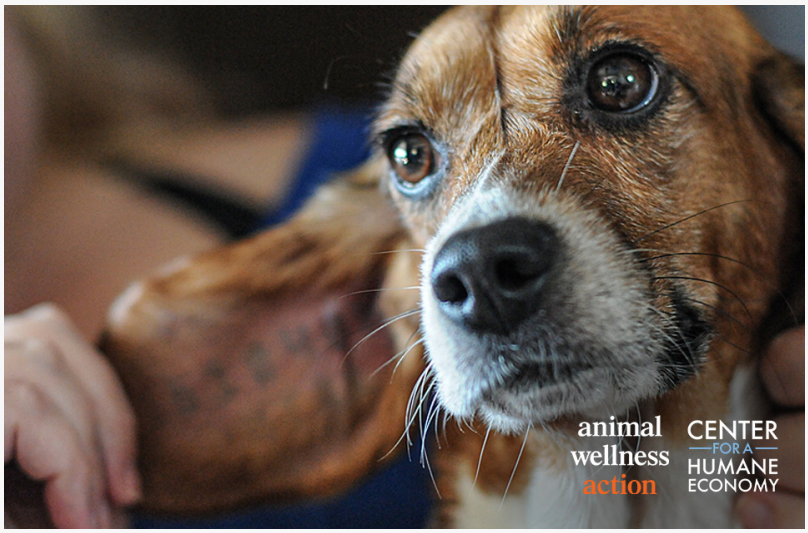
Reset of FDA's Drug Development Paradigm Moving Forward

Progress reflects desperate need to reduce animal testing and usher in 21st-century science



Each year, thousands of beagles like this one are needlessly hurt or killed in the name of antiquated, ineffective science.

WASHINGTON, D.C., UNITED STATES, May 11, 2022 /EINPresswire.com/ -- By Wayne Pacelle and Tamara Drake

In a game-changing legislative act, Democrat and Republican leaders of the U.S. House Committee on Energy and Commerce have included the FDA Modernization Act as a "rider" to a broader legislative package to reauthorize the Food and Drug Administration (FDA) user-fee agreements. If enacted, this measure will eliminate a federal mandate for animal testing for all new drug development protocols that has been in place since the Great Depression of the 1930s.

Passing the FDA Modernization Act—in the form of H.R. 2565 from Reps. Vern Buchanan, R-Fla., and Elaine Luria, D-Va., and S.2952 from Sens. Rand Paul, R-Ky., and Cory Booker, D-N.J. —is a top priority for Animal Wellness Action and its sister organization, the Center for a Humane Economy. We have assembled a coalition of 135 groups and businesses, representing patient advocacy, medical associations, biotech and pharma, and animal welfare concerns.

> We cannot have progress for animals … until the Federal Food, Drug and Cosmetics Act of 1938 is changed."
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> *Wayne Pacelle, president, Animal Wellness Action*

The new package, H.R. 7667, which includes the FDA Modernization Act, is set for final action in the Energy and Commerce Committee this month and may pave the way for the phase-in of non-animal test methods in new drug development and a reduction in the use of animals. Every year, tens of thousands of beagles and primates are used in protocols, along with hundreds of thousands of

other animals. The Senate is expected to introduce a parallel legislative package in the coming days, with the two chambers hoping to complete all work on the new policies by the end of summer.

We cannot have progress for animals in the realm of drug development until the Federal Food, Drug and Cosmetics Act of 1938 is changed. Should this reform be enacted this year, our task will be to apply the principles that undergird it—changing the culture at the FDA and in the pharmaceutical industry so that alternative methods are developed and put into practical use. It's been 83 years of required animal testing, hindering the movement toward 21st-century human-based biology.

There are hopeful signs that the FDA is paying close attention to the dramatic level of bipartisan support we've built for the FDA Modernization Act. In its write-up accompanying its 2023 proposed budget to the Congress, the agency states:

"New alternative methods have the potential to provide both more timely and more predictive information to accelerate drug development and enhance emergency preparedness for the benefit of U.S. patients, consumers, and animals. Additionally reducing the need for animal testing is a priority for FDA...."

The FDA has proposed a total of $12.5 million in funding to advance alternatives to animal testing in its Fiscal Year 2023 budget, a $5 million increase from 2022 levels.

In the FDA's budget justification for the prior year, "reducing animal testing" was mentioned once and "alternatives to animal tests" seven times. The use of that important vocabulary exploded in print in the agency's just-released budget for FY 2023. The budget justification mentions "reduction of animal testing" 27 times and "alternatives to animal tests" 62 times. That's a 10-fold increase in explicit references to language that recognizes the importance of moving away from animal testing.

Any fair-minded analysis shows that the current drug-development paradigm, built on the backs of animals, is archaic and counterproductive to our goals to allow Americans to live long, healthy lives.

- There is an abysmal 90 to 95 percent failure rate in human clinical trials after a drug has passed muster in preclinical animal tests.
- The timeline with animal testing is 10 to 15 years, and $1 billion to $6 billion in R&D capital costs, just to bring a single new drug to market.
- Adverse reactions to drugs are the fourth leading cause of death in the U.S.
- Most diseases have no cures, and a reliance on animal models may be hindering the pace in developing treatments to address long-standing human afflictions.

We know that Americans don't want to see animal testing conducted when alternative methods

are available. In fact, the FDA itself has publicly embraced the “3 Rs” approach to animal testing: supporting “refinement” of techniques to minimize pain and distress to animals, “reduction” in the number of animals in protocols, and “replacement” of animal tests where alternative methods exist.

The inclusion of the FDA Modernization Act within the five-year renewal of a key funding mechanism for the FDA is good for pharma companies that will see great R&D productivity. It is good for patients who are desperate for safer, more effective drugs delivered at less expense and at a faster pace. And it’s good for animals subjected to painful and frequently lethal tests but whose conscription does little to identify health risks for humans or guarantee experimental drugs will work.

We have much work to do in the coming weeks, but there are promising signs of a reset in our national drug development strategies.

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