling of drugs and biological products.

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PUBLIC HEALTH SERVICE ACT

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART H—ORGAN TRANSPLANTS

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ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

SEC. 372. (a) IN GENERAL—The Secretary shall provide for the continued operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The Secretary may award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, for purposes of carrying out this section.

(b) COMPOSITION.—

(1) IN GENERAL.—The Organ Procurement and Transplantation Network shall—

(A) be operated through awards to public or private entities made by the Secretary that are distinct from the awards made to support the organization tasked with sup-

porting the board of directors described in subparagraph (B); and

(B) have a board of directors—

(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 371), transplant centers, voluntary health associations, and the general public; and

(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.

(2) The Organ Procurement and Transplantation Network shall—

(A) establish in one location or through regional centers—

(i) a national list of individuals who need organs, and

(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

(B) establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria,

(C) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

(D) assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients,

(E) adopt and use standards of quality for the acquisition and transportation of donated organs,

(F) prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

(G) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

(H) provide information to physicians and other health professionals regarding organ donation,

(I) collect, analyze, and publish data concerning organ donation and transplants,

(J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation,

(K) work actively to increase the supply of donated organs,

(L) submit to the Secretary an annual report containing information on the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network,

(M) recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children,

(N) carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement

and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs, including children and individuals who are members of racial or ethnic minority groups, and among populations with limited access to transportation, and

(O) provide that for purposes of this paragraph, the term "children" refers to individuals who are under the age of 18.

(3) CLARIFICATION.—In adopting and using standards of quality under paragraph (2)(E), the Organ Procurement and Transplantation Network may adopt and use such standards with respect to organs infected with human immunodeficiency virus (in this paragraph referred to as "HIV"), provided that any such standards ensure that organs infected with HIV may be transplanted only into individuals who—

(A) are infected with HIV before receiving such organ; and

(B)(i) are participating in clinical research approved by an institutional review board under the criteria, standards, and regulations described in subsections (a) and (b) of section 377E; or

(ii) if the Secretary has determined under section 377E(c) that participation in such clinical research, as a requirement for such transplants, is no longer warranted, are receiving a transplant under the standards and regulations under section 377E(c).

(c) The Secretary shall establish procedures for—

(1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b); and

(2) the consideration by the Secretary of such critical comments.

(d) REGISTRATION FEES.—

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

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

(3) DISTRIBUTION.—The Secretary may distribute such fees among the awardees described in subsection (b)(1)(A).

(4) TRANSPARENCY.—The Secretary shall—

(A) promptly post on the Internet website of the Organ Procurement and Transplant Network—

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

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

(B) update the information posted pursuant to subparagraph (A), as applicable for each calendar quarter for which fees are collected under paragraph (1).

(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—

(A) conduct a review concerning the activities under this subsection; and

(B) submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on such review, including related recommendations, as applicable.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

(1) IN GENERAL.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs, biological products, or indications that require study. The list shall be revised every three years.

(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary—

(A) shall consider—

(i) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

(ii) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, and identification of biomarkers for such diseases, disorders, or conditions, may be beneficial in pediatric populations; and

(iii) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators; and

(B) may consider the availability of qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), and qualified

pandemic or epidemic products (as defined in section 319F–3) to address the needs of pediatric populations, in consultation with the Assistant Secretary for Preparedness and Response, consistent with the purposes of this section.

(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in paragraphs (1) and (2)(A) of subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

(c) PROCESS FOR PROPOSED PEDIATRIC STUDY REQUESTS AND LABELING CHANGES.—

(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, or section 351(m) of this Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or section 351(k) of this Act; or

(ii) there is a submitted application that could be approved under the criteria of such section; and

(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, and every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of this Act, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act has ended for at least one form of the drug; and

(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

(2) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug iden-

tified under subsection (a) to all holders of an approved application for the drug. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of this Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

(3) REQUESTS FOR PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

(4) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

(5) CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS.—A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(6) REPORTING OF STUDIES.—

(A) IN GENERAL.—On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.

(B) AVAILABILITY OF REPORTS.—

(i) IN GENERAL.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and not later than 90 days after submission of such report, shall be—

(I) posted on the internet website of the National Institutes of Health in a manner that is accessible and consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

(aa) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

(bb) proprietary interests, confidential commercial information, and intellectual property rights; and

(II) assigned a docket number by the Commissioner of Food and Drugs and made available for the submission of public comments.

(ii) SUBMISSION OF COMMENTS.—An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the submitted comments shall become part of the docket file with respect to each of the drugs.

(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take action in a timely and appropriate manner in response to the reports submitted under subparagraph (A), and shall begin such action upon receipt of the report under subparagraph (A), in accordance with paragraph (7).

(7) REQUESTS FOR LABELING CHANGE.—Within the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

(C)(i) include in the public docket file a reference to the location of the report on the internet website of the National Institutes of Health and a copy of any requested labeling changes; and

(ii) publish through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

(8) DISPUTE RESOLUTION.—

(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the hold-

ers of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

[(d) AUTHORIZATION OF APPROPRIATIONS.—

[(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, $5,753,425 for the period beginning on October 1, 2022 and ending on December 23, 2022.

[(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.**]**

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

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