Congress of the United States

Washington, DC 20515

December 19, 2025

The Honorable Jayanta Bhattacharya Director, National Institutes of Health 9000 Rockville Pike Bethesda, MD 20891

Dear Dr. Bhattacharya:

According to recent reporting from *Science* magazine,¹ the Centers for Disease Control and Prevention (CDC) is preparing to shut down its in-house primate research program in late November. The decision reportedly reflects a combination of practical and scientific concerns — rising costs associated with securing and caring for non-human primates (NHPs), growing evidence that NHP models often fail to accurately predict human therapeutic outcomes, and increasing scrutiny over the ethics of invasive research involving intelligent, socially complex animals.

We urge other federal life-science agencies to follow this example and critically examine their continued use of non-human primates (NHPs) in intramural and extramural research. Your own stated intention to reduce NIH's reliance on animal testing reflects meaningful progress toward modernizing U.S. research infrastructure and promoting more humane, human-relevant scientific methods. From terminating testing on beagles at the NIH campus to excluding the use of non-human models from a recent funding initiative for autism, the agency's policies signal NIH's ongoing commitment to humane and ethical testing practices. We applaud NIH's plan,² announced in April, to refocus the agency on emerging New Approach Methodologies (NAMs) and advanced technologies (e.g., AI, advanced cell models), which further underscores the meaningful shift toward modernizing research.

Given the progress by NIH toward reduction and replacement of animal testing, we write to recommend three additional steps:

Give preference in grantmaking to proposals that use NAMs

As the largest public funder of biomedical research, the NIH plays a preeminent role in setting research priorities both for our nation and the world. For well over a decade, your predecessors acknowledged the failures of the animal testing paradigm and the value of human-relevant models. As early as 2011, Dr. Francis Collins observed that "[w]ith earlier and more rigorous target validation in human tissues, it may be justifiable to skip the animal model assessment of efficacy altogether." In 2013, Dr. Elias Zerhouni noted that "researchers have over relied on animal data" and "[w]e need to refocus and adapt new methodologies for use in humans to understand disease biology in humans."

¹ Exclusive: CDC to end all monkey research | Science | AAAS, by David Grimm; Science magazine, November 21, 2025.

² NIH. NIH to prioritize human-based research technologies. In: NIH, ed. *New initiative aims to reduce use of animals in NIH-funded research*: NIH; 2025.

³ Collins FS. Reengineering Translational Science: The Time Is Right. *Science Translational Medicine*. 2011;3(90):90cm17-90cm17.

⁴ NIH. Ex-Director Zerhouni Surveys Value of NIH Research, In: NIH, ed. NIH Record Vol 13; 2013.

Under your leadership, the NIH now has an opportunity to make good on its past promises by prioritizing grant applications that use animal-free NAMs over those that rely on animal use. Such a reform is long overdue in many contexts where the translatability of animal results from the laboratory to the clinic have consistently shown high failure rates above 90%, such as urological (96%), cardiovascular (95%), oncological (95%) and neurological (94%) diseases, to name just a few.⁵ In these areas, favoring NAMs (which have been shown to outperform animal packages in critical safety assessments^{6,7}) will transform the clinical research landscape and lead to faster breakthroughs.

We therefore encourage you to direct all NIH institutes to set aside an appropriate minimum percentage of funding opportunities to proposals that seek to utilize animal-free NAMs instead of animal protocols. This shift will foster more reliable, ethical, and cost-effective scientific methods, aligning with both public expectations and the evolving needs of medical research.

Reassess funding for the National Primate Research Centers

The paradigm centered on animal research in predicting safety and efficacy of drugs yields on average a high failure rate of 92%. Recognizing this, the U.S. Commissioner of Food and Drugs, Dr. Marty Makary, announced in April that FDA will replace animal testing with NAMs for monoclonal antibody (mAb) assessments, which are conducted today chiefly on NHPs. Additionally, the FDA announced its intention to make animal testing an exception, rather than the norm, for all drug development within three to five years. Yet the NIH recently reissued a funding opportunity to "encourage grant applications that support the activities of the National Primate Research Centers (NPRCs)," without examining the changing demand in the field.

Given the disparity between the FDA's timetable and the decades-long lifespan of NHPs, this funding announcement appears to undermine both your strategic vision and the Administration's efforts to phase out animal use across multiple agencies. We therefore encourage you to initiate a review of the NPRCs' programmatic goals with an aim of reducing federal primate research funding by a percentage over time consistent with the FDA's three-to-five-year plan. By ramping down spending on NPRCs, the NIH can generate savings that can be invested in research that utilizes animal-free NAMs while improving human health.

⁵ Thomas et al., 2021, D. Thomas, D. Chancellor, A. Micklus, S. LaFever, M. Hay, S. Chaudhuri, R. Bowden, A.W. Lo Clinical development success rates and contributing factors 2011–2020. BIO, Informa Pharma Intelligence, and QLS advisors

https://www.bio.org/clinical-development-success-rates-and-contributing-factors-2011-2020 (2021)

⁶ Ewart L, Apostolou A, Briggs SA, et al. Performance assessment and economic analysis of a human Liver-Chip for predictive toxicology. *Commun Med (Lond)*. Dec 6 2022;2(1):154.

⁷ Fäs L, Chen M, Tong W, et al. Physiological liver microtissue 384-well microplate system for preclinical hepatotoxicity assessment of therapeutic small molecule drugs. *Toxicol Sci.* Jan 1 2025;203(1):79-87.

⁸ BIO. Clinical Development Success Rates and Contributing Factors 2011–2020: Biotechnology Innovation Organization 2021.

⁹ FDA. (2025). Roadmap to reducing animal testing in preclinical safety studies. Retrieved from https://www.fda.gov/media/186092/download.

¹⁰ Limited Competition: National Primate Research Centers (P51) (Clinical Trials Not Allowed), and Notice of Extension of the Expiration Date for PAR-23-126 " Limited Competition: National Primate Research Centers (P51) (Clinical Trials Not Allowed)" https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-149.html

Reaffirm NIH's 3 Rs commitment and clarify NAMs are not "complements" to animal use

Lastly, we noted with concern the NIH's continued mischaracterization of NAMs as "complements" to animal experimentation, including by categorizing NAMs under the Complement Animal Research In Experimentation (Complement-ARIE) program. The mischaracterization of NAMs under this program conflicts with the agency's direction on animal testing, undermining the principle of the 3Rs (to refine, reduce, and replace animal use in research wherever possible), a doctrine long embraced by our nation's public health agencies across multiple administrations. We ask that you reaffirm the NIH's commitment to the 3 Rs by appropriately renaming Complement-ARIE and reassessing similar programs on NAMs at the NIH.

We look forward to working with you to accomplish these goals and respectfully request your response within 60 days of the date of this letter.

Sincerely,

Diana Harshbarger, Pharm.D.

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Gus M. Bilirakis
Member of Congress

Nancy Mace Member of Congress

¹¹ Nahle Z. Making NAMs a 'Complement' to animal experimentation is the Trojan Horse of the animal-industrial complex — A scheme to nullify the principles of the 3Rs and void the quest to 'replace' animals for good! *NAM Journal*. 2025/01/01/2025;1:100030.

¹² The Guide for the Care and Use of Laboratory Animals (8th Edition), https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf, PHS Policy on Humane Care and Use of Laboratory Animals, https://olaw.nih.gov/policies-laws/phs-policy.htm?utm_source=chatgpt.com, https://www.fda.gov/science-research/about-science-research-fda/advancing-alternative-methods-fda

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cc: The Honorable Martin A. Makary, M.D., M.P.H., Commissioner, U.S. Food & Drug Administration