

Congress Can Expedite Drug Testing and Save Animals with the FDA Modernization Act

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-- The FDA Modernization Act of 2021 allows a market approval applicant for a new drug to use methods other than animal testing to establish the drug's safety and effectiveness. These alternative methods may include:

- . Cell-based assays,
- . Organ chips and micro physiological systems,
- . Sophisticated computer modeling, and
- . Other human biology-based test methods.

The U.S. Food and Drug Administration (FDA) requires animal testing to ensure the safety of many drugs and devices. The FDA can mandate drug sponsors or manufacturers to provide reports on "preclinical tests (including tests on animals) ... adequate to justify the proposed clinical testing" or "primary data tabulations from animal or human studies," according to federal law. Click on the link in this paragraph





to see the 'Animals Behind Top Drugs' chart and the list of animals used in testing each product.

On April 20, 2021, the House of Representatives, led by lawmakers Reps. Vern Buchan, R-Fla.,

Elaine Luria, D-Virginia, Nancy Mace, R-S.C., Mikie Sherrill, D-N.J., and Brendan Boyle, D-Pa. introduced their bill, H.R. 2565, to reduce animal testing. The House bill currently has forty-five cosponsors. Representative Earl L. "Buddy" Carter of Georgia's District 1 is a co-sponsor.

https://www.wbtw.com/news/newlegislation-to-change-requirement-onanimal-testing/

The Senate followed in this effort on October 7, 2021, when U.S. Senators Cory Booker (D-NJ) and Rand Paul (R-KY) introduced the FDA Modernization Act to end animal testing mandates in their Chamber. This legislation, S. 2952, would end an outdated FDA mandate that experimental drugs must be tested on animals before they are used on humans in clinical trials. The bill would not ban animal testing outright, but would allow the option for drug sponsors to use alternative methods where they are suitable. The Senate bill currently has six co-sponsors.





Modernization Act furthers high tech testing in drug production.

https://www.booker.senate.gov/news/press/booker-paul-introduce-bipartisan-fda-modernization-act-to-end-animal-testing-mandates

In an article written by Erik Gatenholm, CEO and co-founder of BICO, a leading bio convergence company, Mr. Gatenholm writes, "While many forward-looking pharmaceutical companies realize that animal testing isn't effective, the current law forces them to conduct these inhumane experiments against their will. In fact, to develop one new pharmaceutical or cosmetic product, hundreds of animals need to be tested on and euthanized."

The article, titled 'The FDA Modernization Act Can Leverage Technology To Accelerate Drug Discovery And Save Millions Of Animals', was published on December 20, 2021 by Forbes. An excerpt from the article reads as follows:

"The FDA Modernization Act would allow us to use tools like 3-D bioprinting to fabricate a miniature "organ on a chip" that contains real human cells and functions similarly to an organ in a person's body — and we could test new drugs on that, providing a much more physiologically

relevant analysis than if we were to test on a mouse. The same goes for skin care products; cell-culturing methods have become so advanced that we are now able to grow human skin in a petri dish to better determine toxicity compared to testing on a live rabbit.

I believe this is a good first <u>step in bringing our pharmaceutical regulation firmly into the 21st century</u>. This bill would not only save billions of animal lives over the years, but it would also enable us to create safer products faster and ensure the United States remains a competitive country in which to develop new drugs and cosmetics."

The public can help in advancing this effort by contacting their U.S. Representative and their U.S. Senators and asking them to co-sponsor their bills. Contact information for lawmakers can be found at house.gov and senate.gov. Interested individuals may also contact their lawmakers by phone. They can call (202) 224-3121 and ask the switchboard operator to connect them to their Representative and Senator's office.

https://www.house.gov/representatives https://www.senate.gov/senators/senators-contact.htm

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