I think that our consumers deserve better than any attempt to try and relieve them of those regulatory actions that would support our consumers. I would ask for a resounding ''no'' vote on this bill that would only feed into the greediness of the major banks of America.

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

Mr. HENSARLING. Mr. Speaker, may I inquire how much time I have remaining?

The SPEAKER pro tempore. The gentleman from Texas has 3 minutes remaining.

Mr. HENSARLING. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, since Dodd-Frank was passed, the big banks have become bigger and the small banks have become fewer. Free checking at banks has been cut in half. Credit cards: 200 basis points more, 15 percent fewer. Many creditworthy borrowers are having to pay almost $600 more for their auto loans.

Mr. Speaker, the American Dream is shrinking. We have 1.6 percent economic growth, stagnant paychecks, decimated savings, and a diminished American Dream. That is the legacy of Dodd-Frank.

Mr. Speaker, I wish I could believe 10 percent of what I heard from the other side of the aisle. I wish it did gut Dodd-Frank. It didn't. You can't find something in here. It is hard, challenging, to find anything in this bill that helps what the ranking member calls the so-called Wall Street megabanks.

Mr. Speaker, listening very carefully to this debate, it is clear that there are some voices that appear to be driven by their loathing of banks and credit unions, and there are other voices that are driven for our love and respect of our fellow citizens, hardworking taxpayers like Dirk in Colton and Sherry, who I mentioned in my opening statement, who are trying to capitalize a small business, who are trying to buy a car that is 10 years old, who are trying to buy that home. It is their American Dream, and they are being challenged due to this law.

I have heard so many of my friends on the other side of the aisle say: Oh, I believe in taking away bureaucracy and red tape from community financial institutions, and I believe in bipartisanship.

Well, they may believe in it, but they are not voting for it. The opportunity is right here in front of us with S. 2155, a strong, bipartisan bill that has come over from the United States Senate. So, again, they claim they believe it in theory; they just don't believe it in practice.

Mr. Speaker, at the end of the day, 3 percent economic growth counts. If you look at the history of our Republic, 3 percent growth is where all the job creation takes place. It is where the paycheck increases take place. It is where the poverty reductions take place. It is the birthright of the American people.

Thankfully, due to the leadership of our President and this Congress, we now have a 3 percent tax policy. We need a 3 percent regulatory policy, especially for our community banks and our credit unions, who help finance the American Dream for all of our citizens.

We should join in unison on this historic day to pass S. 2155, the Economic Growth, Regulatory Relief, and Consumer Protection Act, for the help of all our citizens.

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

Mr. PALAZZO. Mr. Speaker, I rise today to discuss the bill before us, S. 2155. I support a majority of the provisions in this bill, as it makes crucial changes to federal banking laws that provide much needed relief from some of the worst, most burdensome financial regulations that have stifled American small businesses and in turn, harmed consumers.

I intend to vote in its favor, but I have a real issue with the way in which we are considering the bill. A huge bill, almost 200 pages—under a closed rule. The section I want to speak on is a section that most folks probably don't even realize is in the bill, and that is Small Public Housing reform, section 209.

This is an issue I've been working on for years now, and while I'm always happy to see others such as Chairman CRAPO caring about it, I'm frustrated by how haphazardly they are written, and disappointed by how good they could be.

Let me just go over a couple of things that are in the bill before us as they relate to small public housing authorities. The Senate tacked on a rural requirement to the definition of ''small public housing authority'' which is generally defined as a housing authority operating 550 or fewer combined units or vouchers.

For starters, how many times have we debated USDA's rural definition? It's one of the most complicated rural definitions that exist—why are we still using this in new legislation even though we know how difficult it is to come to a consensus on it? The small PHA definition of 550 and under covers approximately 76 percent of PHAs across the country—that number drops to a little over a half when we add the rural definition.

Moreover, there are already existing distinctions when it comes to small PHAs—fewer than 250 get to report less, fewer than 400 are exempt from asset management, etc. Now, we've created a new subsection—rural or non-rural.

So in theory we could have two PHAs of identical sizes in adjoining or nearby counties operating under different rules for performance and oversight. Both likely will have similar resource challenges but only one of them will get regulatory relief as a result of S. 2155.

We're creating complexity, not lessening it. We move physical inspection standards currently used in public housing (UPCS) and we say, let's move them to the less burdensome section 8—which, again, I'm all for, but we don't clarify which section 8. There are two types of section 8, tenant-based and project-based. Presumably they meant tenant-based, but that's something we need to clarify.

These are just a couple of small, non-controversial common sense corrections.

I'll be introducing authorizing legislation that makes these changes and a few others that I didn't have time to go over—and hopefully, we'll be able to attach some technical corrections to a must-pass piece of legislation I know many others share my frustration, to have this massive bill shoved down our throat with no opportunity to make the legislation better.

Isn't that our job as lawmakers? To make sure the bills we pass are the very best they could be. I applaud the deregulatory efforts on the financial side as well as the small public housing side, I'm jut disappointed to see that we don't have the opportunity to make some of these common sense edits on the front end, instead of having to make technical corrections afterwards because what has been signed into law contains well intended, but confusing and imperfect provisions.

Mr. ROYCE of California. Mr. Speaker, it was 5:39 a.m. on June 25, 2010 when we passed the Dodd-Frank Conference Committee Report. At that early morning hour—other than a need for sleep—there was little we agreed upon. But one thing stood out, Republicans and Democrats openly discussed that there were problems in the bill that would need fixing. We knew some of the unintended (and intended) consequences that community banks and credit unions would face when looking to lend to homeowners and small businesses.

Sadly, Mr. Speaker, it has taken nearly 8 years for us to pass into law any meaningful changes of those sweeping reforms. Smaller institutions have suffered; they have fewer assets over which to spread ever-increasing compliance costs. That's what leads to this conundrum where we have fewer banks today than we did during the Great Depression.

Today, we take a step in rewriting these wrongs. I'm particular proud that the bill before us includes many provisions I authored on a bipartisan basis. S. 2155 provides potential homeownership for the so-called ''credit invisibles,'' increases small business lending from credit unions, and improves access to capital for companies looking to go public and hire more workers.

I urge my colleagues to pass these overdue reforms.

The SPEAKER pro tempore (Mr. DUNCAN of Tennessee). All time for debate has expired.

Pursuant to House Resolution 905, the previous question is ordered on the bill.

The question is on the third reading of the bill.

The bill was ordered to be read a third time, and was read the third time.

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. HENSARLING. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER. Pursuant to clause 8 of rule XX, further proceedings on this question will be postponed.

CHILDHOOD CANCER SURVIVORSHIP, TREATMENT, ACCESS, AND RESEARCH ACT OF 2018

Mr. BURGESS. Mr. Speaker, I move to suspend the rules and pass the bill

(S. 292) to maximize discovery, and accelerate development and availability, of promising childhood cancer treatments, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 292

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 ''Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018'' or the ''Childhood Cancer STAR Act''.

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

TITLE I—MAXIMIZING RESEARCH THROUGH DISCOVERY

Subtitle A—Caroline Pryce Walker Conquer Childhood Cancer Reauthorization Act

SEC. 101. CHILDREN'S CANCER BIOREPOSITORIES AND BIOSPECIMEN RESEARCH.

Section 417E of the Public Health Service Act (42 U.S.C. 285a–11) is amended—

(1) in the section heading, by striking ''**RESEARCH AND AWARENESS**'' and inserting ''**RESEARCH, AWARENESS, AND SURVIVORSHIP**'';

(2) by striking subsection (a) and inserting the following:

''(a) CHILDREN'S CANCER BIOREPOSITORIES.—

''(1) AWARD.—The Secretary, acting through the Director of NIH, may make awards to an entity or entities described in paragraph (4) to build upon existing research efforts to collect biospecimens and clinical and demographic information of children, adolescents, and young adults with selected cancer subtypes (and their recurrences) for which current treatments are least effective, in order to achieve a better understanding of the causes of such cancer subtypes (and their recurrences), and the effects and outcomes of treatments for such cancers.

''(2) USE OF FUNDS.—Amounts received under an award under paragraph (1) may be used to carry out the following:

''(A) Collect and store high-quality, donated biospecimens and associated clinical and demographic information on children, adolescents, and young adults diagnosed with cancer in the United States, focusing on children, adolescents, and young adults with cancer enrolled in clinical trials for whom current treatments are least effective. Activities under this subparagraph may include storage of biospecimens and associated clinical and demographic data at existing biorepositories supported by the National Cancer Institute.

''(B) Maintain an interoperable, secure, and searchable database on stored biospecimens and associated clinical and demographic data from children, adolescents, and young adults with cancer for the purposes of research by scientists and qualified health care professionals.

''(C) Establish and implement procedures for evaluating applications for access to such biospecimens and clinical and demographic data from researchers and other qualified health care professionals.

''(D) Provide access to biospecimens and clinical and demographic data from children, adolescents, and young adults with cancer to researchers and qualified health care professionals for peer-reviewed research—

''(i) consistent with the procedures established pursuant to subparagraph (C);

''(ii) only to the extent permitted by applicable Federal and State law; and

''(iii) in a manner that protects personal privacy to the extent required by applicable Federal and State privacy law, at minimum.

''(3) NO REQUIREMENT.—No child, adolescent, or young adult with cancer shall be required under this subsection to contribute a specimen to a biorepository or share clinical or demographic data.

''(4) APPLICATION; CONSIDERATIONS.—

''(A) APPLICATION.—To be eligible to receive an award under paragraph (1) an entity shall submit an application to the Secretary at such a time, in such manner, and containing such information as the Secretary may reasonably require.

''(B) CONSIDERATIONS.—In evaluating applications submitted under subparagraph (A), the Secretary shall consider the existing infrastructure of the entity that would allow for the timely capture of biospecimens and related clinical and demographic information for children, adolescents, and young adults with cancer for whom current treatments are least effective.

''(5) PRIVACY PROTECTIONS AND INFORMED CONSENT.—

''(A) IN GENERAL.—The Secretary may not make an award under paragraph (1) to an entity unless the Secretary ensures that such entity—

''(i) collects biospecimens and associated clinical and demographic information only from participants who have given their informed consent in accordance with Federal and State law; and

''(ii) protects personal privacy to the extent required by applicable Federal and State law, at minimum.

''(B) INFORMED CONSENT.—The Secretary shall ensure biospecimens and associated clinical and demographic information are collected with informed consent, as described in subparagraph (A)(i).

''(6) GUIDELINES AND OVERSIGHT.—The Secretary shall develop and disseminate appropriate guidelines for the development and maintenance of the biorepositories supported under this subsection, including appropriate oversight, to facilitate further research on select cancer subtypes (and their recurrences) in children, adolescents, and young adults with such cancers (and their recurrences).

''(7) COORDINATION.—To encourage the greatest possible efficiency and effectiveness of federally supported efforts with respect to the activities described in this subsection, the Secretary shall ensure the appropriate coordination of programs supported under this section with existing federally supported cancer registry programs and the activities under section 399E–1, as appropriate.

''(8) SUPPLEMENT NOT SUPPLANT.—Funds provided under this subsection shall be used to supplement, and not supplant, Federal and non-Federal funds available for carrying out the activities described in this subsection.

''(9) REPORT.—Not later than 4 years after the date of enactment of the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018, the Secretary shall submit to Congress a report on—

''(A) the number of biospecimens and corresponding clinical demographic data collected through the biospecimen research efforts supported under paragraph (1);

''(B) the number of biospecimens and corresponding clinical demographic data requested for use by researchers;

''(C) barriers to the collection of biospecimens and corresponding clinical demographic data;

''(D) barriers experienced by researchers or health care professionals in accessing the biospecimens and corresponding clinical demographic data necessary for use in research; and

''(E) recommendations with respect to improving the biospecimen and biorepository research efforts under this subsection.

''(10) DEFINITIONS.—For purposes of this subsection:

''(A) AWARD.—The term 'award' includes a grant, contract, or cooperative agreement determined by the Secretary.

''(B) BIOSPECIMEN.—The term 'biospecimen' includes—

''(i) solid tumor tissue or bone marrow;

''(ii) normal or control tissue;

''(iii) blood and plasma;

''(iv) DNA and RNA extractions;

''(v) familial DNA; and

''(vi) any other sample relevant to cancer research, as required by the Secretary.

''(C) CLINICAL AND DEMOGRAPHIC INFORMATION.—The term 'clinical and demographic information' includes—

''(i) date of diagnosis;

''(ii) age at diagnosis;

''(iii) the patient's sex, race, ethnicity, and environmental exposures;

''(iv) extent of disease at enrollment;

''(v) site of metastases;

''(vi) location of primary tumor coded;

''(vii) histologic diagnosis;

''(viii) tumor marker data when available;

''(ix) treatment and outcome data;

''(x) information related to specimen quality; and

''(xi) any other applicable information required by the Secretary.''; and

(3) in subsection (c), by striking ''(42 U.S.C. 202 note)''.

SEC. 102. IMPROVING CHILDHOOD CANCER SURVEILLANCE.

(a) IN GENERAL.—Section 399E–1 of the Public Health Service Act (42 U.S.C. 280e–3a) is amended—

(1) in subsection (a)—

(A) by striking ''shall award a grant'' and inserting ''may make awards to State cancer registries''; and

(B) by striking ''track the epidemiology of pediatric cancer into a comprehensive nationwide registry of actual occurrences of pediatric cancer'' and inserting ''collect information to better understand the epidemiology of cancer in children, adolescents, and young adults''; and

(C) by striking the second sentence and inserting ''Such registries may be updated to include each occurrence of such cancers within a period of time designated by the Secretary.'';

(2) by redesignating subsection (b) as subsection (d);

(3) by inserting after subsection (a) the following:

''(b) ACTIVITIES.—The grants described in subsection (a) may be used for—

''(1) identifying, recruiting, and training potential sources for reporting childhood, adolescent, and young adult cancer cases;

''(2) developing practices to ensure early inclusion of childhood, adolescent, and young adult cancer cases in State cancer registries through the use of electronic reporting;

''(3) collecting and submitting deidentified data to the Centers for Disease Control and Prevention for inclusion in a national database that includes information on childhood, adolescent, and young adult cancers; and

''(4) improving State cancer registries and the database described in paragraph (3), as appropriate, including to support the early inclusion of childhood, adolescent, and young adult cancer cases.

''(c) COORDINATION.—To encourage the greatest possible efficiency and effectiveness of federally supported efforts with respect to the activities described in this section, the Secretary shall ensure the appropriate coordination of programs supported under this section with other federally supported cancer registry programs and the activities under section 417E(a), as appropriate.''; and

(4) in subsection (d), as so redesignated, by striking ''registry established pursuant to subsection (a)'' and inserting ''activities described in this section''.

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 417E(d) of the Public Health Service Act (42 U.S.C. 285a–11(d)) is amended—

(1) by striking ''2009 through 2013'' and inserting ''2019 through 2023''; and

(2) by striking the second sentence.

Subtitle B—Pediatric Expertise at NIH

SEC. 111. INCLUSION OF AT LEAST ONE PEDIATRIC ONCOLOGIST ON THE NATIONAL CANCER ADVISORY BOARD.

Clause (iii) of section 406(h)(2)(A) of the Public Health Service Act (42 U.S.C. 284a(h)(2)(A)) is amended—

(1) by striking ''Board not less than five'' and inserting ''Board—

''(I) not less than 5'';

(2) by inserting ''and'' after the semicolon; and

(3) by adding at the end the following:

''(II) not less than one member shall be an individual knowledgeable in pediatric oncology;''.

SEC. 112. SENSE OF CONGRESS REGARDING PEDIATRIC EXPERTISE AT THE NATIONAL CANCER INSTITUTE.

It is the sense of Congress that the Director of the National Cancer Institute should ensure that all applicable study sections, committees, advisory groups, and panels at the National Cancer Institute include one or more qualified pediatric oncologists, as appropriate.

Subtitle C—NIH Reporting on Childhood Cancer Activities

SEC. 121. REPORTING ON CHILDHOOD CANCER RESEARCH PROJECTS.

The Director of the National Institutes of Health shall ensure that childhood cancer research projects conducted or supported by the National Institutes of Health are included in appropriate reports to Congress, which may include the Pediatric Research Initiative report.

TITLE II—MAXIMIZING DELIVERY: CARE, QUALITY OF LIFE, SURVIVORSHIP, AND CAREGIVER SUPPORT

SEC. 201. CANCER SURVIVORSHIP PROGRAMS.

(a) PILOT PROGRAMS TO EXPLORE MODEL SYSTEMS OF CARE FOR PEDIATRIC CANCER SURVIVORS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may make awards to eligible entities to establish pilot programs to develop, study, or evaluate model systems for monitoring and caring for childhood cancer survivors throughout their lifespan, including evaluation of models for transition to adult care and care coordination.

(2) AWARDS.—

(A) TYPES OF ENTITIES.—In making awards under this subsection, the Secretary shall, to the extent practicable, include—

(i) small, medium, and large-sized eligible entities; and

(ii) sites located in different geographic areas, including rural and urban areas.

(B) ELIGIBLE ENTITIES.—In this subsection, the term ''eligible entity'' means—

(i) a medical school;

(ii) a children's hospital;

(iii) a cancer center;

(iv) a community-based medical facility; or

(v) any other entity with significant experience and expertise in treating survivors of childhood cancers.

(3) USE OF FUNDS.—Funds awarded under this subsection may be used—

(A) to develop, study, or evaluate one or more models for monitoring and caring for cancer survivors; and

(B) in developing, studying, and evaluating such models, to give special emphasis to—

(i) design of models of follow-up care, monitoring, and other survivorship programs (including peer support and mentoring programs);

(ii) development of models for providing multidisciplinary care;

(iii) dissemination of information to health care providers about culturally and linguistically appropriate follow-up care for cancer survivors and their families, as appropriate and practicable;

(iv) development of psychosocial and support programs to improve the quality of life of cancer survivors and their families, which may include peer support and mentoring programs;

(v) design of systems for the effective transfer of treatment information and care summaries from cancer care providers to other health care providers (including risk factors and a plan for recommended follow-up care);

(vi) dissemination of the information and programs described in clauses (i) through (v) to other health care providers (including primary care physicians and internists) and to cancer survivors and their families, where appropriate and in accordance with Federal and State law; and

(vii) development of initiatives that promote the coordination and effective transition of care between cancer care providers, primary care physicians, mental health professionals, and other health care professionals, as appropriate, including models that use a team-based or multi-disciplinary approach to care.

(b) WORKFORCE DEVELOPMENT FOR HEALTH CARE PROVIDERS ON MEDICAL AND PSYCHOSOCIAL CARE FOR CHILDHOOD CANCER SURVIVORS.—

(1) IN GENERAL.—The Secretary shall, not later than 1 year after the date of enactment of this Act, conduct a review of the activities of the Department of Health and Human Services related to workforce development for health care providers who treat pediatric cancer patients and survivors. Such review shall include—

(A) an assessment of the effectiveness of supportive psychosocial care services for pediatric cancer patients and survivors, including pediatric cancer survivorship care patient navigators and peer support programs;

(B) identification of existing models relevant to providing medical and psychosocial services to individuals surviving pediatric cancers, and programs related to training for health professionals who provide such services to individuals surviving pediatric cancers; and

(C) recommendations for improving the provision of psychosocial care for pediatric cancer survivors and patients.

(2) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and Committee on Energy and Commerce of the House of Representatives, a report concerning the findings and recommendations from the review conducted under paragraph (1).

SEC. 202. GRANTS TO IMPROVE CARE FOR PEDIATRIC CANCER SURVIVORS.

(a) IN GENERAL.—Section 417E of the Public Health Service Act (42 U.S.C. 285a–11), as amended by section 101, is further amended by striking subsection (b) and inserting the following:

''(b) IMPROVING CARE FOR PEDIATRIC CANCER SURVIVORS.—

''(1) RESEARCH ON PEDIATRIC CANCER SURVIVORSHIP.—The Director of NIH, in coordination with ongoing research activities, may continue to conduct or support pediatric cancer survivorship research including in any of the following areas:

''(A) Outcomes of pediatric cancer survivors, including within minority or other medically underserved populations and with respect to health disparities of such outcomes.

''(B) Barriers to follow-up care for pediatric cancer survivors, including within minority or other medically underserved populations.

''(C) The impact of relevant factors, which may include familial, socioeconomic, and other environmental factors, on treatment outcomes and survivorship.

''(D) The development of indicators used for long-term follow-up and analysis of the late effects of cancer treatment for pediatric cancer survivors.

''(E) The identification of, as applicable—

''(i) risk factors associated with the late effects of cancer treatment;

''(ii) predictors of adverse neurocognitive and psychosocial outcomes; and

''(iii) the molecular basis of long-term complications.

''(F) The development of targeted interventions to reduce the burden of morbidity borne by cancer survivors in order to protect such cancer survivors from the late effects of cancer.

''(2) BALANCED APPROACH.—In conducting or supporting research under paragraph (1)(A)(i) on pediatric cancer survivors within minority or other medically underserved populations, the Director of NIH shall ensure that such research addresses both the physical and the psychological needs of such survivors, as appropriate.''.

SEC. 203. BEST PRACTICES FOR LONG-TERM FOLLOW-UP SERVICES FOR PEDIATRIC CANCER SURVIVORS.

The Secretary of Health and Human Services may facilitate the identification of best practices for childhood and adolescent cancer survivorship care, and, as appropriate, may consult with individuals who have expertise in late effects of disease and treatment of childhood and adolescent cancers, which may include—

(1) oncologists, which may include pediatric oncologists;

(2) primary care providers engaged in survivorship care;

(3) survivors of childhood and adolescent cancer;

(4) parents of children and adolescents who have been diagnosed with and treated for cancer and parents of long-term survivors;
(5) nurses and social workers;
(6) mental health professionals;
(7) allied health professionals, including physical therapists and occupational therapists; and
(8) others, as the Secretary determines appropriate.

SEC. 204. TECHNICAL AMENDMENT.

(a) IN GENERAL.—Section 3 of the Hematological Cancer Research Investment and Education Act of 2002 (Public Law 107–172; 116 Stat. 541) is amended by striking ''section 419C'' and inserting ''section 417C''.
(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in section 3 of the Hematological Cancer Research Investment and Education Act of 2002 (Public Law 107–172; 116 Stat. 541).

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

The Chair recognizes the gentleman from Texas.

GENERAL LEAVE

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

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

There was no objection.

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

Mr. Speaker, today, we are here to debate the Childhood Cancer Survivorship, Treatment, Access, and Research Act, also known as the Childhood Cancer STAR Act.

Each of us knows someone who has suffered from cancer, whether it is a family member, friend, patient, or loved one. It is especially heartwrenching to watch children go through a cancer diagnosis and cancer treatment.

The bill we are considering today is for our children, the future of our Nation. I would like to acknowledge and thank my fellow Texan, Congressman MICHAEL MCCAUL, for leading our work to deliver hope to America's youngest cancer patients.

Congress has done remarkable work to pass legislation such as the 21st Century Cures Act, which provided Americans with great hope that increased investment in biomedical research would lead to treatment and even cures for our most devastating diseases.

The 21st Century Cures Act authorized over $4.5 billion in new funding for the National Institutes of Health, including nearly $2 billion for the Cancer Moonshot.

The Childhood Cancer STAR Act builds upon the mission of 21st Century Cures but focuses on empowering the National Institutes of Health and the Centers for Disease Control and Prevention to increase the amount of research and surveillance for cancer in children, adolescents, and young adults.

Groundbreaking discoveries rely on robust and reliable investment in research, and this requires robust and reliable dollars for research.

This bill authorizes $30 million a year through fiscal year 2023 for the National Childhood Cancer Registry, which will provide grant funding for the purpose of collecting information to better understand the epidemiology of cancer in children, adolescents, and young adults.

The bill also authorizes the National Cancer Institute at the National Institutes of Health to make awards that will support childhood cancer biorepositories, giving physicians and researchers tools to better understand these diseases.

Mr. Speaker, it is vital that physicians and their teams can provide comprehensive and coordinated care for pediatric cancer patients. The bill allows the Secretary of the Department of Health and Human Services to make grants to establish pilot programs to develop, study, or evaluate model systems to improve the quality and the efficiency of care for childhood cancer survivors.

It also provides for greater efficiency and coordination of care for those survivors as they transition into adulthood and for the Secretary to work with experts to identify best practices.

Similarly, this bill gives the National Institutes of Health Director the authority to make grants to programs that conduct or support research relating to pediatric cancer survivors.

As I have said, this legislation is for our children. It is for the families that are building our Nation's future. If we can ensure that these young patients receive treatment and cures for childhood cancer, they may grow up to become biomedical researchers who will find the next generation of cures; they may write the next great American classic; they may become prima ballerinas, Olympic athletes, or all of the above.

This legislation is for kids like Sadie. Sadie was diagnosed with ALL, acute lymphoblastic leukemia, on February 25, 2015. She was just 7 years old at the time. This young north Texan fought through infections, blood transfusions, and rare side effects. She missed out on second grade and she missed out on third grade as she underwent weekly chemotherapy sessions.

Today, it is my great joy to share that Sadie beat the odds and Sadie survived leukemia. She received her last chemotherapy treatment May 26, 2017. Now, at 10 years old, Sadie is able to live the life of a normal kid.

I would like to thank Sadie and her family for their willingness to share their story and for their advocacy in support of this important legislation.

Mr. Speaker, I met Sadie in my office last spring, and I was inspired by her story. She started a nonprofit, the Sadie Keller Foundation, to raise money to help other kids who are facing cancer. Her mission is pretty simple. It is to put a smile on the faces of children fighting cancer all over the country and to remind them to keep fighting.

So, today, I urge Members of Congress to support this important bipartisan legislation. In sending this bill to the President's desk, we will help Sadie achieve her mission of putting a smile on the faces of children fighting cancer. We will provide families across this country with hope for a better tomorrow.

Mr. Speaker, 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 S. 292, the Childhood Cancer Survivorship, Treatment, Access, and Research Act.

I want to particularly thank our lead Democratic sponsor, Mr. BUTTERFIELD of North Carolina, for promoting this bill.

Nearly 16,000 children are diagnosed with cancer in the U.S. each year. Those children are forced to bravely battle a disease and carry burdens that no one their age should. The Childhood Cancer STAR Act gives those children and their families hope by encouraging improved research as well as survivorship programs for children with cancer.

This legislation urges the National Institutes of Health to find new opportunities to expand research into pediatric cancer and survivorship, such as supporting the collection of biospecimens, as well as supporting research on the causes of health disparities in pediatric cancer survivorship.

The bill also allows the Centers for Disease Control and Prevention to award funding to help States strengthen their infrastructure to track the epidemiology of pediatric cancer.

□ 1530

This improves childhood cancer surveillance and helps to guide public health decisionmaking as well as research inquiry.

Finally, this bill recognizes that expanding research that leads to treatments and cures is only part of the equation in improving the experience of children diagnosed with this disease. We must ensure that quality care is available to meet their needs for the remainder of their lives.

Unfortunately, the battle with pediatric cancer extends beyond beating the disease. As many as two-thirds of pediatric cancer survivors suffer from long-term effects of their disease and treatment, including secondary cancers and organ damage.

That is why this bill allows the Secretary of Health and Human Services to establish a pilot program to develop, study, or evaluate model systems for monitoring and caring for childhood cancer survivors through their lifespan, as well as to develop best practices for long-term followup services for pediatric cancer survivors.

I will continue to support efforts like this to improve outcomes for cancer

patients and survivors. However, unlike with this legislation, such efforts should proceed through the regular order process.

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

Mr. BURGESS. Mr. Speaker, I yield as much time as he may consume to the gentleman from Oregon (Mr. WALDEN), the chairman of the full committee.

Mr. WALDEN. Mr. Speaker, I would thank my colleagues on both sides of the aisle, and our staffs, who worked so hard on this legislation.

I rise to offer my strong support for S. 292, the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018, simply known as the Childhood Cancer STAR Act. The House version of this important legislation was spearheaded by several, including my colleague Representative MICHAEL MCCAUL of Texas, the chairman of the House Committee on Homeland Security. I would like to thank the gentleman for his leadership on this bipartisan initiative.

Being told your child has cancer is probably every parent's worst nightmare. Even though childhood cancer is rare, it is still the second leading cause of death in children aged 1 to 14. In the last Congress we passed the 21st Century Cures Act. This landmark legislation modernized the Nation's biomedical and innovation infrastructure, and it streamlined the process for how drugs and medical devices are approved so we can get new treatments to patients faster.

And we have invested heavily in the National Institutes of Health through the appropriations process—then and now—recently increasing their budget by $3 billion in the 2018 spending bill, which I supported. The STAR Act builds on these investments and expands the reach of the 21st Century Cures legislation by focusing critical resources to advance both research and treatments for pediatric cancer.

By reauthorizing and modifying the National Childhood Cancer Registry; supporting childhood cancer biorepositories; improving the tracking of cancer in children, adolescents, and young adults; and supporting efforts to improve the pediatric cancer survivorship care, the STAR Act will improve both treatment of children currently battling cancer and the quality of life for the young survivors who have beaten this terrible disease.

So I want to thank my colleagues on both sides of the aisle. This is good work we are doing here today in a bipartisan way in the United States House of Representatives. We will save lives. We will help families. Especially, we will help these children who are suffering mightily.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentleman from North Carolina (Mr. BUTTERFIELD), the lead Democratic sponsor, who is always out front on so many important healthcare issues.

Mr. BUTTERFIELD. Mr. Speaker, I thank Mr. PALLONE for his friendship and leadership on the committee. He has been an extraordinary leader in the healthcare space, and I want to publicly thank the gentleman for his work. As well as to Dr. BURGESS: I have been on the committee now for more than 10 years, and I have watched him and Mr. WALDEN, Mr. BARTON, and others engage in debate. I know that all of them are seriously and totally committed to improving health outcomes in this country, and I thank them all for their leadership.

Mr. Speaker, I rise today to urge my colleagues to support S. 292, the Childhood Cancer Survivorship, Treatment, Access, and Research Act, commonly referred to as the STAR Act. Along with Mr. MCCAUL, JACKIE SPEIER, and MIKE KELLY, I introduced H.R. 820, which is the House companion to S. 292.

Over 85 percent of the House has cosponsored this bill. It is, therefore, my great honor to serve as cochair of the bipartisan House Childhood Cancer Caucus. Through the work of this caucus, I have had the opportunity to work closely with pediatric patient groups and stakeholders to promote legislation that can help save and improve the lives of young people.

Passage of the STAR Act has long been a goal of those patients and of the Childhood Cancer Caucus, and I am grateful that the House is poised to send this important piece of legislation now to the President's desk for his signature.

Mr. Speaker, 16,000—16,000—children in the United States are diagnosed with cancer every year. Many of those have limited treatment options. The STAR Act, Mr. Speaker, is an important piece of legislation that will expand the opportunities for childhood cancer research, improve efforts to identify and track childhood cancer, and enhance the quality of life of childhood cancer survivors.

Childhood cancer remains the leading cause of death in American children. As many as two-thirds of childhood cancer survivors suffer from late effects of their disease or treatment, including secondary cancers or organ damage. That is why passage and enactment of this legislation is so important.

The bill enhances research on the late effects of childhood cancers, improves collaboration among providers so that doctors are better able to care for survivors as they age, and explores innovative models of care for childhood cancer survivors.

When enacted, S. 292 will help to advance pediatric cancer research and child-focused cancer treatments while also improving childhood cancer surveillance and providing enhanced resources for survivors. This bill, Mr. Speaker, is the most comprehensive childhood cancer legislation ever slated to be passed by this Congress.

The STAR Act will give young cancer patients and their families better access to life-saving treatments and the support they need even after beating cancer. I strongly urge my colleagues to support this legislation. Mr. Speaker, I thank all of the leaders of the committee for their work.

Mr. BURGESS. Mr. Speaker, I yield 2 minutes to the gentleman from New Jersey (Mr. LANCE), vice chairman of one of our subcommittees.

Mr. LANCE. Mr. Speaker, I rise today in strong support of the Childhood Cancer STAR Act, one of the most comprehensive pieces of childhood cancer legislation ever taken up by the Congress and another major bipartisan accomplishment of the House Committee on Energy and Commerce. I certainly congratulate Dr. BURGESS.

It is heartbreaking when a child is stricken with one of these life-threatening diseases. I have met with families who have faced these terrible circumstances, and I have been touched by their stories of perseverance and hope.

There is more work to be done. We need to improve Federal services for the pediatric cancer community, from research and access to treatment and survivorship. Federal healthcare and research entities must do all they can. The Childhood Cancer STAR Act delivers more resources and reform to make sure we are winning the fight against pediatric cancer by expanding grants for promising and expanded programs.

Last week I stopped by the Hunterdon County Relay for Life event in Ringoes, New Jersey. The event brought together cancer patients, survivors, and their families. The crowd was large and enthusiastic in the fight against these terrible diseases.

We owe it to those participants to ensure that federally supported research entities are doing all that they can do in this area. The Energy and Commerce Committee has made the cause of Cures a centerpiece of our work. This bill provides greater hope for all of the Nation's youngest patients and their loved ones.

Mr. Speaker, I urge a ''yes'' vote.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentlewoman from Florida (Ms. CASTOR), the vice ranking member of the House Committee on Energy and Commerce.

Ms. CASTOR of Florida. Mr. Speaker, I thank the gentleman for his leadership and for yielding the time.

Mr. Speaker, we simply must do more for pediatric cancer and the children and families who are impacted by it. That is why I urge adoption of S. 292. It is also H.R. 820. I would like to thank my colleagues—Congressman MCCAUL, Congresswoman SPEIER, Congressman BUTTERFIELD, and Congressman KELLY—for leading the charge on this. It has broad bipartisan support.

Mr. Speaker, I mostly want to thank the families and the parents across America who have helped educate us—folks like Bonnie Woodworth; her husband, Scott; and kids Joe, Delaney, and Piper—who have educated me and

many policymakers across the Tampa Bay area. See, they lost their daughter and sister, Tatum, in 2012 to pediatric cancer.

On behalf of so many families who often are held back by the pain of losing a child or dealing with childhood cancer, they channeled their energy into making things better for other families. They have educated me and others, along with Mary Ann Massolio with the 1Voice Foundation, back in the Tampa Bay area.

I am so happy that it is paying off today. What they have explained is that, after you suffer this diagnosis, it is very isolating. America doesn't do a lot of research on pediatric cancer. It is not coordinated very well, and the resources just are not there to help bring families together to get through these kinds of varied diagnoses.

The STAR Act hopefully will make things better because we are going to ask the Centers for Disease Control to do more with States to track pediatric cancer. We are going to do a little more research on how it is best to care for survivors. We are going to try to endeavor to do better in coordination of care for kids with pediatric cancer, do more on research, and also, help folks in the minority community who often don't have the resources dedicated to them that they need.

Hopefully this will bring great relief to the families, and I urge a swift adoption.

Mr. BURGESS. Mr. Speaker, I yield 5 minutes to the gentleman from Texas (Mr. MCCAUL), chairman of the House Committee on Homeland Security, fellow Texan, and the principal author of the bill that we have before us today.

Mr. MCCAUL. Mr. Speaker, I want to thank my good friend Dr. BURGESS for shepherding this bill through the Energy and Commerce Committee and taking us to the point where we are today on the floor.

Mr. Speaker, I rise in support of this bill, the Childhood Cancer STAR Act. The bill addresses 4 major concerns facing the pediatric cancer community: survivorship, treatment, access, and research.

I was proud to introduce this bill with Ms. JACKIE SPEIER, with G.K. BUTTERFIELD, and Mr. MIKE KELLY of Pennsylvania. This is the most comprehensive childhood cancer bill ever considered before this House. This bill passed the House in 2016, and I encourage the support of all Members today so we can finally send it to the President's desk for his signature. I am proud to say that today is the day. I know a lot of the advocates have been waiting for this day for quite some time.

Childhood cancer, unfortunately, remains the deadliest killer of our children. At some point we, as a Congress and as a Nation, must say enough is enough. In short, the STAR Act elevates and prioritizes the fight against childhood cancer at the NIH. Specifically, STAR places a pediatric oncologist on the board at the National Cancer Institute, so childhood cancer will now have a voice at the table when funding decisions are made.

It also expands opportunities to childhood cancer research, allowing doctors to better understand and track how cancer develops in children. Finally, we must also address the needs of the nearly 500,000 survivors of childhood cancer. Due to their treatments using chemotherapy, a World War I chemical agent, two-thirds of these survivors will face serious, lifelong medical conditions.

When I think about what this means, I think of my friend Sadie Keller. She is perhaps the strongest person I know. Sadie underwent over 2 years of chemotherapy at the age of 7 after being diagnosed with leukemia. She has been, at her young age, perhaps the most relentless advocate for this cause, this bill here on Capitol Hill, and throughout the childhood cancer community.

I just want to refer to this picture of little Sadie and myself when she was going through remission, on the Speaker's balcony, looking out over The Mall, with a vision towards the future, a future where children will no longer have to go through this disease, looking at the dark clouds but the sunlight coming through. That is what this bill represents is sunlight for the children who have been afflicted with this terrible disease.

□ 1545

While now her cancer is in remission, that does not mean her medical challenges are over. We must do more as a Nation to care for these survivors. To that end, the STAR Act will improve collaboration among providers so doctors are better able to care for survivors as they age.

I want to close by thanking Sadie, but I also want to thank people like Danielle Leach and the Alliance for Childhood Cancer team for their relentless advocacy on the Hill and work on this bill. I also want to thank Nancy Goodman and Kids v. Cancer and the entire childhood cancer advocacy community for standing up and getting us to the point where we are today.

They are the voice of these children. They made this event possible here today. And I want to thank them from the bottom of my heart.

I urge passage of this life-altering piece of legislation.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentleman from Virginia (Mr. CONNOLLY).

Mr. CONNOLLY. Mr. Speaker, I thank my good friend, the ranking member, the gentleman from New Jersey (Mr. PALLONE).

I rise today in support of the Childhood Cancer STAR Act.

Thanks to research funded by the National Institutes of Health, the private sector, and philanthropic funds, we have made progress in the study and treatment of childhood cancers. However, every year, 16,000 children and their families receive that terrible, nightmarish news that their child has been diagnosed with cancer.

My constituent Allison Easter-Lara was diagnosed with stage IV neuroblastoma when she was about 2 years old. Throughout her fight, she endured some of the harshest cancer treatments there are, with chemotherapy and stem cell transplants.

Allison's dad, Keith, visited my office earlier this year, and he shared a remarkable update. Allison is beating the odds. She is currently in remission and in a phase two drug trial.

We must pass the STAR Act because we need more good outcomes like Allison's. This bill will expand childhood cancer research opportunities at the NIH, improve our understanding of cancer as a disease, and work to enhance the quality of life for all survivors.

It may be a moonshot, but I believe we can find new treatments and eventually a cure for childhood cancer.

Mr. BURGESS. Mr. Speaker, I yield 2 minutes to the gentleman from Tennessee (Mr. ROE).

Mr. ROE of Tennessee. Mr. Speaker, I thank Dr. BURGESS.

Mr. Speaker, I rise today in strong support of S. 204, the Right to Try Act.

I am a physician and scientist with almost 40 years of experience in treating patients, and far too many of them, Mr. Speaker, have been diagnosed with cancer.

A little over 3 years ago, my beloved wife, Pam Roe, who was a nurse, died of stage IV colon cancer, 5 weeks to the day after she was operated on. Pam would have liked the right to try.

Less than 2 months after that, one of the best friends I will ever have in my life, Phil Street, a Vietnam veteran, Air Force veteran, died of cancer related to Agent Orange. Phil would have liked to have had the right to try.

My senior partner in medical practice, a year later, good friend, Dr. Bill Bone, was diagnosed with brain cancer. Bill died. He would have liked to have had the right to try.

Shortly after that, Linda Baines, a scrub nurse that I operated with hundreds of times in my medical practice, was diagnosed with brain cancer and died shortly after that. Linda would have liked to have had the right to try.

Currently, I have three friends at this moment who are being treated with stage IV cancer. If those treatments don't work, they would like to have the right to try.

Mr. Speaker, my first pediatric rotation in medical school was at St. Jude Children's Hospital, where, at that time, 80 percent of children died of their disease. I can still see many of those children's faces today, and that was almost 50 years ago. Those children, today, have an 80 percent chance of living, but, as was stated, 16,000 parents have to face that this year.

I have had the misfortune of having to look patients in the eye and say: Your life is not in my hands anymore;

it is in God's hands. In that moment, I will tell you this: all that these patients want and deserve is a right to try.

Please support this legislation.

Mr. PALLONE. Mr. Speaker, I just want to urge support for this legislation. The support is obviously bipartisan, and I urge all my colleagues to support it.

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

Mr. BURGESS. Mr. Speaker, I, too, want to express my strong support for S. 292, the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018, Childhood Cancer STAR Act.

And, once again, I want to thank my colleague, the gentleman from Texas (Mr. MCCAUL), for spearheading this effort.

I urge all my colleagues to support the legislation.

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

Ms. SPEIER. Mr. Speaker, I rise today in support of the Childhood Cancer Survivorship, Treatment, Access & Research (STAR) Act, a bill that will touch many lives affected by childhood cancer. This has been a true example of bipartisanship. I particularly want to thank my colleague Congressman MCCAUL for his leadership on this critical bill and my other fellow co-chairs of the Congressional Childhood Cancer Caucus, Congressmen BUTTERFIELD and KELLY. I also want to thank our Senate partners, Senators REED, MOORE CAPITO, VAN HOLLEN, and ISAKSON. And to all children and families affected by childhood cancer, this is their victory. It is because of their tireless advocacy that this landmark legislation will be sent to the President's desk and signed into law.

With the STAR Act, we have won a battle in our long-fought war against childhood cancer. This bill creates an arsenal of tools for the National Institutes of Health to promote vital research into childhood cancer, such as the establishment of National Biorepositories. It also improves the quality of life for survivors, including by funding models of long-term care to help monitor the progress of survivors as they age.

Mr. Speaker, I want to take a moment to recognize two of my constituents who have personally inspired my work on this important bill. The first is Christie Chaudry, who after surviving childhood cancer grew up to become a pediatric oncology nurse practitioner. For the last seven years, Christie has helped run the inpatient chemotherapy unit at Lucile Packard Children's Hospital at Stanford—the same hospital where she was treated as a child.

The second is Andrea Church, a childhood cancer advocate from San Carlos, California, who set a goal to have San Francisco City Hall lit up in gold in honor of Childhood Cancer Awareness Month. Andrea's daughter, Riley, passed away at age 14 due to an inoperable brain tumor. In her daughter's honor, Andrea reached and surpassed her goal two years ago. Not only did San Francisco City Hall go gold, so did Oakland City Hall, AT&T Park—the home of the San Francisco Giants—and the Oakland Coliseum—the home of the Oakland A's.

Mr. Speaker, the STAR Act opens the door to numerous opportunities for research and innovation in the treatment of childhood cancer. It addresses critical gaps in the care of childhood cancer survivors, and it creates a holistic approach to studying the disease. With the passage of this legislation, we are moving closer to a future where children and their families may one day live cancer-free. I thank my colleagues for their support.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Texas (Mr. BURGESS) that the House suspend the rules and pass the bill, S. 292.

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

A motion to reconsider was laid on the table.

TRICKETT WENDLER, FRANK MONGIELLO, JORDAN MCLINN, AND MATTHEW BELLINA RIGHT TO TRY ACT OF 2017

Mr. BURGESS. Mr. Speaker, pursuant to House Resolution 905, I call up the bill (S. 204) to authorize the use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law, and for other purposes, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Pursuant to House Resolution 905, the bill is considered read.

The text of the bill is as follows:

S. 204

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 ''Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017''.

SEC. 2. USE OF UNAPPROVED INVESTIGATIONAL DRUGS BY PATIENTS DIAGNOSED WITH A TERMINAL ILLNESS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561A (21 U.S.C. 360bbb–0) the following:

''SEC. 561B. INVESTIGATIONAL DRUGS FOR USE BY ELIGIBLE PATIENTS.

''(a) DEFINITIONS.—For purposes of this section—

''(1) the term 'eligible patient' means a patient—

''(A) who has been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));

''(B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who—

''(i) is in good standing with the physician's licensing organization or board; and

''(ii) will not be compensated directly by the manufacturer for so certifying; and

''(C) who has provided to the treating physician written informed consent regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent;

''(2) the term 'eligible investigational drug' means an investigational drug (as such term is used in section 561)—

''(A) for which a Phase 1 clinical trial has been completed;

''(B) that has not been approved or licensed for any use under section 505 of this Act or section 351 of the Public Health Service Act;

''(C)(i) for which an application has been filed under section 505(b) of this Act or section 351(a) of the Public Health Service Act; or

''(ii) that is under investigation in a clinical trial that—

''(I) is intended to form the primary basis of a claim of effectiveness in support of approval or licensure under section 505 of this Act or section 351 of the Public Health Service Act; and

''(II) is the subject of an active investigational new drug application under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, as applicable; and

''(D) the active development or production of which is ongoing and has not been discontinued by the manufacturer or placed on clinical hold under section 505(i); and

''(3) the term 'phase 1 trial' means a phase 1 clinical investigation of a drug as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

''(b) EXEMPTIONS.—Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 502(f), 503(b)(4), 505(a), and 505(i) of this Act, section 351(a) of the Public Health Service Act, and parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible investigational drug or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs.

''(c) USE OF CLINICAL OUTCOMES.—

''(1) IN GENERAL.—Notwithstanding any other provision of this Act, the Public Health Service Act, or any other provision of Federal law, the Secretary may not use a clinical outcome associated with the use of an eligible investigational drug pursuant to this section to delay or adversely affect the review or approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act unless—

''(A) the Secretary makes a determination, in accordance with paragraph (2), that use of such clinical outcome is critical to determining the safety of the eligible investigational drug; or

''(B) the sponsor requests use of such outcomes.

''(2) LIMITATION.—If the Secretary makes a determination under paragraph (1)(A), the Secretary shall provide written notice of such determination to the sponsor, including a public health justification for such determination, and such notice shall be made part of the administrative record. Such determination shall not be delegated below the director of the agency center that is charged with the premarket review of the eligible investigational drug.

''(d) REPORTING.—

''(1) IN GENERAL.—The manufacturer or sponsor of an eligible investigational drug shall submit to the Secretary an annual summary of any use of such drug under this section. The summary shall include the number of doses supplied, the number of patients treated, the uses for which the drug was made available, and any known serious adverse events. The Secretary shall specify by regulation the deadline of submission of such annual summary and may amend section