Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

NEWBORN SCREENING SAVES LIVES REAUTHORIZATION ACT OF 2021

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 482) to amend the Public Health Service Act to reauthorize certain programs under part A of title XI of such Act relating to genetic diseases, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 482

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 ''Newborn Screening Saves Lives Reauthorization Act of 2021''.

SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING AND FOLLOW-UP FOR HERITABLE DISORDERS.

(a) PURPOSES.—Section 1109(a) of the Public Health Service Act (42 U.S.C. 300b–8(a)) is amended—

(1) in paragraph (1), by striking ''enhance, improve or'' and inserting ''facilitate, enhance, improve, or'';

(2) by amending paragraph (3) to read as follows:

''(3) to develop, and deliver to parents, families, and patient advocacy and support groups, educational programs that—

''(A) address newborn screening counseling, testing (including newborn screening pilot studies), follow-up, treatment, specialty services, and long-term care;

''(B) assess the target audience's current knowledge, incorporate health communications strategies, and measure impact; and

''(C) are at appropriate literacy levels;''; and

(3) in paragraph (4)—

(A) by striking ''followup'' and inserting ''follow-up''; and

(B) by inserting before the semicolon at the end the following: '', including re-engaging patients who have not received recommended follow-up services and supports''.

(b) APPROVAL FACTORS.—Section 1109(c) of the Public Health Service Act (42 U.S.C. 300b–8(c)) is amended—

(1) by striking ''or will use'' and inserting ''will use''; and

(2) by inserting '', or will use amounts received under such grant to enhance capacity and infrastructure to facilitate the adoption of,'' before ''the guidelines and recommendations''.

SEC. 3. ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

Section 1111 of the Public Health Service Act (42 U.S.C. 300b–10) is amended—

(1) in subsection (b)—

(A) in paragraph (5), by inserting ''and adopt process improvements'' after ''take appropriate steps'';

(B) in paragraph (7) by striking ''and'' at the end;

(C) by redesignating paragraph (8) as paragraph (9);

(D) by inserting after paragraph (7) the following:

''(8) develop, maintain, and publish on a publicly accessible website consumer-friendly materials detailing—

''(A) the uniform screening panel nomination process, including data requirements, standards, and the use of international data in nomination submissions; and

''(B) the process for obtaining technical assistance for submitting nominations to the uniform screening panel and detailing the instances in which the provision of technical assistance would introduce a conflict of interest for members of the Advisory Committee; and'';

(E) in paragraph (9), as redesignated—

(i) by redesignating subparagraphs (K) and (L) as subparagraphs (L) and (M), respectively; and

(ii) by inserting after subparagraph (J) the following:

''(K) the appropriate and recommended use of safe and effective genetic testing by health care professionals in newborns and children with an initial diagnosis of a disease or condition characterized by a variety of genetic causes and manifestations;''; and

(2) in subsection (g)—

(A) in paragraph (1) by striking ''2019'' and inserting ''2026''; and

(B) in paragraph (2) by striking ''2019'' and inserting ''2026''.

SEC. 4. CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

Section 1112(c) of the Public Health Service Act (42 U.S.C. 300b–11(c)) is amended by striking ''and supplement, not supplant, existing information sharing efforts'' and inserting ''and complement other Federal newborn screening information sharing activities''.

SEC. 5. LABORATORY QUALITY AND SURVEILLANCE.

Section 1113 of the Public Health Service Act (42 U.S.C. 300b–12) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking ''performance evaluation services,'' and inserting ''development of new screening tests,''; and

(ii) by striking ''and'' at the end;

(B) in paragraph (2)—

(i) by striking ''performance test materials'' and inserting ''test performance materials''; and

(ii) by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(3) performance evaluation services to enhance disease detection, including the development of tools, resources, and infrastructure to improve data analysis, test result interpretation, data harmonization, and dissemination of laboratory best practices.''; and

(2) in subsection (b) to read as follows:

''(b) SURVEILLANCE ACTIVITIES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, shall provide for the coordination of national surveillance activities, including—

''(1) standardizing data collection and reporting through the use of electronic and other forms of health records to achieve real-time data for tracking and monitoring the newborn screening system, from the initial positive screen through diagnosis and long-term care management; and

''(2) by promoting data sharing linkages between State newborn screening programs and State-based birth defects and developmental disabilities surveillance programs to help families connect with services to assist in evaluating long-term outcomes.''.

SEC. 6. HUNTER KELLY RESEARCH PROGRAM.

Section 1116 of the Public Health Service Act (42 U.S.C. 300b–15) is amended—

(1) in subsection (a)(1)—

(A) by striking ''may'' and inserting ''shall''; and

(B) in subparagraph (D)—

(i) by inserting '', or with a high probability of being recommended by,'' after ''recommended by''; and

(ii) by striking ''that screenings are ready for nationwide implementation'' and inserting ''that reliable newborn screening technologies are piloted and ready for use''; and

(2) in subsection (b) to read as follows:

''(b) FUNDING.—In carrying out the research program under this section, the Secretary and the Director shall ensure that entities receiving funding through the program will provide assurances, as practicable, that such entities will work in consultation with State departments of health, as appropriate.''.

SEC. 7. AUTHORIZATION OF APPROPRIATIONS FOR NEWBORN SCREENING PROGRAMS AND ACTIVITIES.

Section 1117 of the Public Health Service Act (42 U.S.C. 300b–16) is amended—

(1) in paragraph (1)—

(A) by striking ''$11,900,000'' and inserting ''$31,000,000'';

(B) by striking ''2015'' and inserting ''2022''; and

(C) by striking ''2019'' and inserting ''2026''; and

(2) in paragraph (2)—

(A) by striking ''$8,000,000'' and inserting ''$29,650,000'';

(B) by striking ''2015'' and inserting ''2022''; and

(C) by striking ''2019'' and inserting ''2026''.

SEC. 8. INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM.

Section 12 of the Newborn Screening Saves Lives Reauthorization Act of 2014 (42 U.S.C. 289 note) is amended to read as follows:

''SEC. 12. INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM.

''Research on nonidentified newborn dried blood spots shall be considered secondary research (as that term is defined in section 46.104(d)(4) of title 45, Code of Federal Regulations (or successor regulations)) with nonidentified biospecimens for purposes of federally funded research conducted pursuant to the Public Health Service Act (42 U.S.C. 200 et seq.).''.

SEC. 9. NAM REPORT ON THE MODERNIZATION OF NEWBORN SCREENING.

(a) STUDY.—Not later than 60 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall seek to enter into an agreement with the National Academy of Medicine (in this section referred to as ''NAM'') (or if NAM declines to enter into such an agreement, another appropriate entity) under which NAM, or such other appropriate entity, agrees to conduct a study on the following:

(1) The uniform screening panel review and recommendation processes to identify factors that impact decisions to add new conditions to the uniform screening panel, to describe challenges posed by newly nominated conditions, including low-incidence diseases, late onset variants, and new treatments without long-term efficacy data.

(2) The barriers that preclude States from adding new uniform screening panel conditions to their State screening panels with recommendations on resources needed to help States implement uniform screening panel recommendations.

(3) The current state of federally and privately funded newborn screening research with recommendations for optimizing the capacity of this research, including piloting multiple prospective conditions at once and addressing rare disease questions.

(4) New and emerging technologies that would permit screening for new categories of disorders, or would make current screening more effective, more efficient, or less expensive.

(5) Technological and other infrastructure needs to improve timeliness of diagnosis and short- and long-term follow-up for infants identified through newborn screening and improve public health surveillance.

(6) Current and future communication and educational needs for priority stakeholders and the public to promote understanding and knowledge of a modernized newborn screening system with an emphasis on evolving communication channels and messaging.

(7) The extent to which newborn screening yields better data on the disease prevalence for screened conditions and improves long-term outcomes for those identified through newborn screening, including existing systems supporting such data collection and recommendations for systems that would allow for improved data collection.

(8) The impact on newborn morbidity and mortality in States that adopt newborn screening tests included on the uniform panel.

(b) PUBLIC STAKEHOLDER MEETING.—In the course of completing the study described in subsection (a), NAM or such other appropriate entity shall hold not less than one public meeting to obtain stakeholder input on the topics of such study.

(c) REPORT.—Not later than 18 months after the effective date of the agreement under subsection (a), such agreement shall require NAM, or such other appropriate entity, to submit to the Secretary of Health and Human Services and the appropriate committees of jurisdiction of Congress a report containing—

(1) the results of the study conducted under subsection (a);

(2) recommendations to modernize the processes described in subsection (a)(1); and

(3) recommendations for such legislative and administrative action as NAM, or such other appropriate entity, determines appropriate.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $2,000,000 for the period of fiscal years 2022 and 2023 to carry out this section.

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

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. 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 on H.R. 482.

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

There was no objection.

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

Mr. Speaker, I rise today in support of H.R. 482, the Newborn Screening Saves Lives Reauthorization Act of 2021.

Newborn screening is a well-established and proven public health program that identifies certain genetic and functional conditions in newborns. Each year, almost all of the 3.8 million babies born in the U.S. are screened for medical conditions that can cause serious disability or death if not detected and treated early.

Newborn screening includes blood, hearing, and heart screening. While most families may likely forget this routine testing ever took place, more than 12,000 families each year will be notified of a positive screening result and referred for immediate diagnosis and treatment. Many of these families might not have considered or had access to these tests without newborn screening. Newborns can appear healthy but, without warning, can quickly deteriorate due to these undetected conditions, and that is why these tests are so critical. If diagnosed early, many of these conditions can be treated and managed successfully.

In 2008, the original Newborn Screening Saves Lives Act was signed into law. It established national newborn screening guidelines and supported the facilitation of newborn screening at the State level. Before 2008, only 10 States and the District of Columbia required newborn screening for recommended disorders. Today, all 50 States and D.C. screen for most or all of these recommended diseases.

This bipartisan program was reauthorized in 2014 and 2019. Those reauthorizations renewed Federal support to help States to expand and improve their newborn screening programs.

H.R. 482, before us today, once again renews Federal funds and activities to assist States in continuing and improving their newborn screening programs. This bill also supports parent and provider education and laboratory quality and surveillance.

Newborn screening, Mr. Speaker, is a simple set of tests that can improve and save the lives of thousands of babies so that they and their families can grow to live healthy and happy lives. Through the national expansion of these life-saving health screenings, no baby should receive inadequate care because of the State that they live in. With the continuous reauthorization of the Newborn Screening Saves Lives Act, every baby in the U.S. can have access to equitable healthcare from the day they are born.

I commend the steadfast champions of this bipartisan legislation—foremost, Representative LUCILLE ROYBAL-ALLARD, who has been working on this for such a long time, and this is something that she and I have talked about quite a bit, and Congressman SIMPSON, Congresswoman HERRERA BEUTLER, and Assistant Speaker KATHERINE CLARK for their ongoing commitment and leadership toward eliminating preventable newborn deaths. No newborn should suffer or die from a condition that can be detected and treated by newborn screening.

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

Mr. GUTHRIE. Mr. Speaker, I ask unanimous consent to control the time on this bill.

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

There was no objection.

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

Mr. Speaker, I rise today in support of H.R. 482, the Newborn Screening Saves Lives Reauthorization Act of 2021.

Newborn screening is critical in the early detection and intervention of health conditions, some life-threatening, for our Nation's infants. They are for serious but rare conditions that families and doctors may otherwise be unable to detect at birth. Newborns are screened in the hospital when they are 1 or 2 days old by blood tests, in addition to hearing and heart screenings.

About 1 in 300 newborns has a condition that can be detected via newborn screening. However, if not detected and left untreated, these conditions can impact a child for the rest of their life by causing disabilities, developmental delays, illness, or even death.

Prior to the passage of the first Newborn Screening Saves Lives Act in 2008, which helped better standardize screening programs, States had varying standards for newborn screening, and they were not screening for many of the core conditions on the Recommended Uniform Screening Panel.

This bill authorizes funding for the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and the National Institutes of Health to ensure that our newborn screening remains comprehensive and that our Nation's healthcare providers are adequately equipped to conduct the screenings.

Specifically, H.R. 482 reauthorizes grants through the Health Resources and Services Administration to expand State screening programs and improve follow-up care after a detection, in addition to allowing for the National Institutes of Health Hunter Kelly Newborn Screening program to continue to identify new treatments for conditions detected by newborn screening.

The importance of newborn screenings can't be overstated. Screening provides physicians and families with critical information regarding infant health, allowing for early intervention and treatment, if necessary.

I urge my fellow Members to support H.R. 482, and I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield such time as she may consume to the gentlewoman from California (Ms. ROYBAL-ALLARD), the prime sponsor of this legislation.

Ms. ROYBAL-ALLARD. Mr. Speaker, I rise to support reauthorization of my Newborn Screening Saves Lives Act. I thank Chairman PALLONE for his support and for bringing my bill to the floor.

My sincere gratitude to my newborn screening partners and colleagues, MIKE SIMPSON, KATHERINE CLARK, and JAIME HERRERA BEUTLER, and my heartfelt appreciation to the public health groups that continue to support my newborn screening efforts, including the March of Dimes, the Association of Public Health Laboratories, the Muscular Dystrophy Association, and

the National Organization for Rare Disorders.

Newborn screening involves a baby receiving a simple blood test to identify life-threatening diseases before symptoms begin. Prior to the development of these tests, children would die or suffer lifelong disabilities.

In 2008, when my original bill passed, newborn screenings and access to follow-up information were not consistent or available to families in all communities. Only 10 States and the District of Columbia required screening for a complete panel of recommended disorders, and there was no Federal repository of information on the diseases.

Today, all 50 States and D.C. screen for at least 30 of the 35 recommended core conditions, and a national clearinghouse has the most recent newborn screening information available to parents and professionals.

Newborn screening is a public health success story that makes the difference between health and disability, or even life and death, for the approximately 12,000 babies who each year test positive for one of these conditions, babies like Cruz, a beautiful little girl born on February 4 this year to one of my district office deputies. Thanks to newborn screening, in just 4 days, Cruz was diagnosed with maple syrup urine disease, which prevents the body from breaking down certain amino acids typically obtained from protein.

If Cruz's disease had gone undetected, the buildup of amino acids in her body would have become toxic, leading to seizures, swelling of the brain, coma, and, ultimately, death. Today, the management of her amino acid levels keeps Cruz out of the hospital, protects her from critical medical complications, and gives her family the gift of watching their daughter grow up healthy.

This is just one of the thousands of success stories that illustrate the critical need to pass H.R. 482 into law. This will guarantee high-quality technical assistance for State programs and public health labs, access to the most current programs and educational materials, and it will ensure the advisory committee continues its work of researching and recommending new screenings for State programs, which also save our healthcare system millions of dollars for each child identified and treated early.

Reauthorization will also commission a National Academy of Sciences study to make recommendations for a 21st century newborn screening system.

Mr. Speaker, I urge a ''yes'' vote on the passage of H.R. 482 to ensure all newborns like Cruz are blessed with early, comprehensive, and consistent testing and follow-up programs for a healthy and productive life.

□ 1430

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

Mr. Speaker, I strongly support this bill and encourage others to do so. When I first was elected to the State Senate, the General Assembly of Kentucky, one of the biggest public policy efforts I got involved in was Governor Patton—our governor at the time—who was proposing a big 0–3 kind of overall for Kentucky's babies and children, and a big part of it was newborn screenings.

And that was a section I was kind of assigned to look into and I spent a lot of time doing research—even going down to see a lady who does this kind of research at Vanderbilt University and walked away convinced that it is the right public policy to do. It is money well-spent. It really changes people's ability. If you can't get your language at an early time, you can never get it back.

So this absolutely prevents—if you want to look at the cost of this system, this system going forward, but more importantly, it really enhances people to have the opportunity to live a full life if we catch it at the youngest level.

So I am convinced of this. I support this bill, and I encourage my colleagues to do so.

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

Mr. PALLONE. Mr. Speaker, I would also ask Members to support this legislation, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 482.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

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

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

PANDEMIC EFFECTS ON HOME SAFETY AND TOURISM ACT

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3752) to require the Consumer Product Safety Commission to study the effect of the COVID–19 pandemic on injuries and deaths associated with consumer products and to direct the Secretary of Commerce to study and report on the effects of the COVID–19 pandemic on the travel and tourism industry in the United States.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3752

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 ''Pandemic Effects on Home Safety and Tourism Act''.

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

TITLE I—COVID–19 HOME SAFETY

SEC. 101. SHORT TITLE.

This title may be cited as the ''COVID–19 Home Safety Act''.

SEC. 102. STUDY AND REPORT ON THE EFFECT OF THE COVID–19 PUBLIC HEALTH EMERGENCY ON INJURIES AND DEATHS FROM CONSUMER PRODUCTS.

(a) COVID–19 REPORT REQUIRED.—Not later than 3 months after the date of enactment of this section and every 3 months thereafter for the duration of the COVID–19 public health emergency, the Consumer Product Safety Commission shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate, and make publicly available, a report on the effect of the COVID–19 public health emergency on injuries and deaths from consumer products.

(b) CONTENTS OF REPORT.—The report shall include the following:

(1) Relevant data and statistics from—

(A) the data sources of the Commission;

(B) other appropriate agencies;

(C) media reports;

(D) poison control centers, to the extent practical; and

(E) any other relevant data sources.

(2) An identification of trends in injuries and deaths from consumer products, comparing data from representative time periods before and during the COVID–19 public health emergency.

(3) An identification of subpopulations that have experienced elevated risk of injury or death from consumer products during the COVID–19 public health emergency, such as minorities, infants, people with disabilities, children, or the elderly.

(4) An identification of where most injuries or deaths from consumer products during the COVID–19 public health emergency are taking place, such as the type of building or outdoor environment.

(5) A specification about whether consumer products associated with a substantial number of injuries or deaths during the COVID–19 public health emergency are—

(A) under recall;

(B) subject to a voluntary consumer product safety standard; or

(C) subject to a mandatory consumer product safety standard.

(6) An identification of emerging consumer products that are posing new risks to consumers.

(c) COVID–19 PUBLIC HEALTH EMERGENCY DEFINED.—The term ''COVID–19 public health emergency'' means a public health emergency declared pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d) as a result of confirmed cases of 2019 novel coronavirus (COVID–19), including any renewal thereof.

TITLE II—PROTECTING TOURISM IN THE UNITED STATES

SEC. 201. SHORT TITLE.

This title may be cited as the ''Protecting Tourism in the United States Act''.