Republican side, Representative BUDDY CARTER, for leading this initiative.

Mr. Speaker, 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. BARRAGÁN), a member of our committee and the lead sponsor of the bill.

Ms. BARRAGÁN. Mr. Speaker, I rise today in support of H.R. 189, the John Lewis National Institute on Minority Health and Health Disparities Research Endowment Revitalization Act. This is a bipartisan bill that I introduced with my colleague from Georgia, Congressman CARTER.

It is fitting that this bill comes before us during National Minority Health Month because this legislation moves us closer to ending the public health disparities facing communities of color. We need to understand why people of color are more likely to get certain illnesses.

It is a tragic reality, but solutions are out there. H.R. 189 will fund the research that will help us find solutions and save lives.

This bill would, once again, allow for current and former NIMHD or Health Resources and Services Administration centers of excellence to receive research endowment funding, money that is critical in the fight to reduce minority health disparities.

The Research Endowment Program at the National Institute on Minority Health and Health Disparities provides funding to the endowments of academic institutions across the country, such as Charles R. Drew University in my district, Morehouse School of Medicine, University of Puerto Rico School of Dental Medicine, University of New Mexico School of Medicine, Howard University College of Pharmacy, and so many others.

The goal of the program includes promoting minority health and health disparities research capacity and infrastructure, increasing the diversity and strength of the scientific workforce, and enhancing the recruitment and retention of individuals from health disparity populations that are underrepresented in the scientific workforce.

This is critical legislation that is going to play a huge role in addressing and researching disparities.

During the COVID–19 health emergency, communities of color were once again disproportionately affected. Research into health disparities is more crucial than ever.

I want to thank my cosponsors, and I want to thank Chairman PALLONE for working to help me get this important bill to the floor. I urge my colleagues to support this bill. Let's get this done and across the finish line.

Mrs. RODGERS of Washington. Mr. Speaker, I yield such time as he may consume to the gentleman from Georgia (Mr. CARTER), an important leader on this legislation as well as on the committee.

Mr. CARTER of Georgia. Mr. Speaker, thank you to Congresswoman BARRAGÁN for being a champion of this issue, and she truly is a champion of this issue.

The coronavirus has wreaked havoc on our communities, especially minority communities. Now more than ever, we must support minority academic institutions and the critical research they conduct.

Minority academic institutions can play a big role in helping to address the systemic health disparities minority communities are feeling.

We must ensure schools, including Morehouse College in my home State of Georgia, are able to conduct their research without disruption. Without a reauthorization of this program, health research will have to be paused or abandoned altogether. We must not let this happen. The efforts of these researchers will help better prepare all of us to respond to the coronavirus and other health inequities more effectively.

I urge passage of this very important legislation.

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

Mr. PALLONE. Mr. Speaker, I urge support for 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. 189.

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.

□ 1300

TIMELY REAUTHORIZATION OF NECESSARY STEM-CELL PROGRAMS LENDS ACCESS TO NEEDED THERAPIES ACT OF 2021

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 941) to reauthorize the Stem Cell Therapeutic and Research Act of 2005, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 941

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 ''Timely Re-Authorization of Necessary Stem-cell Programs Lends Access to Needed Therapies Act of 2021'' or the ''TRANSPLANT Act of 2021''.

SEC. 2. REAUTHORIZATION OF THE C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM.

(a) ADVISORY COUNCIL MEETINGS.—Subsection (a) of section 379 of the Public Health Service Act (42 U.S.C. 274k) is amended by adding at the end the following new paragraph:

''(7) The Secretary shall convene the Advisory Council at least two times each calendar year.''.

(b) INCREASING COLLECTION.—

(1) TECHNICAL CLARIFICATION.—Effective as if included in the enactment of Public Law 114–104 (the Stem Cell Therapeutic and Research Reauthorization Act of 2015), the amendment to section 379(d)(2)(B) of the Public Health Service Act (42 U.S.C. 274k(d)(2)(B)) in section 2(a)(2) of Public Law 114–104 is amended by inserting ''goal of increasing collections of high quality'' before ''cord blood units,''.

(2) ELIMINATING DEADWOOD.—Subparagraph (B) of section 379(d)(2) of the Public Health Service Act (42 U.S.C. 274k(d)(2)) is amended by striking the second and third sentences in such subparagraph.

(c) PERIODIC REVIEW OF STATE OF SCIENCE.—Section 379 of the Public Health Service Act (42 U.S.C. 274k) is amended by adding at the end the following new subsection:

''(o) PERIODIC REVIEW OF STATE OF SCIENCE.—

''(1) REVIEW.—Not less frequently than every 2 years, the Secretary, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, the Administrator of the Health Resources and Services Administration, the Advisory Council, and other stakeholders, where appropriate given relevant expertise, shall conduct a review of the state of the science of using adult stem cells and birthing tissues to develop new types of therapies for patients, for the purpose of considering the potential inclusion of such new types of therapies in the Program.

''(2) RECOMMENDATIONS.—Not later than June 30, 2025, the Secretary shall—

''(A) complete the second review required by paragraph (1); and

''(B) informed by such review, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives recommendations on the appropriateness of the inclusion of new types of therapies in the Program.''.

(d) AUTHORIZATION OF APPROPRIATIONS.—Section 379B of the Public Health Service Act (42 U.S.C. 274m) is amended by striking ''$33,000,000 for fiscal year 2015 and $30,000,000 for each of fiscal years 2016 through 2020'' and inserting ''$31,009,000 for each of fiscal years 2022 through 2026''.

SEC. 3. CORD BLOOD INVENTORY.

Subsection (g) of section 2 of the Stem Cell Therapeutic and Research Act of 2005 (42 U.S.C. 274k note) is amended to read as follows:

''(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $23,000,000 for each of fiscal years 2022 through 2026.''.

SEC. 4. ADVANCING THE FIELD OF REGENERATIVE MEDICINE.

Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by adding at the end the following:

''(o) REGENERATIVE MEDICINE.—The Director of NIH shall, as appropriate, continue to consult with the directors of relevant institutes and centers of the National Institutes of Health, other relevant experts from such institutes and centers, and relevant experts within the Food and Drug Administration, to further the field of regenerative medicine using adult stem cells, including autologous stem cells, therapeutic tissue engineering products, human cell and tissue products, human gene therapies, and genetically modified cells.''.

SEC. 5. GAO REPORT ON REGENERATIVE MEDICINE WORKFORCE.

Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and

Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that assesses a specialized health care workforce in the field of regenerative medicine. The report shall include—

(1) an overview of the current employment levels, in both commercial and academic settings, for—

(A) positions necessary for the collection and transplantation of stem cell therapeutics, including bone marrow and cord blood; and

(B) positions in the field of regenerative medicine using adult stem cells and related to product development;

(2) the identification of gaps, if any, in the projected workforce capacity for—

(A) positions described in paragraph (1)(A); and

(B) the field of regenerative medicine using adult stem cells, including workforce gaps related to the development of new cellular therapies using adult stem cells;

(3) an overview of the availability of training programs related to the development, refinement, and utilization of adult stem cells, including training on good manufacturing practices for such activities, and the performance of such programs; and

(4) recommendations, if any, for improving the workforce capacity related to—

(A) the positions described in paragraph (1)(A); or

(B) the field of regenerative medicine using adult stem cells.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Florida (Mr. BILIRAKIS) 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. 941.

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, the C.W. Bill Young Transplant Program and the National Cord Blood Inventory Program facilitate lifesaving bone marrow and umbilical cord blood donations to help patients suffering from blood cancers, disorders, and diseases.

These critical programs assist transplant patients by providing additional information about bone marrow and cord blood transplants, maintaining an efficient process for identifying donor matches, and increasing the number of unrelated donors available for transplant. The programs also collect data and expand research to improve patient outcomes.

I thank my colleagues—Representatives MATSUI, BILIRAKIS, and PINGREE—for their bipartisan leadership on this bill, and I would urge my colleagues to support H.R. 941.

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

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

Mr. Speaker, I rise today in support of H.R. 941, the Timely Reauthorization of Necessary Stem-Cell Programs Lends Access to Needed Therapies Act, or the TRANSPLANT Act.

As co-chair of the Blood Cancers Caucus, I urge my colleagues to support the TRANSPLANT Act. This bill is about providing hope to those who are struggling with life-threatening illnesses. The TRANSPLANT Act reauthorizes the C.W. Bill Young Transplant Program, in addition to the National Cord Blood Inventory Program.

I remember Bill Young, Chairman Young, a great friend of ours, and he said that this was one of his greatest accomplishments. I also know that CHRIS SMITH, who will be speaking later, was also involved in this. He has been a champion on this issue, Mr. Speaker. So I appreciate both of them.

This Federal program provides critical support in the advancement of research for better treatments and the infrastructure necessary to organize registries, which will help ensure transplant patients have access to lifesaving procedures. Simply put, its continued reauthorization is vital for patients with diseases like blood cancer, sickle cell anemia, and inherited metabolic or immune system disorders.

I sincerely appreciate the work of my friend and colleague and fellow Blood Cancers Caucus co-chair, Congresswoman MATSUI, in addition to the legacy of bipartisan leadership and support of these programs by Members like, as I said, CHRIS SMITH.

I thank the chairman, as well and the ranking member, for placing this particular bill on the agenda. I know it will get through the Senate this time.

Additionally, I appreciate the critical daily work of the National Marrow Donor Program, operating the Be the Match national registry, connecting patients in search of a cure with lifesaving bone marrow donors, even in the midst of this historic pandemic.

I would also like to take a moment to recognize the great work of Dr. Joanne Kurtzberg, the president of the Cord Blood Association. She also serves in multiple roles at Duke University, including the director of Carolinas Cord Blood Bank. Dr. Kurtzberg has dedicated her professional career to cord blood research, banking, and transplantation; and she is an internationally recognized umbilical cord blood transplanter. She advised Congress on the creation of the public cord blood banking program, which was part of the Stem Cell Therapeutic and Research Act of 2005. Dr. Kurtzberg continues to be a trusted adviser to Congress on this important program.

Mr. Speaker, I urge all my colleagues to join us in expediting passage of this lifesaving bipartisan bill.

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

Mr. PALLONE. Mr. Speaker, I have no additional speakers, but I think my colleague does, so I reserve the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I yield 4 minutes to the gentleman from New Jersey (Mr. SMITH).

Mr. SMITH of New Jersey. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, today, the House of Representatives will vote to reauthorize the Stem Cell Therapeutic and Research Act, a law that I authored in 2005. This was an original idea of mine 20 years ago.

My good friend from Florida just mentioned Dr. Kurtzberg. Dr. Kurtzberg was in the meetings that we held in drafting this legislation, and she provided incredible insights as to what we should do, what path we should follow. So I appreciate him recognizing her.

I also thank Artur Davis, who was my Democratic colleague and the principal Democratic cosponsor of the bill during those several years. It took 5 long years of hard work and numerous setbacks, but the bill was finally signed into law on December 20, 2005.

The new law created a nationwide umbilical cord blood stem cell program designed to collect, derive, type, and freeze cord blood units for transplantation into patients to mitigate and even cure serious disease. Pursuant to the law, it also provided stem cells for research. The new cord blood program was combined with an expanded bone marrow initiative, which was crafted over several years by our distinguished colleague, Congressman Bill Young.

Umbilical cord blood stem cells, Mr. Speaker, obtained after the birth of a child have proved to be highly efficacious in treating some 70 diseases, including sickle cell disease, lymphoma, leukemia, and in treating metabolic and immune deficiencies. Scientists are continuing to study and better understand the regenerative effects of cord blood cell therapies for other diseases and disabilities, including autism. I would say in like manner, bone marrow donations are also providing lifesaving transplants for some of those very same diseases. So we have great regenerative initiatives that will be continued.

The National Cord Blood Inventory, NCBI, provides funding to public cord blood banks participating in the program to allow them to expand the national inventory of cord blood units available for transplant. These units are then listed on the registry by the Be the Match program. The funds appropriated thus far have led to an important increase in the overall number of high-quality cord blood units available through the national registry, now totaling 111,000 NCBI units. Within the Be the Match Registry, there are now more than 800,000 worldwide.

The program registry, Mr. Speaker, allows patients and physicians to locate matching cord blood units, as well as adult donors for marrow and peripheral blood stem cells. The program is the world's largest, most diverse donor registry, with more than 23 million volunteers. To date, the National Marrow Donor Program/Be the Match, through its operation of the program, has facilitated more than 105,000 transplants.

According to Be the Match, more than 40,000 patients have received cord blood transplants.

The reauthorization before us authorizes $23 million each year for 5 years for the cord blood side and, again, some $30 million each year for the bone marrow program.

Mr. Speaker, each year, nearly 4 million babies are born in America. In the past, virtually every placenta and umbilical cord was tossed as medical waste. Today, doctors have turned this medical waste into medical miracles.

Not only has God, in His wisdom and goodness, created a placenta and an umbilical cord to nurture and protect the precious life of an unborn child, but now we know that another gift awaits immediately after birth. Something very special is left behind: Cord blood that is teeming with lifesaving stem cells.

Mr. BILIRAKIS. Mr. Speaker, this is a very important bill and needs to pass as soon as possible. I really appreciate the chairman placing the bill on the agenda. I urge the Senate to pass it as soon as possible, and, of course, my colleagues today, if we can pass this bill immediately so we can get it to the Senate.

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

Mr. PALLONE. Mr. Speaker, I also urge support for the 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 New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 941.

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. CLINE. 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.

ADVANCING EDUCATION ON BIOSIMILARS ACT OF 2021

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (S. 164) to educate health care providers and the public on biosimilar biological products, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 164

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 ''Advancing Education on Biosimilars Act of 2021''.

SEC. 2. EDUCATION ON BIOLOGICAL PRODUCTS.

Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following:

''SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.

''(a) INTERNET WEBSITE.—

''(1) IN GENERAL.—The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

''(2) CONTENT.—Educational materials provided under paragraph (1) may include—

''(A) explanations of key statutory and regulatory terms, including 'biosimilar' and 'interchangeable', and clarification regarding the use of interchangeable biosimilar biological products;

''(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

''(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

''(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 351(k) and reference products (as defined in section 351(i)), including the standards for review and licensing of each such type of biological product.

''(3) FORMAT.—The educational materials provided under paragraph (1) may be—

''(A) in formats such as webinars, continuing education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

''(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

''(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish—

''(A) the action package of each biological product licensed under subsection (a) or (k) of section 351; or

''(B) the summary review of each biological product licensed under subsection (a) or (k) of section 351.

''(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

''(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Florida (Mr. BILIRAKIS) 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 S. 164.

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, the rising cost of prescription drugs continues to be a major issue for families all across the country. These costs are particularly daunting at a time when we are facing a severe economic downturn and the ongoing pandemic.

We are committed to continuing to find solutions to make prescription drugs more affordable for the American people. One important way to help families out is to ensure they are aware of more affordable options, like biosimilars and generics. These are both cheaper options, but, unfortunately, utilization of these products continues to be too low here in the United States.

The Advancing Education on Biosimilars Act of 2021 is commonsense legislation that will help provide patients and healthcare providers with greater information about biologics and biosimilars. To do this, the bill requires the FDA to establish a public website with educational materials, including what products are interchangeable, as well as how to report any adverse events.

In addition, the bill would support the development of continuing education programs for healthcare providers about biologics. It is critical that healthcare providers and patients are aware of all of their options, and this legislation will certainly help do that.

I am pleased to work with my colleagues in the Senate on this legislation, and I urge my colleagues to support the bill.

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

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

Mr. Speaker, I rise today in support of S. 164, the Advancing Education on Biosimilars Act.

This bill is a bipartisan companion to H.R. 1873, championed in the House by Dr. BUCSHON and Congressman PETERS.

This bill would require the FDA to maintain and operate an internet website to provide educational materials for healthcare providers, patients, and caregivers on biological products, including biosimilar products and interchangeable biosimilar products.

It also would require the Department of Health and Human Services, HHS, to develop continuing education programs or to improve existing programs for healthcare providers, such as doctors and nurses, to promote a better understanding of biosimilar interchangeable products.

By increasing awareness about available biosimilar products and providing educational resources for physicians