November 25, 2024

The Honorable Tom Cole Chair Committee on Appropriations U.S. House of Representatives Washington, DC 20515

The Honorable Rosa DeLauro Ranking Member Committee on Appropriations U.S. House of Representatives Washington, DC 20515 The Honorable Patty Murray Chair Committee on Appropriations U.S. Senate Washington, DC 20510

The Honorable Susan Collins Vice Chair Committee on Appropriations U.S. Senate Washington, DC 20510

Dear Chair Cole, Chair Murray, Ranking Member DeLauro, and Vice Chair Collins,

On behalf of the 27 undersigned organizations representing scientific societies, nonprofits, veterinary groups, and academic institutions, we are writing to urge robust investments in biomedical animal research as House and Senate appropriators finalize the Fiscal Year (FY) 2025 appropriations bills. Congress has played a crucial role in advancing U.S. biomedical research, and we greatly appreciate its bipartisan support over the past several decades. Investments in legislation such as the 21<sup>st</sup> Century Cures Act, as well as support for research programs like the BRAIN Initiative and the Cancer Moonshot, have led to essential insights into fundamental biology and diseases. Research involving animals is a significant aspect of these efforts and will remain vital for scientists and veterinarians as they continue to build on existing findings and develop new and improved treatments that benefit both humans and animals.

However, the current research environment poses considerable challenges to sustaining the U.S.'s competitive edge in science and technology. Legislative mandates included in appropriations bills and reports have created unnecessary obstacles for scientific research. Challenges include resource shortages amid increasing demand, lack of staff and technical experts, and increased costs and administrative burden causing research delays. This situation not only threatens the strength of our biomedical workforce but also diminishes our nation's ability to respond effectively and rapidly to public health challenges.

Proposed language in the draft FY25 appropriations bills could worsen these challenges at a time when scientific leadership remains paramount. Topics that are particularly problematic include:

- Premature use of non-animal alternatives (e.g., New Approach Methods or NAMs);
- Funding restrictions for research with dogs, cats, and nonhuman primates; and
- Arbitrary deadlines to phase out animal studies.

The FY25 appropriations discussions represent an opportunity to shape the future of biomedical research and achieve a stronger, more sustainable research environment. We strongly encourage the House and Senate Appropriations Committees to work in a bipartisan manner to implement the following recommendations:

- 1. Affirm and invest in necessary animal research to maintain biomedical progress, including the development of NAMs;
- 2. Emphasize high-quality science rather than funding restrictions and arbitrary deadlines;

3. Provide dedicated funding to support and expand the scientific workforce and animal research infrastructure.

Additional details for each recommendation are included below, referencing proposed language in the House and Senate FY25 draft appropriations bills.

# Recommendation 1: Affirm and Invest in Necessary Animal Research to Advance Biomedical Progress, Including the Development of NAMs.

To advance biomedical progress, we urge the House and Senate Appropriations Committees to affirm and invest in essential animal research. We applaud the House<sup>1</sup> and Senate<sup>2</sup> Labor, Health and Human Services, Education, and Related Agencies (LHHS) Appropriations subcommittees for recognizing the critical need for nonhuman primates (NHPs) in understanding biological processes and improving the effectiveness of treatments for the millions of Americans who suffer from chronic and degenerative diseases. In addition to including this language in the final funding package, similar recognition and support for animal studies in other areas of biomedical research is needed to promote a strong and sustainable research environment.

Secondly, we request House and Senate appropriators refrain from including language found in the House LHHS and Agriculture, Food and Drug Administration, and Related Agencies reports that increase administrative burden through duplicative reporting requirements and hinder other Congressional biomedical investments. For example, the House LHHS report language regarding NIH dog and cat research<sup>3</sup> will weaken vital efforts to fulfill the Cancer Moonshot initiative. Dogs remain a crucial part of studying the genetic and molecular underpinnings of cancer. This knowledge enables researchers and clinicians to develop more targeted immunotherapies for both canine and human cancers while accelerating the development of personalized cancer treatments.

Finally, we urge Congressional support for necessary animal studies to facilitate the research community's collective efforts to reduce, refine, and replace animal use. This includes the development of NAMs. Currently, there are numerous scientific and regulatory barriers precluding the seamless integration of NAMs in all biomedical research disciplines. For example, NAM qualification and validation require robust animal studies to ensure safety and efficacy. Although multiple federal agencies have initiatives aimed at achieving this objective—including the NIH Complement-ARIE program<sup>4</sup>, the Food and Drug Administration (FDA) Science Board's New Alternative Methods Subcommittee<sup>5</sup>, and the Environmental Protection Agency's (EPA) NAMs Work Plan<sup>6</sup>--researchers face challenges in conducting animal studies for NAMs characterization due to insufficient funding and lack of resources. By affirming necessary animal research through supportive appropriations language, agencies can implement these initiatives more effectively.

Congress, pgs. 152-153. https://www.appropriations.senate.gov/imo/media/doc/fy25 lhhs senate report7.pdf

House Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Report, 2025, 118<sup>th</sup> Congress, pg. 120. https://docs.house.gov/meetings/AP/AP00/20240710/117503/HMKP-118-AP00-20240710-SD002.pdf
Senate Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Report, 2025, 118<sup>th</sup>

 <sup>&</sup>lt;sup>3</sup> House Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Report, 2025, 118<sup>th</sup> Congress, pgs. 115-116.. https://docs.house.gov/meetings/AP/AP00/20240710/117503/HMKP-118-AP00-20240710-SD002.pdf
<sup>4</sup> NIH Complement Animal Research in Experimental (Complement-ARIE) Program. Office of Strategic Coordination—The Common Fund. 2024. https://commonfund.nih.gov/complementarie

<sup>&</sup>lt;sup>5</sup> FDA Science Board, New Alternative Methods Subcommittee Report, "Potential Approaches to Drive Future Integration of New Alternative Methods for Regulatory Decision-Making." October 2024. https://www.fda.gov/media/182478/download?attachment <sup>6</sup> EPA New Approach Methods Work Plan: Reducing Use of Vertebrate Animals in Chemical Testing. 2024. https://www.epa.gov/chemical-research/epa-new-approach-methods-work-plan-reducing-use-vertebrate-animals-chemical

### Recommendation 2: Emphasize High-Quality Science Rather Than Funding Restrictions and Arbitrary Deadlines

In negotiating final funding provisions, we encourage prioritizing high-quality science that yields reliable results rather than imposing funding restrictions or subjective deadlines that prematurely phase out animal studies in favor of NAMs. While NAMs are progressing and hold promise, they are currently more effective in testing simple hypotheses or used in the early stages of drug screening. Diseases such as autoimmune disorders, mental health conditions, and neurodegenerative diseases require a whole-body organism that allows scientists to investigate complex biological phenomena such as hormonal regulation, multi-organ interactions, disease progression, and drug responses.

We recommend Congress refrain from including language in the House<sup>7</sup> and Senate<sup>8</sup> Military Construction and Veterans Affairs (MilCon-VA) bills and reports that direct the agency to eliminate research with dogs, cats, and nonhuman primates by 2026 (or another specified date). While well-intentioned, a rigid focus on nonscientific metrics and timelines could inadvertently delay progress in areas of critical need. Not only does the 2026 deadline jeopardize potential lifesaving treatments for veterans (including a current primate study using stem cells to treat spinal cord injury that is close to clinical trials<sup>9</sup>), but the vagueness of the language will also undermine the VA's broader research capabilities and collaborations. This is because the language fails to distinguish essential details such as invasive and non-invasive studies or purpose-bred animals versus client-owned animals. These specifications are essential for protecting the VA's partnerships with veterinary colleges, and the clinical research they conduct.

Furthermore, the MilCon-VA bill and report language departs from previous Congressional language directing the VA to "eliminate or reduce" research with sensitive species rather than strictly "eliminate" as currently proposed. While subtle, this change in the language disrupts established agency initiatives and undermines the optimal use of government resources, including animals. Instead, we urge Congress to provide the VA with the flexibility it needs to continue implementing its Five-Year Plan for Reducing Research with Sensitive Species<sup>10</sup>. To ensure the agency can address the evolving challenges affecting veterans' health in the future, we also recommend integrating a mechanism that affords the VA Secretary discretion to approve meritorious research proposals that may require necessary animal models to answer research questions.

Similarly, we request Congress to omit the House Interior, Environment, and Related Agencies report language regarding the EPA's decision to eliminate its 2025 and 2035 deadlines from its NAMs work plan. As stated above, arbitrary deadlines are risky and counterproductive, as they cannot guarantee faster scientific advancements nor ensure improved animal welfare. Furthermore, the directives outlined in the House report are duplicative of previous Congressional language and, thus, divert resources from the agency's ongoing work to reduce animal use in toxicity testing<sup>11</sup>. Recently, the EPA published several reports detailing its metrics for

<sup>&</sup>lt;sup>7</sup> House Military Construction, Veterans Affairs, and Related Agencies Appropriations Bill, 2025. 118<sup>th</sup> Congress, pgs. 70-73. https://www.govinfo.gov/content/pkg/BILLS-118hr8580rh/pdf/BILLS-118hr8580rh.pdf

<sup>&</sup>lt;sup>8</sup> Senate Military Construction, Veterans Affairs, and Related Agencies Appropriations Bill, 2025. 118<sup>th</sup> Congress, pgs. 68-72. https://www.appropriations.senate.gov/imo/media/doc/FY25%20MCVA%20Senate%20Bill.PDF

<sup>&</sup>lt;sup>9</sup> VA Research with Current Approval for Work with Non-Human Primates. Accessed 2024.

https://www.research.va.gov/programs/animal\_research/current\_research.cfm#nhp <sup>10</sup> VA Five Year Plan for Reducing Research with Sensitive Species, Accessed 2024.

https://www.research.va.gov/programs/animal research/VA-5-year-plan-for-Sensitive-Species-reduction-elimination.docx

<sup>&</sup>lt;sup>11</sup> House Interior, Environment, and Related Agencies Appropriations Report, 2025. 118<sup>th</sup> Congress, pg. 67. https://docs.house.gov/meetings/AP/AP00/20240709/117502/HMKP-118-AP00-20240709-SD003.pdf

animal use, efforts to establish scientific confidence in NAMs, and new grant programs to investigate non-animal models<sup>12</sup>. We recommend providing EPA the flexibility to continue implementing its NAMs work plan with minimal administrative burden.

## Recommendation 3: Provide Dedicated Funding to Support and Expand the Scientific Workforce and Infrastructure

To ensure the biomedical research community is equipped to advance science and medicine, targeted investments supporting the scientific workforce and infrastructure are essential. We applaud the Senate for including \$30 million to the National Primate Research Centers (NPRCs) in the LHHS proposal<sup>13</sup> and encourage its inclusion in the final bill. This funding would significantly improve infrastructure to boost primate capacity and enhance the NPRCs' ability to provide centralized expertise and resources for researchers conducting innovative studies. Given the ongoing instability of the NHP supply chain following the COVID-19 pandemic, and the persistent challenges investigators face in securing necessary resources, consistent and robust funding for these centers and similar research infrastructure projects is essential for ensuring we are prepared for the next public health crisis, which is inevitable.

Alongside infrastructure investments, we strongly recommend targeted funding for NIH to provide additional training opportunities that support the next generation of the scientific workforce, including experts at the forefront of animal research and NAM development. More broadly, commensurate support for the scientific workforce is central to our global competitiveness and will create a thriving environment that attracts the best and brightest scientific talent. However, NIH grant opportunities for scientists, veterinarians, animal behaviorists, and other experts in laboratory animal medicine remain limited. Targeted investments for NIH to establish new and/or expand existing mechanisms—such as the T, K-, and R25 grants—will enhance preclinical research and foster partnerships between animal researchers and NAM developers, the latter of which depends on animal expertise for qualification, validation, and safety testing.

#### Conclusion

We appreciate Congress' bipartisan support for biomedical research and believe sustained and strategic investments for animal research, as outlined in the three recommendations, are a crucial part of driving progress forward. By concentrating on arbitrary deadlines or metrics, we lose sight of our shared goals: effectively harnessing available resources to produce high-quality science, rapidly addressing public health challenges, and solidifying our role as leaders in science and medicine.

#### Sincerely,

American Association of Immunologists (AAI) American Association for Laboratory Animal Science (AALAS) American Association of Veterinary Medical Colleges (AAVMC) American Brain Coalition (ABC) American College of Neuropsychopharmacology (ACNP)

<sup>&</sup>lt;sup>12</sup> EPA New Approach Methods Work Plan: Reducing Use of Vertebrate Animals in Chemical Testing. Accessed 2024. https://www.epa.gov/chemical-research/epa-new-approach-methods-work-plan-reducing-use-vertebrate-animals-chemical#Evaluate%20regulatory%20flexibility%20for%20accommodating%20NAMs

<sup>&</sup>lt;sup>13</sup> Senate Labor, Health and Human Services, Educated and Related Agencies Appropriations Report, 2025. 118<sup>th</sup> Congress, pg. 151. https://www.appropriations.senate.gov/imo/media/doc/fy25 lhhs senate report7.pdf

Americans for Medical Progress (AMP)

American Physiological Society (APS)

American Psychological Association Services

American Society for Pharmacology and Experimental Therapeutics (ASPET)

American Thoracic Society (ATS)

Associated Medical Schools of New York

Association for Independent Research Institutes (AIRI)

Association of American Medical Colleges (AAMC)

Association of American Universities (AAU)

Association of Public and Land-Grant Universities (APLU)

Federation of American Societies for Experimental Biology (FASEB)

Massachusetts Society for Medical Research (MSMR)

National Association for Biomedical Research (NABR)

National Animal Interest Alliance (NAIA)

National Association of Veterans' Research and Education Foundations (NAVREF)

The National Primate Research Centers

New Jersey Association for Biomedical Research (NJABR)

North Carolina Association for Biomedical Research (NCABR)

Northwest Association for Biomedical Research (NWABR)

Pennsylvania Association for Biomedical Research (PSBR)

Society for Neuroscience (SfN)

Texas Society for Biomedical Research (TSBR)