

Testimony of Stephen Jameson, Ph.D., President of the American Association of Immunologists (AAI), submitted on behalf of AAI to the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, regarding the FY 2026 budget for the National Institutes of Health (NIH) and the Advanced Research Projects Agency for Health (ARPA-H)

April 7, 2025

The American Association of Immunologists (AAI), the nation's largest organization of immunologists and scientists in related disciplines, with a mission to improve global health and well-being by advancing immunology and elevating public understanding about the immune system, respectfully submits this testimony regarding fiscal year (FY) 2026 appropriations for the National Institutes of Health (NIH) and the Advanced Research Projects Agency for Health (ARPA-H). AAI recommends an appropriation of **at least \$51.3 billion for the NIH base budget for FY 2026.** Within that budget, AAI recommends an appropriation of **at least \$7.29 billion for the National Institute of Allergy and Infectious Diseases (NIAID)**. In addition, AAI recommends an appropriation of **at least \$1.7 billion for the Advanced Research Projects Agency for Health (ARPA-H)** but believes that this funding should supplement the NIH base budget.

Robust funding for NIH will allow the agency to continue making necessary investments in high priority chronic diseases that involve the immune system, including cancer, Alzheimer's disease, and more than 100 autoimmune diseases. It is also crucial to preparing for and combating known and future infectious disease threats, including the current measles outbreak and the concerning possibility of an H5N1 influenza pandemic.

NIH-funded basic research is vital to ensuring that the U.S. has a strong portfolio of foundational discoveries upon which to build. NIAID funds a large proportion of the immunology research in this country, a wide-ranging portfolio that includes infectious, chronic, and immune-mediated diseases, like type-1 diabetes, multiple sclerosis, asthma and allergies.

Increased funding for ARPA-H will help energize and accelerate its mission to achieve better health outcomes by supporting high-risk, high-impact research proposals that would not ordinarily be funded by NIH or the private sector.

Recent Immunology-related Breakthroughs Fueled by NIH Funding

Immune-Based Advances in Cancer Treatment



Immunotherapy is a treatment approach that harnesses a patient's immune system to combat cancer. It has successfully placed countless cancer patients in remission and holds tremendous promise for treating cancers of all kinds, including traditionally hard-to-treat solid tumors. Notably, two first-of-their-kind T cell-based cellular therapies were recently approved by the Food and Drug Administration (FDA) to treat solid tumors. The first, pioneered by scientists at the National Cancer Institute (NCI), is called tumor-infiltrating lymphocyte therapy and is approved to treat advanced-stage melanoma.¹ The second is called T-cell receptor therapy and is approved to treat synovial sarcomas.² These kinds of novel treatments, made possible through decades of NIH-funded research, also hold promise for combatting childhood cancers.^{3,4}

In addition, substantial advancements have been made in vaccination-based therapies for the prevention and treatment of cancer. A recent NIH-supported clinical trial found that a new vaccine-based approach activated the immune system and had beneficial outcomes for patients with the most aggressive form of breast cancer.⁵ Scientists are also leveraging artificial intelligence to design more effective cancer treatments and vaccines, improve cancer detection, predict which patients are more likely to respond to which drug, and advance fundamental knowledge of cancer biology. NIH funding is paramount to the discovery of new and innovative treatments for cancer.

Breakthroughs in the Treatment of Autoimmunity and Inflammatory Diseases

Chimeric Antigen Receptor T-cell (CAR-T) therapy is a personalized form of immunotherapy. Originally developed to treat cancer, this immunotherapy involves taking a patient's own immune cells out of their body, enhancing their ability to kill tumor cells, and reinfusing them back into the patient. Physicians are now conducting clinical trials to use CAR-T cells to eliminate cells that cause lupus, paving the way for potential widespread application of this approach to treat other autoimmune diseases and chronic inflammation. The management of autoimmune diseases, which affect up to 50 million people in the U.S., often relies on broad suppression of the immune system. Immunotherapy approaches like CAR-T therapy enable more specific targeting of the parts of the immune system that are working incorrectly, with the benefit of avoiding adverse effects of broad immunosuppression such as increased risk of infections.

⁵ Zhang, X., Goedegebuure, S.P., Chen, M.Y. *et al.* Neoantigen DNA vaccines are safe, feasible, and induce neoantigen-specific immune responses in triple-negative breast cancer patients. *Genome Med* **16**, 131 (2024). <u>https://doi.org/10.1186/s13073-024-01388-3</u>



¹ https://www.fda.gov/news-events/press-announcements/fda-approves-first-cellular-therapy-treat-patients-unresectable-ormetastatic-melanoma

² https://www.cancer.gov/news-events/cancer-currents-blog/2024/fda-tecelra-synovial-sarcoma-mage-a4

³ Gupta, S., Rau, R., Kairalla, J., *et al.* Blinatumomab in Standard-Risk B-Cell Acute Lymphoblastic Leukemia in Children. *NEJM* 392, 875-891 (2024). <u>https://doi.org/10.1056/NEJM0a2411680</u>

⁴ Monje, M., Mahdi, J., Majzner, R. *et al.* Intravenous and intracranial GD2-CAR T cells for H3K27M⁺ diffuse midline gliomas. *Nature* **637**, 708–715 (2025). <u>https://doi.org/10.1038/s41586-024-08171-9</u>



A significant breakthrough in the field of autoimmunity was the discovery of a possible explanation for why 80% of patients with autoimmune diseases are women. Females have two X chromosomes while males have one X and one Y chromosome. To prevent problematic duplication of gene expression, females produce a molecule called Xist that interacts with other molecules to turn off one X chromosome. An NIH-funded study discovered that patients with autoimmunity have antibodies that mistakenly target Xist (and other molecules it interacts with) while healthy patients do not. Since males do not produce Xist, this represents one potential reason why autoimmunity disproportionately affects women. Identifying this new mechanism unlocks new avenues of research into the diagnosis and treatment of autoimmune diseases.

The Economic Impact of NIH Research

NIH is the largest public funder of biomedical and behavioral research in the world and this investment fuels economic activity all across America. Every state and nearly every congressional district in the nation receives NIH funding, flowing to more than 300,000 researchers at approximately 2,500 institutions. In FY 2024, NIH funding supported 407,782 jobs and led to \$94.58 billion in economic activity.⁶

About half of the NIH budget supports fundamental research, which is essential to accumulating knowledge and answering foundational questions about how life works and why disease occurs. Pharmaceutical companies and other private sector research entities are far less likely to fund this type of research because it does not immediately result in products that can be commercialized (like drugs and devices). Basic research is a prerequisite to developing these products, as demonstrated by a 2023 study published in *JAMA Health Forum* which found that NIH funding contributed to 354 of the 356 (99.4%) drugs approved by the FDA from 2010 to 2019.⁷

The Role of NIAID in Addressing Threats to Public Health

NIAID supports a vast array of immunologic, infectious, and allergic disease research that underpins the very health of our nation. NIAID-funded discoveries were crucial to the development of the COVID-19 vaccines that were produced through the Trump Administration's Operation Warp Speed, the recently FDA-approved protein vaccines against respiratory syncytial virus (RSV), and the LEAP-Trio study, which found that peanut consumption in infancy significantly reduces the risk of acquiring a peanut allergy. These

⁷ Galkina Cleary, E., Jackson, M., Zhou, E., *et al.* (2023) Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019. *JAMA Health Forum*. <u>https://doi.org/10.1001/jamahealthforum.2023.0511</u>



⁶ https://www.unitedformedicalresearch.org/annual-economic-report/



preventative measures are already reaping extremely positive results and open the door to preventative options against many other diseases.

NIAID research is also imperative to being prepared for, and responding to, emerging and re-emerging diseases. The Institute is engaged in research against current threats like H5N1 influenza ("bird flu") and in recent years has been the primary NIH Institute responsible for responding to outbreaks of diseases like Dengue fever, Ebola, Mpox, and Zika, diseases that started outside of the U.S. but that know no borders. As Representative Tom Cole (R-OK, 4th), then-Chair of the House Labor-HHS Appropriations Subcommittee said in 2017, "[D]o you want to deal with Ebola in West Africa or do you want to deal with it in West Dallas? . . . The federal government defending you from Ebola is probably as important as defending you from a terrorist attack because a pandemic will kill more people..."

The Immense Promise of ARPA-H

ARPA-H was created in 2022 to address some of society's greatest health-related challenges by supporting high-risk, high-reward projects. Each project must seek to answer a big question. Currently funded ARPA-H projects seek to answer questions like, "what if your immune system could manufacture cures to devastating diseases?" and "what if we could bioprint any organ on demand?" ARPA-H investigators must develop and adhere to a rigid set of milestones and award payments are contingent on meeting those milestones.

The ARPA-H budget has been frozen at \$1.5 billion since FY 2023. Increased funding for ARPA-H is necessary to continue to invest in new, bold, and innovative solutions that have the potential to make an immediate, transformative impact on the nation's health. It is crucial, however, that this funding supplement the NIH base budget.

Conclusion

AAI is deeply thankful for this subcommittee's past support for NIH and urges it to provide NIH with a base budget of at least \$51.3 billion for FY 2026, including \$7.29 billion for NIAID. This increase will enable NIH to invest in a strong portfolio of biomedical research focused on preventing, treating, and curing disease, to address the great health challenges of today and those on the horizon. AAI also recommends providing at least \$1.7 billion for ARPA-H to further invest in innovative health solutions.