Modernization Act 3.0, bipartisan legislation that ensures the FDA fully embraces modern science while reducing unnecessary animal testing.

Many of our families would feel incomplete without the pets and animals that bring unconditional love into our lives. Yet every year, millions of animals, including dogs, man's best friend, are still subjected to testing in the development of new medicines.

As policymakers, we have a responsibility to protect those who cannot protect themselves. That responsibility includes embracing scientific innovation that can reduce unnecessary animal suffering while continuing to deliver safe and effective treatments to patients.

In 2022, Congress took an important first step by passing the FDA Modernization Act 2.0. I was proud to help lead that effort. That law gave drug developers the ability to use modern, scientifically validated alternatives to traditional animal testing when appropriate.

Congress made its intent clear. We wanted to encourage more effective, more humane, and more innovative approaches to drug development.

Unfortunately, the previous administration failed to fully implement the law. Without clear implementation, too many researchers have lacked the certainty they need, and too many animals continue to be used in testing that modern science can increasingly replace.

H.R. 2821 ensures the FDA finally carries out the will of Congress. This bill is not lowering standards. It is about raising them.

Today's researchers have access to technologies that simply did not exist a generation ago: advanced human cell models, organ-on-a-chip technology, artificial intelligence, and computational modeling. These innovative tools have the potential to better predict how medicines will perform in humans while reducing reliance on animal testing. Our laws should reflect the science of today, not the science of decades past.

Modernizing drug development doesn't just benefit animals. It benefits patients. By providing greater clarity and encouraging the use of validated alternative methods, we can make the drug development process more efficient. That means fewer unnecessary delays and more innovation. Ultimately, that means lifesaving treatments can reach patients more quickly without compromising the FDA's rigorous standards for safety and effectiveness.

This is a commonsense, bipartisan bill. It reflects a simple principle: We can advance medical innovation while improving animal welfare. Those goals are not in conflict. In fact, they go hand in hand.

Mr. Speaker, the FDA Modernization Act 3.0 fulfills the promise Congress made when we passed the FDA Modernization Act 2.0. It ensures that modern science is fully incorporated into our regulatory process. It helps reduce unnecessary animal testing and strengthens American medical innovation. It also helps bring new therapies to patients more efficiently.

I urge my colleagues to support H.R. 2821, the FDA Modernization Act 3.0.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentleman from Louisiana (Mr. CARTER).

Mr. CARTER of Louisiana. Mr. Speaker, I rise in strong support of H.R. 2821, the FDA Modernization Act 3.0, introduced by the gentleman from Georgia (Mr. CARTER).

I am proud to co-lead this bill with him and a bipartisan group of my colleagues: Representatives BARRAGAN, BUCHANAN, DELAURO, and HARSHBARGER.

Over 3 years ago, the FDA Modernization Act 2.0 was signed into law, allowing the agency to approve human drugs without requiring animal testing through modern, often more effective, alternatives.

Despite this progress, the FDA has still not issued updated regulations to clarify where alternatives to animal testing are, in fact, permissible.

This legislation takes action to close the gap by requiring the FDA to fully implement the reforms that Congress has already enacted and to help reduce unnecessary animal testing in drug development. By ensuring the full implementation of the FDA Modernization Act 2.0, this legislation will help modernize and transform drug development for the 21st century; accelerate safer, more effective medical breakthroughs; and advance more humane scientific research.

This is long overdue. We see the unnecessary slaughtering of animals for research when there are other alternatives that may be, in fact, more humane, more effective, and more cost effective, yet we continue to do the same thing as if.

I am proud to be a part of this bill that will go a long way toward protecting lives, advancing technological scientific finds, and creating a better, more humane system. Overall, our bill is a big win for patients, a big win for innovation, and a big win for animal welfare.

Mr. Speaker, I encourage all my colleagues to vote ''yes'' on passing this critical legislation.

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

Mr. PALLONE. Mr. Speaker, I urge passage of this bipartisan bill, and I yield back the balance of my time.

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

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Kentucky (Mr. GUTHRIE) that the House suspend the rules and pass the bill, H.R. 2821.

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.

REAUTHORIZING THE KAY HAGAN TICK ACT

Mr. GUTHRIE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4348) to reauthorize the Kay Hagan Tick Act, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4348

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

SECTION 1. REAUTHORIZATION OF PROGRAMS.

(a) NATIONAL STRATEGY AND REGIONAL CENTERS OF EXCELLENCE IN VECTOR-BORNE DISEASE.—Section 317U of the Public Health Service Act (42 U.S.C. 247b–23) is amended—

(1) in subsection (b), in the matter preceding paragraph (1), by striking ''the Tick-Borne Disease Working Group established under section 2062 of the 21st Century Cures Act (42 U.S.C. 284s) and other individuals, as appropriate'' and inserting ''appropriate individuals'';

(2) in subsection (c)(4), by inserting '', including by increasing capacity to identify, report, prevent, and respond to such diseases'' before the period at the end; and

(3) in subsection (f), by striking ''2021 through 2025'' and inserting ''2026 through 2030''.

(b) ENHANCED SUPPORT TO ASSIST HEALTH DEPARTMENTS IN ADDRESSING VECTOR-BORNE DISEASES.—Section 2822(c) of the Public Health Service Act (42 U.S.C. 300hh–32(c)) is amended by striking ''2021 through 2025'' and inserting ''2026 through 2030''.

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

The Chair recognizes the gentleman from Kentucky.

GENERAL LEAVE

Mr. GUTHRIE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks on the legislation and to include extraneous material on H.R. 4348.

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 in strong support of H.R. 4348, led by my colleagues, the gentleman from New Jersey (Mr. SMITH) and the gentleman from Texas (Mr. DOGGETT), which authorizes the national and regional centers for excellence in vector-borne disease in the CDC's cooperative agreements with health departments in high-risk areas for vector-borne diseases.

Vectors like mosquitoes, ticks, and fleas carry dangerous diseases, and vector-borne diseases can happen to anyone. They can have debilitating effects. Preventing these diseases is a bipartisan issue that I hope we all can support.

In addition to thanking the bill's sponsors for their leadership in advancing the efforts to reduce the alarming threat of vector-borne disease, I also thank the administration for their support of this bill and for their commitment to the American people by combating Lyme disease, which affects almost half a million Americans annually.

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

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

Mr. Speaker, I rise in support of H.R. 4348, the Kay Hagan Tick Act, sponsored by my colleagues CHRIS SMITH of New Jersey and LLOYD DOGGETT of Texas. I understand that Mr. KEAN from New Jersey is also a sponsor.

This bill reauthorizes the national strategy and regional centers of excellence in vector-borne diseases. Tick-borne diseases, including Lyme disease, have rapidly increased over the last decades. The Centers for Disease Control and Prevention estimates that nearly a half million people may, in fact, be diagnosed and treated for Lyme disease every year in the United States. That is a dramatic increase from 30,000 annual cases just two decades ago.

□ 1500

H.R. 4348 would expand research, improve testing, and coordinate vector-borne disease efforts across the Federal Government. The bill would also reauthorize funding for Regional Centers of Excellence for surveillance, prevention, and response to vector-borne diseases and reauthorize grants to State health departments to support vector-borne disease infrastructure.

Tick and vector-borne disease have rapidly increased, Mr. Speaker, particularly in the northeastern part of our country. I encourage all of my colleagues to honor the legacy of Senator Kay Hagan, who died of complications from a tick-borne disease, by voting ''yes'' on H.R. 4348.

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

Mr. GUTHRIE. Mr. Speaker, I yield to the gentleman from New Jersey (Mr. SMITH).

Mr. SMITH of New Jersey. Mr. Speaker, I thank Chairman GUTHRIE for his personal and extraordinarily strong support of H.R. 4348, and his staff, director Megan Jackson, Health Subcommittee staff Jay Gulshen and Emma Schultheis. I also thank my good friend, FRANK PALLONE, our Health Subcommittee Chair MORGAN GRIFFITH, Ranking Member DIANA DEGETTE, as well as the original sponsors, LLOYD DOGGETT, PAUL TONKO, and TOM KEAN.

Mr. Speaker, at a May 29th press conference in New Hampshire, HHS Secretary Robert F. Kennedy, Jr., who has been a tremendous leader in the war on Lyme disease, announced a ''sweeping plan to combat Lyme disease and to advance treatment.''

Secretary Kennedy said: ''Millions of Americans battling Lyme disease and other tick-borne illnesses have spent years searching for answers, treatment, and support. Today, the Trump administration is launching one of the most ambitious Federal efforts ever to combat Lyme disease by accelerating research, expanding innovation, and improving care for patients and families. We are going after this disease at its source, driving faster diagnostics and new prevention strategies, and delivering the urgency and action Americans deserve.''

He said: ''The initiative will develop and deploy practical strategies to target and eliminate ticks on wildlife before they can spread diseases to humans.'' That has been lacking for decades. They are going after the ticks themselves.

''Lyme disease,'' Mr. Speaker, he said: ''remains one of the Nation's fastest growing vector-borne health threats. More than 476,000 Americans are diagnosed with Lyme disease each year, and recent data show emergency room visits for tick bites reached their highest springtime level in nearly a decade.''

Secretary Kennedy also announced new actions to combat Alpha-gal syndrome, a tick-associated condition that can trigger potentially serious allergic reactions to red meat and other products. The CDC estimates nearly 500,000 Americans are living with Alpha-gal syndrome, though emerging evidence suggests the true number may be significantly higher.

Mr. Speaker, as my colleagues know, ticks not only transmit Lyme disease but other deadly and debilitating illnesses, such as Alpha-gal, babesiosis, Powassan disease, Rocky Mountain spotted fever, and anaplasmosis. Vector-borne diseases are now endemic in regions of the country where they have not historically been present.

Disease-laden ticks are now found in all 48 contiguous States. The problem is exploding. It is not abating. It is, therefore, critical that Congress take immediate action to support and further sustain ongoing efforts to combat these insidious diseases that kill and disable.

I urge my colleagues to support H.R. 4348, a 5-year reauthorization of the Kay Hagan Tick Act, a law that expires on September 30th. My colleagues will recall that our distinguished colleague, North Carolina Senator Kay Hagan, suffered a tick bite and died in 2019 from encephalitis caused by the Powassan virus. The current law and reauthorization is named in her honor.

The original Kay Hagan Tick Act, which I led in 2019 here in the House and SUSAN COLLINS led it in the Senate, became part of the appropriations act in 2020. The act created, among other things, a whole-of-government national strategy to combat Lyme and other tick-borne diseases with special focus on surveillance, diagnosis, treatment, education, and prevention.

I would note parenthetically that I have been working on Lyme disease since 1992, when Pat Smith—no relation—of Wall Township, who actually formed the Lyme Disease Association of America, came up to me in Wall Township and said: What are you doing about Lyme? I said: Nothing. We had lunch. I have been working on it ever since.

I introduced my first comprehensive bill—one of many, at times we had over 100 cosponsors—called the Lyme Disease Initiative Act of 1998, almost 30 years ago. We could not move it. It was blocked over and over again. There were some people in HHS and at CDC and elsewhere who were saying, just take 2 weeks of doxycycline and you are cured.

When you have chronic Lyme, it takes a very serious effort, very often with a Lyme literate doctor, in order to overcome and put that disease into remission.

In February 2024, I remind my colleagues, HHS released the National Public Health Strategy to prevent and control vector-borne diseases. It is an excellent strategy. We are acting on that now as well. It also supports the whole-of-government assault on Lyme.

It authorizes $50 million over 5 years for Regional Centers of Excellence. It also, as we did in the original law, authorizes $100 million over 5 years to tangibly assist States' public health departments and other local entities to support the development and implementation of evidence-based research interventions and treatment with respect to the Lyme disease epidemic.

I urge my colleagues to support it.

Mr. Speaker, in February, 2024, HHS released the National Public Health Strategy to Prevent and Control Vector-borne Diseases in People with mutually reinforcing goals to:

Better understand when, where, and how people are exposed to and get sick or die from VBDs.

Develop, evaluate, and improve tools, methods, and guidance to diagnose VBDs and their pathogens.

Develop, evaluate, and improve tools, methods, and guidance to prevent and control VBDs.

Develop and assess drugs and treatment strategies for VBDs.

Disseminate and implement public health tools, programs, and collaborations to prevent, detect, diagnose, and respond to VBD threats.

H.R. 4348, supports this whole of government assault on Lyme and other vector borne diseases.

H.R. 4348 again authorizes $50 million over five years for the regional centers of excellence, which coordinate with academia and local public health agencies to conduct research on Lyme in their areas and train public health professionals to identify and treat Lyme.

Finally, H.R. 434—again as we did in the original law—authorizes cooperative agreement funding for states and localities—$100 million over five years—to tangibly assist state public health departments and other local entities to support the development and implementation of evidence-based research, interventions, and treatment with respect to—

educating and informing the public, based on evidence-based public health research and data, about Lyme Disease and other vector-borne diseases;

supporting early detection and diagnosis;

supporting prevention;

improving treatment; and

supporting care planning and management for individuals with Lyme disease and other tick- and vector-borne diseases.

I thank the Chairman BRETT GUTHRIE for his personal and extraordinarily strong support of H.R. 4348, as well as his Staff Director Megan Jackson and Health Subcommittee staff Jay Gulshen and Emma Schultheis.

Special thanks to Ranking Member FRANK PALLONE, Health Subcommittee Chair MORGAN GRIFFITH and Ranking Member DIANA DEGETTE as well as original cosponsors LLOYD DOGGETT, PAUL TONKO, and TOM KEAN.

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

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentleman from New York (Mr. TONKO).

Mr. TONKO. Mr. Speaker, I rise in strong support of the Kay Hagan Tick Act legislation that I am leading along with my colleagues, Representatives CHRIS SMITH, LLOYD DOGGETT, and TOM KEAN.

The Kay Hagan Tick Act would reauthorize key programs at the CDC that fund both research and support for local public health agencies to address tick-borne diseases such as Lyme disease.

Tick-borne diseases are a large and growing problem in New York, with more than 18,000 cases of Lyme disease reported in New York State in 2024. Lyme can cause serious health consequences, and for some, long-term complications persist after treatment.

With a warming climate, tick populations and ranges are on the rise, leading to fears that tick-borne diseases will continue to increase in frequency in the years to come. Already, warning signs are blaring that 2026 could be the worst year for tick exposures since 2017, based on CDC tracking data.

In this backdrop, research investments and public health resources are more vital than ever. That is what the Kay Hagan Tick Act will deliver.

I am proud to have worked on this commonsense bipartisan bill, and I would urge all of my colleagues to support this legislation.

Mr. PALLONE. Mr. Speaker, again, I would urge my colleagues to support this bill on a bipartisan basis, and I yield back the balance of my time.

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

The SPEAKER pro tempore (Mr. NEWHOUSE). The question is on the motion offered by the gentleman from Kentucky (Mr. GUTHRIE) that the House suspend the rules and pass the bill, H.R. 4348.

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.

□ 1510

STEM CELL THERAPEUTIC AND RESEARCH REAUTHORIZATION ACT OF 2025

Mr. GUTHRIE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5160) to reauthorize the Stem Cell Therapeutic and Research Act of 2005, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5160

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 ''Stem Cell Therapeutic and Research Reauthorization Act of 2025''.

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

Section 379B of the Public Health Service Act (42 U.S.C. 274m) is amended—

(1) by striking ''appropriated $31,009,000'' and inserting the following: ''appropriated—

''(1) $31,009,000'';

(2) in paragraph (1), as so inserted, by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(2) $33,009,000 for each of fiscal years 2027 through 2031.''.

SEC. 3. CORD BLOOD INVENTORY.

(a) IN GENERAL.—Section 2(a) of the Stem Cell Therapeutic and Research Act of 2005 (42 U.S.C. 274k note) is amended by striking ''at least 150,000 new units of high-quality cord blood'' and inserting ''a sufficient supply, as determined by the Secretary, of high-quality cord blood units''.

(b) APPLICATION.—Section 2(c) of such Act (42 U.S.C. 274k note) is amended—

(1) in paragraph (2), by striking ''in perpetuity or''; and

(2) by amending paragraph (5) to read as follows:

''(5) if the Secretary determines through an assessment, or through petition by the applicant, that a cord blood bank is no longer operational, does not meet the requirements described in subsection (d)(4), or does not meet the requirements of section 379(d)(4) of the Public Health Service Act, and as a result may not distribute the high-quality units, the Secretary may transfer the units collected pursuant to this section to another qualified cord blood bank or entity approved by the Secretary to ensure continued availability of high-quality cord blood units.''.

(c) DURATION OF CONTRACTS.—Section 2(d)(4) of such Act (42 U.S.C. 274k note) is amended to read as follows:

''(4) CONSIDERATION OF BEST SCIENCE.—The Secretary shall take into consideration current scientific and clinical information in order to maximize the availability of high-quality cord blood units meeting applicable clinical and quality standards for transplant when entering into contracts under this section, or when extending a period of funding under such a contract under paragraph (2).''.

(d) INVENTORY MANAGEMENT.—Section 2 of such Act (42 U.S.C. 274k note) is amended—

(1) by redesignating subsections (e), (f), and (g) and as subsections (f), (g), and (h), respectively; and

(2) by inserting after subsection (d) the following:

''(e) INVENTORY MANAGEMENT.—

''(1) IN GENERAL.—The Secretary shall manage the size and composition of the National Cord Blood Inventory to maximize clinical utility, ensure genetic diversity, and promote the efficient use of resources.

''(2) CONSIDERATIONS.—In carrying out paragraph (1), the Secretary may—

''(A) on the Secretary's own initiative or upon petition by a qualified cord blood bank, make determinations regarding the continued storage of cord blood units based on the best available scientific and clinical evidence; or

''(B) prioritize the collection, retention, or disposition of cord blood units based on scientific, clinical, or operational considerations that the Secretary determines to be relevant.''.

(e) DEFINITIONS.—Section 2(g) of such Act, as redesignated by subsection (d)(1) of this section, is amended—

(1) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

(2) by inserting after paragraph (3) the following:

''(4) The term 'high quality cord blood unit' means a cord blood unit that meets current industry standards and any requirements of the Food and Drug Administration.''.

(f) AUTHORIZATION OF APPROPRIATIONS.—Section 2(h) of such Act, as redesignated by subsection (d)(1) of this section, is amended by striking ''fiscal years 2022 through 2026'' and inserting ''fiscal years 2027 through 2031''.

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

The Chair recognizes the gentleman from Kentucky.

GENERAL LEAVE

Mr. GUTHRIE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks and include extraneous material on H.R. 5160.

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 in support of H.R. 5160, led by my colleagues Representatives SMITH and MATSUI to reauthorize the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory program. The C.W. Bill Young Cell Transplantation Program supports patients across the country with identifying matching and facilitating the distribution of bone marrow peripheral blood stem cells and cord blood donors for those who need blood stem cell transplants.

This is critically important for those patients without a related family member who is unable to donate.

For some patients, blood stem cell transplants are an opportunity for remission or even a cure when other treatments have failed. This bill ensures patients have access to these lifesaving opportunities.

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

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

Mr. Speaker, I rise in support of H.R. 5160, the Stem Cell Therapeutic and Research Reauthorization Act. This bill reauthorizes the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory, two programs that serve as national registries to connect patients with lifesaving care.