

**Testimony of Peter E. Jensen, M.D., Chair of the Committee on Public Affairs of  
The American Association of Immunologists (AAI),  
Submitted on behalf of AAI to the Senate Appropriations Subcommittee on  
Labor, Health and Human Services, Education, and Related Agencies,  
Regarding the Fiscal Year 2024 Budget for the National Institutes of Health  
May 17, 2023**

The American Association of Immunologists (AAI), the nation's largest professional association of research scientists and physicians who are dedicated to understanding the immune system through basic, translational, and clinical research, respectfully submits this testimony regarding fiscal year (FY) 2024 appropriations for the National Institutes of Health (NIH). AAI recommends an appropriation of at least \$51 billion for NIH's base budget for FY 2024. AAI also recommends providing substantial funding for the Advanced Research Projects Agency for Health (ARPA-H) that supplements, but does not supplant, the amount provided for NIH's base budget.

Robust investment in NIH's base budget will support research needed to prevent and treat disease, fund meritorious research projects and talented scientists at all career stages, and ensure the growth and continued productivity of our nation's preeminent biomedical research enterprise. Substantial investment in ARPA-H will help this new agency conduct some of the most cutting edge research intended to solve wide-ranging biomedical and health challenges.

### **The Role of Immunology in Advancing Vaccine Research and Development**

Three years ago, there was little public understanding of immunology. Today, as a result of the COVID-19 pandemic, immunological advances are dinner-table conversation for families across the U.S. and around the world. The rapid, record-breaking development, deployment, and use of safe and effective vaccines to protect against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, saved more than 3.2 million lives in the U.S. alone from December 2020 through November 2022.<sup>1</sup> While these vaccines continue to provide strong protection against severe disease, hospitalization, and death, the latest variants (Omicron and its subvariants), which spread much more easily, are a reminder that we must be prepared for the future of COVID-19, including whether a novel variant is able to evade vaccine-induced immunity.

Fortunately, immunological research has already led to the development of the more effective bivalent mRNA vaccine that targets both the original strain and the Omicron variants. Now, there is urgent need for transmission blocking vaccines to prevent infection, especially for vulnerable populations like the elderly and immunocompromised. Currently, there are many such vaccine candidates, administered intranasally, that are being tested in clinical trials.<sup>2</sup> In addition, future vaccines should provide long-lasting protection and help prevent the development of Long COVID.

Respiratory syncytial virus (RSV) is another respiratory illness that poses great risk, especially for older adults and infants. In 2023, the Food and Drug Administration (FDA) approved an RSV vaccine for use in adults 60 years and older, representing a major milestone in the prevention of this disease.<sup>3</sup> A phase III trial of another RSV vaccine candidate showed over 80% efficacy against severe illness in infants, through vaccination during pregnancy.<sup>4</sup> The development of these vaccines is built upon decades of basic scientific discoveries and clinical trials funded by NIH.

Several other important vaccine advances have also been supported by NIH-funded research. Influenza (flu) causes significant morbidity and mortality, especially in the elderly. Recently, scientists at the National Institute of Allergy and Infectious Diseases developed a universal flu vaccine candidate which would provide protection against all known strains of the flu, and are currently testing it in adults, both intramuscularly and intranasally, in a phase I clinical trial.<sup>5</sup> Initial studies from NIH show promising results for a vaccine against the Sudan virus, which caused the recent Ebola outbreak in Uganda and resulted in 142 confirmed cases and 55 deaths.<sup>6</sup> In addition, NIH-funded research launched a new era of HIV vaccine development, including a phase I trial evaluating three experimental mRNA vaccines against HIV.<sup>7</sup>

### **Advances in Immunotherapy for Treatment of Cancer and Autoimmunity**

Scientists continue to make significant advances in the development of immunotherapies (treatments that utilize a patient's own immune cells to fight disease) for a variety of illnesses, including cancer and autoimmunity. Chimeric antigen receptor (CAR) based therapies have typically involved T cells (CAR-T cell therapy); however, other immune cell types that contribute to effective disease control, like natural killer (NK) cells and macrophages, are now being tested clinically.<sup>8</sup> Currently, all CAR-T cell therapies approved for use target blood cancers, but scientists are also working on ways to create effective CAR therapies for solid tumors.

NIH research has also advanced our understanding of Type 1 diabetes (T1D), an autoimmune disease that occurs when the immune system impairs the ability of the pancreas to produce insulin, often leading to serious long-term complications for even those treated with insulin therapy. NIH funding has supported research into novel ways of preventing the immune system from attacking insulin-producing cells; for example, a small phase I study showed the safety of adoptive cell transfer of regulatory T cells, which can restore normal immune function and protect remaining insulin producing cell.<sup>9</sup>

### **Breakthroughs in Antibody Therapeutics**

Innovative monoclonal antibody (mAb) therapeutics have revolutionized the treatment of, and outcomes for, diseases including cancer, T1D, and some infectious diseases, such as COVID-19. In a recent small clinical trial testing the efficacy of the mAb dostarlimab in patients with a certain type of colorectal cancer, all 12 patients who completed the therapy experienced complete remission.<sup>10</sup> The FDA recently approved the mAb teplizumab to delay progression of T1D in children over 8 and in adults.<sup>11</sup> Additionally, an NIH-funded clinical trial found that another mAb was up to 88.2% effective at preventing malaria infection in adults who live in an endemic area.<sup>12</sup>

### **The Importance of NIH as the Engine for National and Local Biomedical Research**

As the nation's major funding agency for biomedical research, NIH supports research institutions and scientists throughout the nation. With more than 84% of its \$47.5 billion budget distributed through nearly 50,000 competitive grants "to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state," NIH funding is the economic engine for many American communities, supporting not only scientific discovery but the jobs that accompany a dynamic commercial environment;<sup>13</sup> in FY 2022, NIH funding supported more than 568,500 jobs and accounted for \$96.84 billion in economic activity across the U.S.<sup>14</sup> Another ~10% of the NIH budget supports ~6,000 researchers and clinicians who work at NIH facilities in Maryland and around the

country.<sup>15</sup> NIH-funded basic research is vital to the development of new drugs to fight disease; it contributed to the discovery of 354 of 356 new drugs that were approved by the FDA from 2010-2019.<sup>16</sup>

As the indisputable leader of biomedical research in the world, NIH leaders and scientists play an indispensable role in responding to both ongoing and emerging health threats. They and their federal agency colleagues have been essential to guiding the nation through the COVID-19 pandemic by advancing our understanding of basic science; rapidly establishing effective programs to advance patient care and therapeutic development including Researched COVID to Enhance Recovery (RECOVER, which targets Long COVID), Rapid Acceleration of Diagnostics (RADx, which speeds innovation of COVID-19 tests), and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV);<sup>17</sup> and providing timely and candid advice to the President, Congress, and the American public.

For many years, strong bipartisan support for biomedical research has led to substantial increases in the NIH budget. While these increases are enormously important and appreciated, they have effectively restored the purchasing power of the NIH budget only to its FY 2003 level. This lackluster growth has prevented NIH from taking full advantage of the unprecedented scientific opportunity of the moment and investing as fully as it should in its most valuable resource: the research workforce. Robustly supporting meritorious scientists at all career stages will foster the success of today's biomedical research enterprise and help prepare us for tomorrow's scientific and workforce challenges. Congress must also provide NIH with the resources needed to boldly invest in the next generation of researchers, including trainees, to ensure that a career in biomedical research in the U.S. remains an attractive option to the best and brightest young minds from all around the world.

## Conclusion

AAI greatly appreciates the subcommittee's history of strong bipartisan support for NIH and urges a base budget of at least \$51 billion for FY 2024. Such a robust increase will help NIH invest in vital immunological research to facilitate the discovery of new ways to prevent, treat, and cure disease. It will also help support the growth and development of our outstanding biomedical research workforce and enhance our ability to provide funding for meritorious biomedical scientists at all career stages. In addition, AAI recommends the appropriation of substantial funding for ARPA-H, which has the potential to facilitate transformative medical and scientific breakthroughs, including in human immunology, that could address some of today's thorniest health and biomedical challenges.

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<sup>1</sup> <https://www.commonwealthfund.org/blog/2022/two-years-covid-vaccines-prevented-millions-deaths-hospitalizations>

<sup>2</sup> <https://www.science.org/doi/10.1126/sciimmunol.add9947>

<sup>3</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-first-respiratory-syncytial-virus-rsv-vaccine>

<sup>4</sup> <https://www.science.org/content/article/extremely-satisfying-scientists-insight-powers-new-rsv-vaccine-infants#note>

<sup>5</sup> <https://www.niaid.nih.gov/news-events/trial-potential-universal-flu-vaccine-opens-nih-clinical-center>

<sup>6</sup> <https://www.nih.gov/news-events/news-releases/experimental-nih-sudan-virus-vaccine-protects-macaques>

<sup>7</sup> <https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trial-three-mrna-hiv-vaccines>

<sup>8</sup> <https://www.cancer.gov/about-cancer/treatment/research/car-t-cells>

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<sup>9</sup> <https://www.science.org/doi/10.1126/scitranslmed.aad4134>

<sup>10</sup> Cercek A, et al. [PD-1 Blockade in Mismatch Repair-Deficient, Locally Advanced Rectal Cancer](#). *N Engl J Med*. 2022 Jun 23;386(25):2363-2376. doi: 10.1056/NEJMoa2201445. Epub 2022 Jun 5. PMID: 35660797; PMCID: PMC9492301.

<sup>11</sup> <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-can-delay-onset-type-1-diabetes>

<sup>12</sup> <https://www.niaid.nih.gov/news-events/monoclonal-antibody-prevents-malaria-infection-african-adults>

<sup>13</sup> <https://www.nih.gov/about-nih/what-we-do/budget>

<sup>14</sup> [https://unitedformedicalresearch.org/wp-content/uploads/2023/03/UMR\\_NIHs-Role-in-Sustaining-the-U.S.-Economy-2023-Update.pdf](https://unitedformedicalresearch.org/wp-content/uploads/2023/03/UMR_NIHs-Role-in-Sustaining-the-U.S.-Economy-2023-Update.pdf)

<sup>15</sup> See endnote 13

<sup>16</sup> <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378>

<sup>17</sup> <https://recovercovid.org/>; <https://www.nih.gov/research-training/medical-research-initiatives/radx>; <https://www.nih.gov/research-training/medical-research-initiatives/activ>