



## The Humane and Existing Alternatives in Research and Testing Sciences [HEARTS] Act HR 1291

Congressman Ken Calvert (R-CA) and Congressman Chris Pappas (D-NH)

### About Humane Alternatives to the use of Animals in Research and Testing

Today ever-evolving science and technology are creating opportunities to move closer to the goal of replacing animals in biomedical research and regulatory testing. Modern and more human-relevant methods include human epidemiological and clinical studies, cell-based methods, computer modeling and simulation, and human tissue studies. These options spare animal lives and advance science while more effectively protecting human health, the environment, and the economy.

Yet, there are some barriers that limit the full realization of these benefits. Lack of overall funding, shortcomings in existing law governing how research projects are funded and outdated requirements have been cited as obstacles capitalizing on alternatives.<sup>1</sup> Modern non-animal methods not only spare animals from pain and death, but they have more predictive value and specificity to human conditions than do animal tests due to differences among species.<sup>2</sup>

### About Prioritizing the Use and Development of Humane Alternatives through the NIH

Today the National Institutes of Health (NIH) spends at least \$20 billion a year on animal testing. However, there is a growing awareness of the limitations of animal research and its inability to make reliable predictions for humans, as a result the return on investment is often low. The NIH reports that approximately 90 percent of promising medications have failed in human clinical studies despite having passed pre-clinical studies, including animal tests.<sup>3</sup>

Nearly everyone can agree that whenever non-animal methods are available for replacing the use of animals in research protocols they should be used. According to a 2019 SurveyUSA nationwide poll, 79 percent of voters said that the NIH should prioritize research proposals that utilize scientifically valid alternatives to animal testing and 80 percent said that medical researchers seeking funding for animal tests should first be required to show that an alternative is not available<sup>4</sup>. Unfortunately, this is not always the case. Office of Inspector General reports have repeatedly note repeated failures to search for alternatives to painful procedures and to document the availability of alternatives in research proposals.<sup>5</sup> **A system of active incentives is needed to encourage researchers to develop and utilize humane, cost-effective, and scientifically suitable non-animal methods based on human biology.**

<sup>1</sup> Katy Taylor, *Recent Developments in Alternatives to Animal Testing in ANIMAL EXPERIMENTATION: WORKING TOWARDS A PARADIGM CHANGE* (Kathrin Herrmann & Jayne Kimberley, eds. 2019) [hereinafter ANIMAL EXPERIMENTATION]; Gary E. Marchant, *Law—Not Science—Impedes Shift to Non-Animal Safety Testing*, BLOOMBERG L. (July 18, 2021), <https://news.bloomberglaw.com/environment-and-energy/law-not-science-impedes-shift-to-non-animal-safety-testing>; Lee, *supra* note 1.

<sup>2</sup> Thomas Hartung, *Look Back in Anger—What Clinical Studies Tell Us About Preclinical Work*, 30 ALTEX 275 (2013), <https://pubmed.ncbi.nlm.nih.gov/23861075/>; Pandora Pound & Michael B. Bracken, *Is Animal Research Sufficiently Evidence Based to be a Cornerstone of Biomedical Research?*, 348 BMJ 3387 (2013), <https://pubmed.ncbi.nlm.nih.gov/24879816/>; Jarrod Bailey et al., *Predicting Human Drug Toxicity and Safety via Animal Tests*, 43 ALT. LAB ANIMAL 393 (2015), <https://pubmed.ncbi.nlm.nih.gov/26753942/>; Isabella WY Mak et al., *Lost in Translation: Animal Models and Clinical Trials in Cancer Treatment*, 6 AM. J. TRANSLATIONAL RSCH. 114 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3902221/>.

<sup>3</sup>National Institutes of Health, NCATS: The Tissue Chip for Drug Screening

<https://ncats.nih.gov/tissuechip#:~:text=Why%20Tissue%20Chips%20Matter,based%20approach%20to%20this%20challenge>

<sup>4</sup>Cruelty Free Int'l, *Ending Medical Testing on Animals in the USA: A Nationwide Poll of 1,000 Adults by SurveyUSA* (Aug. 2019),

<https://crueltyfreeinternational.org/sites/default/files/2021-11/Medical%20testing%20-%20USA%20polling.pdf>

<sup>5</sup> Audit Report APHIS Animal Care Program Inspection and Enforcement Activities, USDA OFF. INSPECTOR GENERAL (2005),

[https://www.animallaw.info/sites/default/files/awa\\_enforcement\\_2005.pdf](https://www.animallaw.info/sites/default/files/awa_enforcement_2005.pdf)

In 2019, the United States Government Accountability Office (GAO) recommended that federal agencies better monitor and report on their efforts to develop and promote replacement alternatives and decrease animal use.<sup>6</sup> Moreover, under the National Institutes of Health Revitalization Act of 1993 (Public Law 103–43), the NIH is supposed to outline a plan for reducing the use of animals in research and is supposed to conduct or support research methods of biomedical research and experimentation that do not require the use of animals. **A dedicated center that provides resources, funding, and training to encourage researchers to utilize humane, cost-effective, and scientifically suitable non-animal methods based on human biology will complete the vision that Congress set out in the Act and will result in more progress toward understanding human diseases and their treatments and cures.**

#### **The Humane and Existing Alternatives in Research and Testing Sciences (HEARTS) Act**

The HEARTS Act will prioritize the use of alternatives by amending the Public Health Services Act to require:

- (1) the establishment of incentives for investigators to use available non-animal methods whenever feasible and applicable;
- (2) the NIH to establish and maintain research proposal guidelines for conducting thorough searches for non-animal alternatives to the use of animals for biomedical and behavioral research;
- (3) that proposal reviewers have access to a reference librarian with expertise in evaluating the adequacy of the search methods for alternatives described in the protocol;
- (4) that proposals be reviewed by at least one person with expertise in non-animal research methods.

Additionally, the HEARTS Act establishes a “National Center for Alternatives to Animals in Research and Testing” within the National Institutes of Health with the goal of aiding, funding, and training to educate scientists in alternatives to the use of animals in research, and support for human-centered methods. The new National Center would also track the number of animals used in federally funded research be tasked with developing a plan for reducing those numbers.

Lastly, the bill updates the definition of “animal” to include cephalopods (octopuses etc.) to ensure that these animals will receive the minimum protections afforded to other animals used in NIH-funded research. This change is consistent with regulations in the EU and UK.

-----

To remain a global leader in science, research, and development, the U.S. must create frameworks to develop and incentivize the use of modern human-relevant methods. Prioritizing the development and use of non-animal methods in taxpayer-funded research at the NIH could improve the cost efficacy of our federal research investment and foster innovation in science which would in turn lead to better therapies for human conditions while sparing millions of animals from needless suffering.

---

<sup>6</sup> U.S. GENERAL ACCOUNTABILITY OFF., GAO-19-629, ANIMAL USE IN RESEARCH: FEDERAL AGENCIES SHOULD ASSESS AND REPORT ON THEIR EFFORTS TO DEVELOP AND PROMOTE ALTERNATIVES (Sep. 2019), <https://www.gao.gov/assets/gao-19-629.pdf>.