

# Senators tell FDA to Update Regulations Regarding Non-Animal Testing Methods

*Proper implementation of unanimously adopted law impossible without adjusting FDA regulations*

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EINPresswire.com/ -- Five Republicans and four Democrats in the U.S. Senate urged FDA Commissioner Robert Califf to revise its animal testing regulations so that the agency follows the dictates of an enormously popular new law to reduce animal testing. Congress enacted the FDA Modernization Act 2.0 in December 2022 to eliminate an 84-year-old animal-testing mandate for new drug approvals. The Center for a Humane Economy and Animal Wellness Action led a broad coalition that advocated for the measure.

## Bill for FDA Modernization Passes!

**Countless beagles, primates and other animals will be spared from drug experiments**



The FDA is supposed to no longer mandate animal-testing for new pharmaceuticals. But the agency needs to revise its regulatory framework to make this occur.

[The Senate letter](#) is signed by Rand Paul, R-Ky; Cory Booker, D-N.J.; Mike Braun, R-Ind.; Roger Marshall, R-Kansas; Angus King, I-Me.; Ben Ray Lujan, D-N.M.; John Kennedy, R-La.; Eric Schmitt, R-Mo.; and Tim Kaine, D-Va. All of these Senators, but for the newly elected Sen. Schmitt, were cosponsors of the FDA Modernization Act. A majority of the lawmakers serve on the Senate Health, Education, Labor and Pensions (HELP) Committee, which has oversight of the FDA.

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*Zaher Nahle, Senior Scientific Advisor for CHE*

“With the enactment of the FDA Modernization Act nearly one year ago, the FDA has been delinquent in not following the directives of Congress and revamping its archaic

regulations relating to animal testing mandates for new drug screening,” said Wayne Pacelle, president of Animal Wellness Action and the Center for a Humane Economy. “The use of human-relevant models must be put to use in our drug development programs for the benefit of

patients, drug sponsors, and animals.”

The lapse in time is underscored by [a social media post today by Sen. Paul](#), which reads:

@POTUS signed my bill to end mandatory animal testing into law. It enables alternative testing and faster drug approvals. So what's the delay @US\_FDA ?

The FDA Modernization Act 2.0 was passed by Congress with “uncommon unanimity,” the senators state in their letter. More than 350 global publications, including news articles, commentaries, scientific reviews, and primary papers have been published since the Act was signed into law in December 2022. All key stakeholders, including a wide range of biotech companies, underscore the significant value of the new law in advancing drug development and shifting the existing paradigm towards 21st-century technologies and applications.

In their letter, senators reminded FDA commissioner Califf, a medical doctor, he had spoken favorably about the Act before the U.S. Senate Committee on Health, Education, Labor, and Pensions, “noting that alternative methods may include cell-based assays, organ chips and micro-physiological systems, computer modeling, bioprinting, and a growing variety of other New Approach Methodologies (NAMs).”

Animal Wellness Action, the Center for a Humane Economy, the Animal Wellness Foundation, and the Center for Responsible Science [wrote to the FDA in August](#) and also asked the commissioner to institute a rulemaking action to address the inconsistencies between the new law and the old regulations.

“Now that the FDA Modernization Act 2.0 has become law, it is time for the FDA to amend its regulations,” said Dr. Neil Wilcox, board president of the Center for Responsible Science and former Senior Science Policy Officer, Office of Science at the FDA. “The Center for Responsible Science requested updated regulations in 2015 via the Administrative Procedures Act to use test-neutral language that would include alternatives to animal tests. While disappointed that we never received a substantive response from the FDA, I’m hopeful that the agency will act expeditiously to update the regulations to comport with the new law, as is required,” said Dr. Wilcox.

“Aligning the statute with regulations will eliminate confusion for drug sponsors, lead to more cures, cut drug development time, lower drug prices, and confirm the FDA’s stated commitment to reducing and replacing animals in drug development,” said Zaher Nahle, Senior Scientific Advisor for the Center for a Humane Economy.

## ABOUT

Animal Wellness Action is a Washington, D.C.-based 501(c)(4) whose mission is to help animals by promoting laws and regulations at federal, state and local levels that forbid cruelty to all animals.

The group also works to enforce existing anti-cruelty and wildlife protection laws. Animal Wellness Action believes helping animals helps us all. Twitter: @AWAction\_News

The Center for a Humane Economy is a Washington, D.C.-based 501(c)(3) whose mission is to help animals by helping forge a more humane economic order. The first organization of its kind in the animal protection movement, the Center encourages businesses to honor their social responsibilities in a culture where consumers, investors, and other key stakeholders abhor cruelty and the degradation of the environment and embrace innovation as a means of eliminating both. The Center believes helping animals helps us all. Twitter: @TheHumaneCenter

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