National Association for BIOMEDICAL RESEARCH

February 12, 2026

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

Re: Concerns Regarding Factual Inaccuracies in Congressional Correspondence on Animal Research

Dear Dr. Bhattacharya,

I am writing to respectfully bring to your attention several factual inaccuracies and policy mischaracterizations contained in a recent letter from 20 members of Congress regarding animal research, drug development failure rates, non-animal methods (NAMs), FDA policy, and funding for the National Primate Research Centers (NPRCs).

First, the letter incorrectly attributes a widely cited "92% drug development failure rate" to deficiencies in preclinical animal testing. As documented in BIO's 2021 analysis[1], this figure reflects overall attrition from Phase 1 clinical trials through FDA approval, not failures of pre-clinical animal studies. In fact, animal research fulfills its intended role by eliminating the vast majority of unsafe or ineffective compounds before human clinical trial exposure. Consistent with this, more than half of drugs entering Phase 1 trials are shown to be safe, underscoring that later-stage failures are driven primarily by human biology, trial design, and commercial factors rather than preclinical animal testing. Weakening animal research requirements before scientifically validated alternatives are available risks increasing, not reducing, human trial failures.

Second, the letter substantially overstates both the timeline and scope of FDA's April 2025 roadmap. The FDA's roadmap does not call for a system-wide elimination of animal testing within three to five years. Rather, it outlines a context-specific, aspirational framework focused largely on certain monoclonal antibody applications and the gradual integration of NAMs as they are validated. FDA explicitly preserves its authority to require animal data where necessary to protect public safety, recognizing that whole-body animal studies remain essential for assessing immune responses, chronic toxicity, and systemic effects across most therapeutic areas.[2]

Third, claims that NAMs broadly "outperform" animal models misrepresent the current scientific consensus. While NAMs show promise in specific, narrow domains such as certain aspects of liver toxicology, they do not yet replicate complex pharmacokinetic, immunology, or multi-organ interactions. As a result, NAMs currently serve as complementary tools rather than standalone replacements, and most regulatory agencies do not accept NAM-only data for most safety determinations. Premature reliance on NAMs alone risks regulatory delays and potential harm to patients.

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[1] https://www.bio.org/clinical-development-success-rates-and-contributing-factors-2011-2020
[2] https://pmc.ncbi.nlm.nih.gov/articles/PMC4284445/

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Fourth, the letter's characterization of NIH's Complement-ARIE program overlooks its alignment with NIH's long-standing commitment to the 3Rs. Complement-ARIE appropriately emphasizes the development and validation of NAMs while preserving animal research where necessary to ensure scientific reliability. For complex diseases and public health threats including Alzheimer's disease, HIV, and emerging pandemics, full replacement of animal models is not yet feasible.

Finally, calls to reduce or eliminate funding for the National Primate Research Centers (NPRCs) fail to account for their essential role in basic biomedical research and national preparedness. In 2025, NIH reaffirmed the importance of the NPRCs and awarded FY26 funding in recognition of their continued necessity for infectious disease, vaccine, aging, genetic, and biodefense research. Abrupt funding reductions would squander decades of federal investment, exacerbate ongoing non-human primate shortages, and delay critical scientific advances. At the same time, strategic competitors, most notably China, are rapidly expanding their primate research capacity, raising significant concerns about U.S. leadership and biosecurity should domestic capabilities be diminished.[3]

Taken together, the congressional letter's arguments rely on cherry-picked data and overstated policy claims that risk undermining patient safety, scientific rigor, and U.S. competitiveness.[4] A balanced, evidence-based approach, integrating NAMs as they are rigorously validated while preserving essential animal research infrastructure, is necessary to advance biomedical innovation responsibly and protect public health.

Thank you for your continued leadership at the National Institutes of Health and for your attention to these concerns. I would welcome the opportunity to provide additional information if helpful.

Sincerely,

Matthew R. Bailey
President
National Association for Biomedical Research

[3] https://www.bloomberg.com/news/audio/2025-11-18/big-take-asia-china-s-animal-tests-fuel-biotech-boom-podcast
[4] China Pushes Animal Testing Limits in Race to Become Biotech Superpower - Bloomberg