

volume each year, undercutting domestic fishermen. Last year, the U.S. imported 6.4 billion pounds of foreign seafood, a 10 percent increase from 2019.

As imports have increased, American commercial seafood landings have declined. In 2024, the U.S. commercial landings totaled 7.7 billion pounds, the first time landings have been below 8 billion pounds since 1988.

Louisiana's commercial fishing industry has particularly been hit hard by this flood of foreign imports. Since 2021, Louisiana shrimpers have seen the value of their catch drop by more than 50 percent, falling from \$131 million in 2021 to just \$61 million in 2024. As you can see, this is, in fact, a real threat.

Passing this bill will deter bad actors from flooding the market with unsafe products and provide American fishermen with a fair playing field, allowing them to sustainably harvest millions of additional pounds of shrimp and other seafood each year.

This is a real issue, and I am proud to be working in a bipartisan way to address an issue that will impact not just Louisiana but our entire country.

Mr. Speaker, I urge the passage of this critical legislation.

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

Mr. GUTHRIE. Mr. Speaker, I encourage my colleagues to vote for this bipartisan 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. 2715, as amended.

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

A motion to reconsider was laid on the table.

FDA MODERNIZATION ACT 3.0

Mr. GUTHRIE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2821) to require the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to publish a final rule relating to nonclinical testing methods.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 2821

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 “FDA Modernization Act 3.0”.

SEC. 2. REGULATIONS ON NONCLINICAL TESTING METHODS.

(a) INTERIM FINAL RULE.—

(1) IN GENERAL.—In order to ensure implementation of the amendments to section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) made by section 3209(a) of the Consolidated Appropriations Act, 2023 (Public Law 117–328; 136 Stat. 5821), not later than 1 year after the date of enact-

ment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish an interim final rule—

(A) to amend the sections of title 21, Code of Federal Regulations, described in paragraph (2) to replace any references to “animal” tests, data, studies, models, and research with a reference to nonclinical tests, data, studies, models, and research; and

(B) to add the definition of “nonclinical test” in section 505(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(z)) to sections 312.3, 314.3, 315.2, and 601.31 of title 21, Code of Federal Regulations.

(2) CFR SECTIONS DESCRIBED.—The sections of title 21, Code of Federal Regulations, described in this paragraph are the following:

(A) Section 312.22(c).

(B) Section 312.23(a)(3)(iv).

(C) Section 312.23(a)(5)(ii).

(D) Section 312.23(a)(5)(iii).

(E) Section 312.23(a)(8).

(F) Section 312.23(a)(8)(i).

(G) Section 312.23(a)(8)(ii).

(H) Section 312.23(a)(10)(i).

(I) Section 312.23(a)(10)(ii).

(J) Section 312.33(b)(6).

(K) Section 312.82(a).

(L) Section 312.88.

(M) Section 314.50(d)(2).

(N) Section 314.50(d)(2)(iv).

(O) Section 314.50(d)(5)(i).

(P) Section 314.50(d)(5)(vi)(a).

(Q) Section 314.50(d)(5)(vi)(b).

(R) Section 314.93(e)(2).

(S) Section 315.6(d).

(T) Section 330.10(a)(2).

(U) Section 601.35(d).

(V) Any other section necessary to ensure regulatory consistency with the amendments to section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) made by section 3209(a) of the Consolidated Appropriations Act, 2023 (Public Law 117–328; 136 Stat. 5821).

(3) EFFECTIVENESS OF INTERIM FINAL RULE.—Notwithstanding subparagraph (B) of section 553(b) of title 5, United States Code, the interim final rule issued by the Secretary of Health and Human Services under paragraph (1) shall become immediately effective as an interim final rule without requiring the Secretary of Health and Human Services to demonstrate good cause therefor.

(b) TECHNICAL AMENDMENT.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by designating the second subsection (z) (relating to clinical trial diversity action plans), as added by section 3601(a) of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022 (division FF of Public Law 117–328), as subsection (aa).

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 in which to revise and extend their remarks and include extraneous material on this legislation.

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 strong support of H.R. 2821, led by my colleagues Representative CARTER of Georgia and Representative BARRAGÁN, which requires the Secretary of HHS to publish rules amending certain regulations by replacing references to “animal” tests, data, studies, models, and research with the broader term “non-clinical” tests, data, studies, models, and research.

Biomedical research typically utilizes animal models to explore biological processes, analyze diseases, and explore potential therapies. However, given the concerns and scientific limitations of animal testing, researchers have increasingly turned to new approach methodologies to evaluate drugs when scientifically justified.

The scientific community has worked diligently to balance animal welfare concerns and the value of animal tests and research. I am pleased with the progress to date and look forward to seeing continued evidence-driven advancements in this space.

I commend the administration for their work to phase out animal testing where it is scientifically appropriate and for achieving the key goals in the first year of implementing the roadmap to reducing animal testing in pre-clinical safety studies.

Mr. Speaker, I appreciate my colleague from Georgia for putting this bill forward, and I reserve the balance of my time.

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

Mr. Speaker, I rise in support of H.R. 2821, the FDA Modernization Act 3.0, led by Representative BARRAGÁN and Representative CARTER of Georgia.

The FDA Modernization Act 3.0 would require the Food and Drug Administration to update regulations to replace references to animal tests, data, studies, models, and research in specified sections of Title 21 of the Code of Federal Regulations with references to nonclinical tests.

This would bring FDA's regulations in line with a law passed in 2022 that allowed for alternatives to animal testing in drug development, including those that leverage recent scientific advancements, such as computer modeling and cell-based assays.

I encourage all my colleagues to vote “yes” on H.R. 2821, and I reserve the balance of my time.

Mr. GUTHRIE. Mr. Speaker, I yield such time as he may consume to the gentleman from Georgia (Mr. CARTER), a dear friend, a great member of the Energy and Commerce Committee, and a leader in this effort with the FDA. With pharmaceuticals, just about anything that is very important to the American people, he is an absolute leader in that.

Mr. CARTER of Georgia. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, I rise today in strong support of my bill, H.R. 2821, the FDA

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 mod-

ern 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.