

December 23, 2025

Office of Science and Technology Policy
1650 Pennsylvania Avenue NW
Washington, DC 20502

Re: Notice of Request for Information; Accelerating the American Scientific Enterprise (90 FR 54412; Docket OSTP-TECH-2025-0100)

The Jacobs Institute of Women’s Health and the Union of Concerned Scientists, which are committed to advancing scientific integrity, appreciate the opportunity to comment in response to the Request for Information (RFI) on “Accelerating the American Scientific Enterprise” (90 FR 54412; Docket OSTP-TECH-2025-0100). We comment in response to two of the questions OSTP poses in the RFI.

I. To Support Innovation in Biomedical Research, Restore NIH Grant Funding and Procedures

The fifth question listed in the RFI reads: “What empirically grounded findings from metascience research and progress studies could inform Federal grantmaking processes to maximize scientific productivity and increase total return on investment? Please provide specific examples of evidence-based reforms that could improve funding allocation, peer review, or grant evaluation.”

We urge the administration to restore National Institutes of Health (NIH) grant funding and grantmaking procedures to what they were in 2024 in order to maintain the kind of high-quality research that has driven so much innovation in our country in recent decades. NIH-funded research has supported development of drugs,¹ vaccines,² prevention programs,³ and other innovations that have improved public health and contributed to economic growth. One empirical study found that NIH funding contributed to *every one* of the 210 new drugs approved by the Food and Drug Administration (FDA) in 2010-2016.¹ The authors reported that more than 90% of the \$100 billion in relevant NIH funding was basic research related to the biological targets for drug actions — that is, it supported industry research and development. Similarly,

¹ Galkina Cleary E, Beierlein JM, Khanuja NS, McNamee LM, Ledley FD. (2018). Contribution of NIH funding to new drug approvals 2010-2016. *Proceedings of the National Academy of Sciences of the United States of America*, 115(10): 2329-2334. <https://doi.org/10.1073/pnas.1715368115>

² National Institutes of Health. (no date). Immune System. Retrieved Dec. 21, 2025 from <https://www.nih.gov/about-nih/impact-nih-research/improving-health/immune-system> and archived at <https://archive.is/nvbq1>

³ National Institutes of Health. (no date). Education and Prevention. Retrieved Dec. 21, 2025 from <https://www.nih.gov/about-nih/impact-nih-research/improving-health/education-prevention>

another analysis found NIH funding spurs private-sector patents, and a \$10 million boost in funding results in an additional 2.7 patents.⁴

Similar future economic growth is in peril, however, as in recent months NIH has cut hundreds of grants, slashed the staff infrastructure that supported such successful grantmaking, and altered grant review procedures. One peer-reviewed empirical analysis found that between February 8, 2025, and April 8, 2025, 694 NIH grants totaling \$1.8 billion were terminated.⁵ Another focused on 383 NIH-funded clinical trials with funding terminated between February 28, 2025, and August 15, 2025, and found that they disproportionately studied infectious diseases, prevention, and behavioral interventions.⁶

The case of hepatitis C virus (HCV) is instructive for considering both the crucial role of NIH funding for basic research and the need for infectious disease and intervention research to realize the gains from drug development. A peer-reviewed empirical study found that NIH funding had a key role in the development of HCV cure sofosbuvir (Sovaldi); specifically, the authors identified \$7.7 million in direct NIH funding and another \$53.2 million in related NIH awards that contributed to the drug's development.⁷ Sovaldi gained FDA approval in 2013 and was the first of several direct-acting antivirals (DAAs) that can cure HCV in 95% of infected patients who use it. However, given that many of those infected with HCV do not know that they are infected, and that many face barriers to care, getting the drug to market is only a first step in realizing the drug's potential benefit.

The US Department of Veterans Affairs (VA) is the nation's largest care provider for HCV-infected patients. Between January 2014 and June 2017, they started 92,000 veterans on DAA treatment thanks to a redesigned process for HCV testing, treatment, and management.⁸ Among the 51,000 veterans remaining potentially eligible for treatment in 2017, authors of a peer-reviewed article explained that "many of those in care who remain to be treated have complex substance use, mental health, and medical comorbidities, and many are challenged by homelessness, lack of transportation, and rurality."⁸ Bringing cures such as DAAs to populations that face barriers to care requires research into what these populations need and how to reach them most effectively. NIH has recognized the need for such research and funded investigators to perform it; for instance, NIH's National Institute on Alcohol Abuse and Alcoholism (NIAAA) funded Yale researchers who found that VA patients with alcohol use disorder were less likely to receive

⁴ Azoulay P, Graff Zivin JS, Li D, Sampat BN. (2019). Public R&D Investments and Private-sector Patenting: Evidence from NIH Funding Rules. *The Review of Economic Studies*, 86(1): 117-152. <https://doi.org/10.1093/restud/rdy034>

⁵ Liu M, Kadakia KT, Patel VR, Krumholz HM. (2025). *JAMA*, 334(6): 534-536. <https://doi.org/10.1001/jama.2025.7707>

⁶ Patel VR, Liu M, Jena AB. (2025). Clinical Trials Affected by Research Grant Terminations at the National Institutes of Health. *JAMA Internal Medicine*, published online November 17, 2025. <https://doi.org/10.1001/jamainternmed.2025.6088>

⁷ Barenie RE, Avorn J, Tessema FA, Kesselheim AS. (2021). Public funding for transformative drugs: the case of sofosbuvir. *Drug Discovery Today*, 26(1):273-281. <https://pmc.ncbi.nlm.nih.gov/articles/PMC7528745/>

⁸ Belperio PS, Chartier M, Ross DB, Alaigh P, Shulkin D. (2017). Curing Hepatitis C Virus Infection: Best Practices From the U.S. Department of Veterans Affairs. *Annals of Internal Medicine*, 167(7): 499-504. <https://doi.org/10.7326/M17-1073>

DAAAs compared with those with lower-risk drinking and made relevant recommendations for improving care.⁹

NIH funding for the basic research that underpins drug development and for studies into other aspects of healthcare have contributed to many years of healthy life gained for our population, and tampering with current funding levels and procedures imperils those gains — as well as the economic and non-economic contributions that people are better able to make when they are healthier. The reduction in NIH-supported knowledge might seem modest at first, but the toll would mount. For instance, a Congressional Budget Office analysis found that a 10% reduction in federal funding for NIH would decrease the number of new drugs coming to market by about two drugs per year.¹⁰ Over a decade, with 20 fewer drugs than we would see under 2024 funding levels and procedures, there is a greater likelihood that one of those drugs would be something like Sovaldi — a transformative advance that can save lives and increase years of healthy life for a large portion of the population.

It is certainly possible to improve NIH’s grantmaking procedures, but such changes should involve a process of in-depth public consultation and study, and any proposals should be analyzed carefully to determine their likely impacts. Slashing grants, upending the established review process, and abruptly altering negotiated facilities and administration costs for grantees is disruptive and endangers the innovation that NIH has supported. We urge the administration to restore grants and procedures to the 2024 status quo and undertake a more deliberative process before making further alterations.

II. To Improve Trust in Federal Science, Rescind the “Gold Standard Science” Executive Order and Guidance

The ninth question listed in the RFI reads: “What specific Federal statutes, regulations, or policies create unnecessary barriers to scientific research or the deployment of research outcomes? Please describe the barrier, its impact on scientific progress, and potential remedies that would preserve legitimate policy objectives while enabling innovation.”

A federal policy that creates unnecessary barriers to scientific research and the use of research is Executive Order 14303, “Restoring Gold Standard Science,”¹¹ and the accompanying

⁹ Haque LY, Fiellin DA, Tate JP, Esserman D, Bhattacharya D, Butt AA, Crystal S, Edelman EJ, Gordon AJ, Lim JK, Tetrault JM, Williams EC, Bryant K, Cartwright EJ, Rentsch CT, Justice AC, Lo Re V 3rd, McGinnis KA. (2022). Association Between Alcohol Use Disorder and Receipt of Direct-Acting Antiviral Hepatitis C Virus Treatment. *JAMA Network Open*, 5(12):e2246604. <https://pmc.ncbi.nlm.nih.gov/articles/PMC9856353/>

¹⁰ Swagel PL. (2025). Re: How Changes to Funding for the NIH and Changes in the FDA’s Review Times Would Affect the Development of New Drugs. [July 18, 2025, letter to Honorable Jeffrey A. Merkley, Honorable Bernard Sanders, Honorable Frank Pallone, Jr., and Honorable Brendan F. Boyle.] https://www.budget.senate.gov/imo/media/doc/cbo_fda_nih_letter_071825.pdf

¹¹ Executive Office of the President. (2025). Restoring Gold Standard Science. Executive Order 14303 of May 23, 2025. *Federal Register*, 90 FR 22601. <https://www.federalregister.gov/documents/2025/05/29/2025-09802/restoring-gold-standard-science>

guidance.¹² Although the order lists several tenets of “gold standard science” that align with accepted best practices, it also creates barriers to high-quality research that can stifle innovation. By instructing agencies to rescind the scientific integrity policies adopted between January 20, 2021, and January 20, 2025 (i.e., during the Biden administration), and to revert to earlier policies (until new ones are developed), the order turns back the clock on progress. The Biden-era scientific integrity policies included several key elements that are not present in EO 14303 or its accompanying guidance, including the following:

- An emphasis on independent science conducted free from political interference;
- A process for developing procedures to investigate alleged violations of scientific integrity; and
- A prohibition on retaliating against scientists who raise concerns about violations of scientific integrity.

The policies that the EO instructs agencies to rescind expressed a commitment to protecting science from political interference and creating procedures to do so. For instance, the *Framework for Federal Scientific Integrity Policies and Practice* — which was developed by a cross-agency working group following a public input process — specifies that agencies’ scientific integrity policies and/or procedures should describe both “protections and a confidential reporting process” and “consequences and enforcement responsibilities” while communicating “confidentiality limits and whistleblower protections” and encouraging reporting of retaliation.¹³ The *Framework’s* model policy, which many agencies adopted with their own agency-specific variations, specifies that each agency should have a scientific integrity official who is a senior career employee. It tasks this employee with drafting procedures to respond to alleged policy violations and states that these procedures should include several steps: “an initial assessment and review, a fact-finding process, an agency adjudication or determination including description of remedies and preventative measures to safeguard the science, an appeals process, follow-up to track implementation of remedies, and reporting.”¹³

By contrast, EO 14303 and its associated guidance make no mention of independence, and the EO specifies that the processes for evaluating alleged violations “shall be the responsibility, and administered under the direction, of a senior appointee designated by the agency head.” It makes no mention of an appeals process or protection from retaliation, and the fact that it gives senior appointees power to evaluate what constitutes a violation of scientific integrity leaves open the possibility that appointees without relevant scientific knowledge or training could retaliate against scientists who are performing their work in accordance with the best practices and standards of their field — the very kind of political interference that Biden-era policies

¹² Kratsios MJ. (2025). Agency Guidance for Implementing Gold Standard Science in the Conduct & Management of Scientific Activities. Office of Science and Technology Policy, Memorandum for the Heads of Executive Departments and Agencies, June 23, 2025. <https://www.whitehouse.gov/wp-content/uploads/2025/03/OSTP-Guidance-for-GSS-June-2025.pdf>

¹³ Scientific Integrity Framework Interagency Working Group of the National Science and Technology Council. (2023). *A Framework for Federal Scientific Integrity Policy and Practice*. <https://bidenwhitehouse.archives.gov/wp-content/uploads/2023/01/01-2023-Framework-for-Federal-Scientific-Integrity-Policy-and-Practice.pdf>

aimed to prevent. Even if appointees do not abuse this discretion, employees might worry that they will do so and fear recommending evidence-based innovations that they perceive as not aligned with appointees' preferences.

Drug development again provides an instructive example. FDA scientists are responsible for examining the research that manufacturers submit as part of their applications for new drug approvals. Their work, along with the input of advisory committees, informs FDA Commissioners' drug approval decisions. A rigorous process for evaluating new drug applications — and, importantly, for monitoring and responding appropriately to data collected once drugs are on the market — helps make sure that the drugs available to US consumers are safe and effective. If the public loses trust in FDA's process because they fear an appointee is pressuring career staff to distort their findings about a drug's safety or efficacy, clinicians will hesitate to prescribe new drugs and consumers will be less willing to take them. Having a process like the one outlined in the Biden-era framework document can demonstrate to the public that scientists have avenues of recourse if they experience inappropriate pressure and thereby increase public confidence in FDA's determinations. Confidence in FDA decision-making allows consumers to take advantage of new pharmaceutical advances and enjoy the improved health and economic activity that comes with widespread use of important drugs like DAAs.

Given that the actions required under EO 14303 and the accompanying guidance present barriers to preventing political interference in science and risk damaging the confidence in government science that the public needs in order to embrace innovations, we urge the administration to rescind EO 14303 and the related guidance and restore the Biden-era scientific integrity policies. Further modifications should be undertaken only after the kind of in-depth process that the Biden administration followed, involving input from career scientific staff and the public.

Thank you for this opportunity to provide input on ways to accelerate our nation's scientific enterprise. By restoring NIH grantmaking to the 2024 status quo and rescinding EO 14303, the administration can advance our shared goal of allowing all Americans to benefit from scientific progress and technological innovation.

Sincerely,

Jacobs Institute of Women's Health
Union of Concerned Scientists