there were no protections for these individuals.

According to a 2019 report from the National Council on Disability, which is the agency that advises the legislative and executive branch on disability policy issues, people with disabilities have been routinely denied due to subjective judgments about the value of a human who happens to have a disability, subjective assumptions about their quality of life, and misconceptions about their ability to comply with postoperative care.

Even more, that same report found that some organ transplant programs have policies that exclude, rather than include, people with disabilities as candidates for transplant.

In 2021, as a freshman Member of Congress, I met Bobbi and Josh Sarmiento. They are from Ocala, Florida, in my district. These constituents reached out and wanted to share the story of their son, baby Zion. I spent time learning about their journey and couldn't help being moved to action as I left them that day.

I couldn't possibly do justice in recounting their story. Instead, I will read an excerpt from baby Zion's mom, Bobbi, in her own words, their story and experience with the organ transplant system that she provided to a congressional panel just last year.

In Bobbi's words, she said:

We learned at 10 weeks gestation that our son, Zion, had Down syndrome, and at his 20-week anatomy scan, he had a heart defect called a complete AVSD, or also called a complete AV canal defect. Simply put, we have four chambers in our heart. Zion had a large hole in the center separating those chambers from forming. This is a common heart defect those with Down syndrome have.

Our beautiful boy was born on June 15, 2021. We spent 40 days in the NICU before being discharged to go home. We have some of the best memories of our time at home before his open-heart surgery was scheduled for September of 2021. We did all the research and asked all the questions. We never knew we would end up being the worst-case scenario.

To make a long story short, Zion had 5 open-heart surgeries in a matter of 12 days. He was such a warrior through each one. After the fifth surgery didn't work as planned, we were told that he would need a heart transplant. The hospital we were at did not do transplants, so we were left with three options in Florida. To qualify, we were told his other organs had to be working, which they were, and we have the autopsy to prove this.

Our first option told us that they had never done a successful heart transplant on someone with Down syndrome. I asked how many they had tried. No response. Through my own research and digging that moms do to get answers, I have since learned that the answer was zero. Our second option said that they didn't feel their team could do a successful heart transplant for Zion, and the third option kept us waiting.

Finally, they came back and said that, because baby Zion was on ECMO life support three times through the five surgeries, he couldn't have brain activity. I would like to note that Zion came off ECMO after the second and fifth surgery, which we knew upfront was vital to being accepted for the heart transplant list. They wanted a brain activity test run and sent to them for their final decision. We were told before it was sent that the test was perfect.

With nothing to disqualify him, we thought that we would be on our way to the next step. They came back and told us that after much deliberation, they concluded that they just couldn't waste a heart.

Wow, that is hard to read.

Our son was worth the same chance at life as anyone else. With no options left, we had to make the decision to remove the machines. On October 8, 2021, our son left our arms and ran into the arms of Jesus.

The SPEAKER pro tempore. The time of the gentlewoman has expired.

Mr. BUCSHON. Mr. Speaker, I yield such time as she may consume to the gentlewoman from Florida.

Mrs. CAMMACK. Baby Zion deserved the same chance at life as any other American, but he was denied a heart transplant by the same doctors because he had Down syndrome, and they ''couldn't waste a heart.''

The tragic story of baby Zion and the courage of his parents, Josh and Bobbi, along with the drive of so many incredible advocates, have led us today to H.R. 2706, the Charlotte Woodward Organ Transplant Discrimination Prevention Act, which would prohibit healthcare providers and other entities from denying or restricting an individual's access to organ transplants solely based on an individual's disability.

The bill would require expedited review of discrimination claims at the Office for Civil Rights at the Department of Health and Human Services. No family should have to wait or be denied.

I thank Charlotte Woodward, Bobbi and Josh, and all of the advocates who have worked so hard to get this bill where it is today. We would not be here without your tireless work to educate and advocate on behalf of individuals with disabilities across the country.

I also want to thank my colleague, DEBBIE DINGELL, for her partnership and work on this bill. It was truly an honor to work with the gentlewoman on important issues like this.

I also acknowledge my Senate counterpart, Senator RUBIO, for championing this issue in the Senate.

Lastly, I thank Chair CATHY MCMORRIS RODGERS for her work and support on this issue. Her leadership in Energy and Commerce on this issue and the multitude of important issues that we deal with in the committee cannot be overstated. Not only is the gentlewoman a trailblazer and an ability advocate, but a force of nature.

Mr. Speaker, I urge my colleagues to support this bill.

Mr. BUCSHON. Mr. Speaker, I have no further speakers, and I am prepared to close. I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, in closing, I think Mrs. CAMMACK explained very well why we need to pass this bill, and I would ask all of my colleagues to support it.

Mr. Speaker, I yield back the balance of my time.

Mr. BUCSHON. Mr. Speaker, in closing, I encourage a ''yes'' vote on this bill, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Indiana (Mr. BUCSHON) that the House suspend the rules and pass the bill, H.R. 2706, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

GIVE KIDS A CHANCE ACT OF 2024

Mr. BUCSHON. Mr. Speaker, I move to suspend the rules and pass 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, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3433

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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 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.''.

(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.—Any amounts collected under this subsection shall—

''(A) be credited to the currently applicable appropriation, account, or fund of the Department of Health and Human Services as discretionary offsetting collections; and

''(B) be available, only to the extent and in the amounts provided in advance in appropriations Acts, to 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.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Indiana (Mr. BUCSHON) and the gentleman from New Jersey (Mr. PALLONE) each will control 20 minutes.

The Chair recognizes the gentleman from Indiana.

GENERAL LEAVE

Mr. BUCSHON. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material in the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Indiana?

There was no objection.

Mr. BUCSHON. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 3433, the Give Kids a Chance Act of 2024, and thank Representatives MCCAUL, ESHOO, and BILIRAKIS for their hard work on this important piece of legislation.

Mr. Speaker, I am excited that we have reached broad bipartisan agreement on this comprehensive bill, which will provide hope to approximately 30 million Americans affected by rare diseases.

Currently, only about 500 of these diseases have FDA-approved treatments. This legislation will foster the development of more pediatric rare disease treatments by strengthening the orphan drug pathway, ensuring drugs are studied for children battling cancer, and reauthorizing the rare pediatric disease priority review voucher program, which is set to expire on September 30.

The PRV program has been a lifeline for patients who require specialized treatments that would not be developed without the incentive this program provides.

I am also supportive of the other provisions in this bill, which would increase organ transplant rates by strengthening OPTN operations and require the FDA to establish an office in a country that has signed the Abraham Accords.

I am grateful to Representatives HARSHBARGER and VARGAS for their leadership on this effort to facilitate operations between the FDA and regulatory authorities and innovators in Abraham Accords countries.

There has been a lot of discussion about moving supply chains for medical products back to the U.S. and our allies, and this office is a good step to help do just that.

Mr. Speaker, I encourage my colleagues to support this bill, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 3433, the Give Kids a Chance Act, sponsored by Representatives MCCAUL and ESHOO.

This bill includes several strong bipartisan pieces of legislation, and I am pleased that our Republican colleagues agreed to work with us on advancing important policies.

This legislation will help expand access to care for patients with rare diseases and complex medical needs, increase research and development into rare pediatric diseases, and improve regulatory certainty.

This bill will help in our efforts to bring new treatments to pediatric patients with more advanced forms of cancer. It also includes important sections of H.R. 6664, Representative ESHOO's bill, the Innovation in Pediatric Drugs Act. Specifically, it gives the Food and Drug Administration new enforcement authority to take action against companies that do not conduct required studies in pediatric patients.

The bill also includes critical language introduced by Representative MATSUI as part of H.R. 7383, the Retaining Access and Restoring Exclusivity Act, or RARE Act, and this will clarify FDA's long-held treatment of orphan drug exclusivity and bring new treatments to more patients suffering from rare diseases. These provisions all advance our goals of accelerating the development of novel, safe, and effective treatments and improving outcomes for patients.

These bills are going to make a difference, but I remain disappointed that my Republican colleagues have been unwilling to consider necessary changes to require drug manufacturers to study their approved rare disease drugs in pediatric populations.

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It is disappointing that my Republican colleagues refuse to hold drug manufacturers' feet to the fire and have decided to move forward with a long-term reauthorization of the priority review voucher program, or PRV, without requiring manufacturers to study rare disease drugs in pediatric patients.

I have been consistent in my belief that we need reforms to the PRV program. Unfortunately, we still have not seen the compelling evidence that this program is functioning how Congress intended it to. That is why I am pleased that the bill includes a requirement for the Government Accountability Office to conduct a new study and report on the effectiveness of the program in attaining our original intent. Previous reports from GAO on the program, and continued research from academics, show that there is little evidence that it incentivized the products Congress intended to help come to market.

I continue to believe that additional guardrails are needed to better target the intent of the program, but despite these concerns, I am pleased that this bill includes important provisions to ensure that our medical product supply chain can be strengthened by working with international partners that believe in both tolerance and respect for every person as well as advancement of science and medicine. I look forward to working with our Republican colleagues to ensure FDA receives the funding necessary to implement this policy and establish an FDA office in Israel.

I am also pleased that this legislation provides the Health Resources and Services Administration the authority to modernize the organ transplant system. This system is lifesaving for many Americans, and I am glad that we can continue to support these much-needed reform efforts.

I believe that we could have achieved more for patients in this legislation. However, since there are strong bipartisan policies included here, I encourage all of my colleagues to vote ''yes'' on this important bill, and I reserve the balance of my time.

Mr. BUCSHON. Mr. Speaker, I yield 5 minutes to the gentleman from Texas (Mr. MCCAUL).

Mr. MCCAUL. Mr. Speaker, I thank the gentleman from Indiana for yielding.

Mr. Speaker, as a founder of the Childhood Cancer Caucus 15 years ago, I have met countless cancer patients and advocates who have asked me for one thing: to give the kids a chance. They want a chance to receive better and safer treatments that preserve their quality of life, a chance to beat childhood cancer, and a chance to eradicate this disease once and for all.

The Give Kids a Chance Act does just that.

The bill is simple. It directs drug companies researching combination drug therapies for adults to also research them for children, where appropriate. This will allow us to treat children the same as we treat adults.

With 235 cosponsors, this legislation is one of the most bipartisan bills in Congress because there is nothing partisan or political about a child with cancer.

Mr. Speaker, I thank Mr. BILIRAKIS from Florida and Ms. ANNA ESHOO from California, my partner in this. I also

thank Chair CATHY MCMORRIS RODGERS and Ranking Member FRANK PALLONE for all of their help in making this come together.

Included in this legislation is another one of my bills, the Creating Hope Reauthorization Act. We first passed this legislation in 2012 to create the pediatric priority review voucher program within the FDA because we found that there was no market incentive for pharmaceutical companies to develop cancer treatments for children. This program provides the incentives.

Since its inception in 2012, 53 vouchers have been awarded for treatments of 39 different rare pediatric diseases, 36 of which previously had no FDA-approved treatments. These diseases typically led to death before a child can reach adulthood, but not anymore.

A dear friend of mine, Dr. Allison from MD Anderson in my home State of Texas, was able to use the voucher program to obtain FDA approval for a treatment called CAR-T immunotherapy. Immunotherapy is a breakthrough cancer treatment not just for children but for all adults. He received the Nobel Prize in medicine for it.

This bill would reauthorize that successful program for another 5 years.

We just had our 15-year summit, and these children, I have to say to the ranking member and to the chair, who I hope is listening, how much joy this gave to their lives. These children who have either survived cancer or are going through cancer, some can make it, some may not, but this gives them hope.

I founded the caucus to give them a voice in the Congress because they didn't have one. They didn't have high-powered lobbyists, but they have us. This is the result of their voices.

We wouldn't be standing here today considering this legislation without the help of patient advocates, including my dear childhood cancer friends, Sadie Keller, Sophie Ryan, Brianna Commerford, and Ailani Myers, and so many other brave children who have joined me in advocating tirelessly on this important issue.

By the way, Mr. Speaker, these kids are tougher than any adults I know, and they are my biggest inspiration in life.

Mr. Speaker, I am proud that my colleagues have come together in a bipartisan spirit to do what is right for our children, which will influence them for decades to come.

Mr. PALLONE. Mr. Speaker, I have no additional speakers, and I reserve the balance of my time.

Mr. BUCSHON. Mr. Speaker, I yield 3 minutes to the gentleman from Florida (Mr. BILIRAKIS).

Mr. BILIRAKIS. Mr. Speaker, I thank Dr. BUCSHON, a great friend of mine who does an outstanding job on our committee, for yielding.

Mr. Speaker, I rise in strong support of H.R. 3433, the Give Kids a Chance Act, by Representative MCCAUL. His legislation strengthens pathways for treatments and cures for children across the Nation.

The Give Kids a Chance Act would require that new studies of pediatric cancer trials focus on combination therapies rather than solely single-use drugs. This bill requires these pathways for children with cancer in cases where both the drugs are FDA approved and owned by the same company.

These combination products may help unlock new treatment options for pediatric cancers and help extend the lives of children battling a rare cancer.

I am proud to cosponsor this legislation. Furthermore, I am particularly glad to see that this comprehensive package contains provisions of two bills I co-lead, the Creating Hope Reauthorization Act and the RARE Act. These bills will support innovation for pediatric rare disease treatments and cures.

The Creating Hope Reauthorization Act will extend the FDA's rare pediatric priority review voucher program for another 5 years, through fiscal year 2029. This voucher serves as a critical and necessary incentive for innovators to invest in research and development of pediatric rare diseases.

Due to their extremely small patient populations, these diseases too often go unnoticed, unfortunately. However, the voucher program allows innovative rare disease companies to receive FDA priority review if they get an approval for a pediatric rare disease. These vouchers can then be used to expedite consideration of new treatments in the pipeline, or transferred or sold to another company to recoup investment losses.

This successful FDA incentive does not cost any taxpayer dollars and must be extended to continue the pipeline of treatments for children with rare diseases.

I was proud to lead the effort in the Energy and Commerce Committee with my good friend and colleague, ANNA ESHOO. We are going to miss her. She is retiring, but hopefully, she will be around to give us some advice in the future.

Again, we have bipartisan agreement on this. It is so very important for our children.

Mr. Speaker, I ask my colleagues to join me in supporting H.R. 3433 off the floor today.

Mr. PALLONE. Mr. Speaker, I reserve the balance of my time.

Mr. BUCSHON. Mr. Speaker, I yield 5 minutes to the gentlewoman from Tennessee (Mrs. HARSHBARGER).

Mrs. HARSHBARGER. Mr. Speaker, I rise today in strong support of H.R. 3433, the Give Kids a Chance Act, which is bipartisan legislation to help speed up the process for getting treatments to children with cancer and other rare diseases.

I am pleased that this bill also includes a modified version of bipartisan legislation I have been leading with Democratic Representative JUAN VARGAS: the United States-Abraham Accords Cooperation and Security Act.

This section of H.R. 3433 will establish a U.S. Food and Drug Administration office in the Abraham Accords region, creating a staging ground for technical assistance and friend-shoring collaboration between the U.S. and Abraham Accords countries, for development of and bringing to our markets lifesaving drugs.

I thank House Committee on Energy and Commerce Chair RODGERS and Ranking Member PALLONE for working with me to advance this important initiative. Chair RODGERS has been a strong ally in developing this.

Our continued dependence on adversarial countries like China for pharmaceutical products endangers our medical supply chains and jeopardizes our national security. More than 80 percent of the active pharmaceutical ingredients for drugs sold in the U.S. are imported from foreign countries, primarily China and India.

As our country works toward securing critical healthcare supply chains from reliance on adversarial countries like China, the strategy of friend-shoring or near-shoring has emerged as part of the solution for industries where domestic production is not yet fully available.

Leveraging the Abraham Accords countries' robust biopharmaceutical industries to help diversify and protect our access to crucial medical supply chains that don't rely on China is a commonsense step to work with our natural allies in our quest to safeguard our access to vital medical products.

We need to begin this process of fortifying our medical supply chains as soon as possible because we have a big hill to climb. With adoption of H.R. 3433 and establishment of an FDA technical assistance office in the Abraham Accords region, we begin climbing that hill.

Mr. Speaker, I urge all of my colleagues to support this bipartisan legislation.

Mr. PALLONE. Mr. Speaker, obviously, this bill does a lot to help childhood disorders. It is a very important bill, and I urge that it be passed on a bipartisan basis.

Mr. Speaker, I yield back the balance of my time.

Mr. BUCSHON. Mr. Speaker, in closing, I encourage a ''yes'' vote on this bill, and I yield back the balance of my time.

Ms. ESHOO. Mr. Speaker, today, the House will vote on my legislation, H.R. 3433, the Give Kids a Chance Act.

My thanks to Reps. MICHAEL MCCAUL (R–TX) and GUS BILIRAKIS (R–FL), the chairwoman of the Energy and Commerce Committee CATHY MCMORRIS RODGERS (R–WA) and Ranking Member FRANK PALLONE (D–NJ) for their very hard work on this important effort.

H.R. 3433 is the most comprehensive legislation to improve and address childhood cancer and rare disease in over a decade.

As medicines become more sophisticated and we improve our understanding of the

deadliest diseases facing children in our country, our laws must keep up.

This legislation will ensure children have access to the most innovative treatments and therapies for cancer and rare disease, and it does that by doing the following.

It reauthorizes the FDA's pediatric priority voucher program for five years. The program expires September 23, 2024 and we cannot let critical tools to encourage the development of drugs for children to lapse.

It directs companies to conduct pediatric trials with combinations of drugs. More than 40 combination therapies are approved for adults, but only 2 are approved for children. This legislation fixes that inequity. Every member of the Energy and Commerce Committee and 392 Members of the House voted for this provision as part of the user fees package last Congress.

It brings the FDA's enforcement capabilities for children on par with that of adults, giving the FDA new options to ensure pediatric studies are completed on time. Today, the FDA can only remove a drug from the market if pediatric studies are not completed. This bill gives the FDA more flexibility to ensure companies follow the law.

The bill dedicates existing funds for pediatric research through the NIH's Best Pharmaceuticals for Children Act Program over the next three years, the program's first funding update since it was authorized in 2002. Zero new funding will be used.

This bill was advanced by the House Energy and Commerce Committee unanimously last week.

Children are not little adults. They deserve effective medicines, just as adults do. The Give Kids a Chance Act will get children what they deserve and save lives.

I urge my colleagues to vote for this critical legislation.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Indiana (Mr. BUCSHON) that the House suspend the rules and pass the bill, H.R. 3433, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

SENIORS' ACCESS TO CRITICAL MEDICATIONS ACT OF 2024

Mr. BUCSHON. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5526) to amend title XVIII of the Social Security Act to clarify the application of the in-office ancillary services exception to the physician self-referral prohibition for drugs furnished under the Medicare program, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5526

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Seniors' Access to Critical Medications Act of 2024''.

SEC. 2. CLARIFYING THE APPLICATION OF THE IN-OFFICE ANCILLARY SERVICES EXCEPTION TO THE PHYSICIAN SELF-REFERRAL PROHIBITION FOR COVERED OUTPATIENT DRUGS FURNISHED UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1877(b)(2) of the Social Security Act (42 U.S.C. 1395nn(b)(2)) is amended by adding at the end the following new sentence: ''With respect to services described in subsection (h)(6)(J) consisting of covered part D drugs (as defined in section 1860D–2(e)) furnished to an individual during the period beginning on January 1, 2025, and ending on December 31, 2029, such drugs shall be treated as having been furnished in accordance with subparagraph (A)(ii) if such drugs are picked up in a building described in subclause (I) or (II) of such subparagraph by such individual, or a family member or caregiver on behalf of such individual, or delivered to such individual by a mail, delivery, or courier service, but only if, during the 1-year period ending on the date such drugs were so furnished, such individual had a face-to-face encounter with the prescriber of such drugs (not including any such encounter conducted via telehealth), and only if such prescriber (or another physician or practitioner (as described in section 1842(b)(18)(C)) in the same practice as such prescriber (as determined by tax identification number)) furnished to such individual, during such 1-year period, another item or service for which payment was made under this title, and only if such individual has an ongoing relationship with such prescriber.''.

(b) REPORT.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that contains—

(1) the number of individuals who were furnished drugs in a manner that would constitute a violation of section 1877 of the Social Security Act (42 U.S.C. 1395nn) but for the amendment made by subsection (a);

(2) an analysis of the change in expenditures under title XVIII of such Act (42 U.S.C. 1395 et seq.) attributable to such amendment;

(3) a description of which drugs were furnished in a manner described in paragraph (1); and

(4) such amendment's impact on prices for such drugs.

SEC. 3. MEDICARE COVERAGE OF EXTERNAL INFUSION PUMPS AND NON-SELF-ADMINISTRABLE HOME INFUSION DRUGS.

Section 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)) is amended by adding at the end the following new sentence: ''Beginning with the first calendar quarter beginning on or after the date that is one year after the date of the enactment of the 'Seniors' Access to Critical Medications Act of 2024', an external infusion pump and associated home infusion drug (as defined in subsection (iii)(3)(C)) or other associated supplies that do not meet the appropriate for use in the home requirement applied to the definition of durable medical equipment under section 414.202 of title 42, Code of Federal Regulations (or any successor to such regulation) shall be treated as meeting such requirement if each of the following criteria is satisfied:

''(1) The prescribing information approved by the Food and Drug Administration for the home infusion drug associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional.

''(2) A qualified home infusion therapy supplier (as defined in subsection (iii)(3)(D)) administers or supervises the administration of the drug or biological in a safe and effective manner in the patient's home (as defined in subsection (iii)(3)(B)).

''(3) The prescribing information described in paragraph (1) instructs that the drug should be infused at least 12 times per year—

''(A) intravenously or subcutaneously; or

''(B) at infusion rates that the Secretary determines would require the use of an external infusion pump.''.

SEC. 4. MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking ''$0'' and inserting ''$114,000,000''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Indiana (Mr. BUCSHON) and the gentleman from New Jersey (Mr. PALLONE) each will control 20 minutes.

The Chair recognizes the gentleman from Indiana.

GENERAL LEAVE

Mr. BUCSHON. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material in the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Indiana?

There was no objection.

Mr. BUCSHON. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, a silver lining of the COVID–19 pandemic, if there is one, was the proliferation of new, effective ways to deliver healthcare.

Of course, we saw the rise of telehealth, but we also saw an increased use of mail to deliver prescription drugs to patients. Mailing prescription drugs to patients, especially those who live in rural communities, helped increase access to care and medication adherence by reducing the need to travel long distances to your nearest pharmacy.

For seniors who may struggle with mobility, this change was especially important.

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Unfortunately, Federal laws limit the ability for seniors to take advantage of these benefits.

CMS states that if a Medicare beneficiary wants to see an independent physician that also owns a pharmacy, the Medicare beneficiary must pick up their drugs from that physician-owned pharmacy in person.

That pharmacy cannot mail the drug directly to the patient or let a family member pick up the drug on the Medicare patient's behalf.

During the COVID–19 pandemic, CMS relaxed this restriction. I have heard from countless oncologists across my home State about how during the COVID–19 pandemic era, those flexibilities improved access to care.

H.R. 5526 would clarify that seniors can get drugs from physician-owned pharmacies through the mail or have someone pick up those medications on their behalf, making it easier for seniors to get the care that they need.

I encourage my colleagues to support this bill, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.