BROOKINGS

COMMENTARY

The Trump administration's NIH and FDA cuts will negatively impact patients

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- → Over the past four months, the Trump administration has made unprecedented reductions in staffing and funding in U.S. science-related agencies, including the National Institutes of Health (NIH) and the Food and Drug Administration (FDA).
- → Eliminating key NIH programs based on concerns about DEI will reduce our ability to generate effective solutions to health challenges through research.
- → FDA inspection cuts will affect the agency's ability to regulate the quality of generic drugs, which constitute 90% of the drugs dispensed in the United States.
- → Reduced facility inspections and product testing will increase the likelihood of unsafe products reaching American consumers, which will both harm people directly and undermine the public's confidence in FDA-approved products.

Over the past four months, and in the budget proposal for the coming fiscal year, the Trump administration has made unprecedented reductions in staffing and funding in U.S. science-related agencies, including the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). By early April, the NIH had experienced $2.4 billion ↗ in canceled and frozen grants and contracts, had fired 1,200 employees, and induced retirement and resignations from a yet unspecified number ↗. The administration's 2026 budget ↗ proposes a 37% further cut to the agency. Meanwhile, over 3,500 jobs at the FDA have been eliminated, and the administration has hinted at further restructuring of the agency.

Together, the NIH, with its unparalleled capacity to conduct and fund health research, and the FDA, with its state-of-the-art regulatory structure, form the underpinning of the many technological and oversight advances that have generated significant improvements in the health of Americans in the post-World War II era. Changes in funding and staffing at these agencies portend serious risks to further progress. The administration argues that such concerns are misplaced because cuts aimed to eliminate initiatives focused on diversity—the new NIH Director, Dr. Jay Bhattacharya, has referred to these as "political ideology ↗"—and on reducing excessive staff capacity at the FDA in order to eliminate waste and improve efficiency. But they are wrong, as the particular changes they have advanced will harm the rate and quality of innovations in addressing Americans' health needs.

NIH, DEI, and health science

Over the past two decades, the NIH has, as the Trump administration decries, prioritized expanding the scope of populations considered in the research it funds. It did so for very good, evidence-based reasons. Historically, research aimed at discovering and assessing conditions and treatments, whether conducted by the NIH or the pharmaceutical industry, has focused on homogeneous populations ↗. Clinical trials, for example, typically minimized diversity in age, gender, race, and ethnicity and ruled out people with comorbid conditions (for example, those with diabetes and heart disease in cancer trials). The rationale for this narrow focus was that heterogeneity within study populations reduced the statistical power of a given sample, making trials more expensive.

By the 1990s, however, scientists had come to realize that restricting sample populations was penny-wise and pound-foolish. When discoveries and treatments studied in narrowly-defined samples were put into practice in the "real world," the outcomes were frequently discordant—and generally much inferior—to what was found in the trials ↗. That difference came to be referred to as the efficacy-effectiveness gap ↗. The gap between efficacy results from trials and effectiveness in practice arises because sick people come with comorbid conditions, are from different racial, ethnic, age groups, and socio-economic groups, live in places with health systems that differ, and are treated by practitioners with varied training and backgrounds. Those sources of variation can produce substantial differences in responses to treatments.

Recognition of the efficacy-effectiveness gap led to increased emphasis on considering the needs of diverse populations throughout the scientific research infrastructure. That effort required more than changing enrollment criteria for clinical trials. The long history ↗ of discrimination and maltreatment of disadvantaged populations in the medical research system meant that simply allowing more populations to enroll in trials would not be enough to have study populations reflect those populations being treated. Increasing participation in the scientific enterprise would require building trust and persuading people that science could work for them.

The efficacy-effectiveness gap exists at the micro level—in the disjunction between the effects of treatments in trials and at the population level. But it also exists at a macro level—in a disjunction between the disease burden (costs) and research opportunities (benefits) associated with different conditions and the amount of attention paid to them. The logic of conducting trials on homogeneous populations also encouraged prioritization of the conditions that imposed burdens on these large populations. The macro problem could not be solved by changing trial participation—indeed, it might be exacerbated by this requirement, which could further induce scientists to prioritize conditions affecting homogeneous populations.

In this context, DEI is not some free-floating ideology that considers a range of backgrounds, treatment differentials, and geographical gaps as ends in themselves. In practice, the NIH infrastructure shifted toward a prioritization of conditions and approaches that evidence indicated were more likely to close the gap between technological development and effectiveness in practice. The list of terminated projects ↗ includes clinical and basic research such as the $3.8 million Asian Bipolar Genetics Network at the Broad Institute, the Skeletal Health and Bone Marrow Composition Among Youth study ($210,000) at Boston Children's Hospital, the Antiviral Countermeasures Development Center ($17.7 million) at Emory University, the National Latino Network for Precision Medicine and Health Disparities research ($812,000) at the University of Puerto Rico, and the Alzheimer's and Related Dementia Risk Resilience and Resilience Among Black Americans: A 20-year Longitudinal Study ($1.05 million) at the University of Michigan. What these studies have in common is that they all focus on conditions and populations that have historically experienced short shrift in NIH funding. Eliminating programs like this will reduce the value of our research investments in generating solutions to our health challenges that are effective in practice, and not just in the lab. While there is room to improve the NIH—for example, by modernizing the peer review system—a blanket disavowal of

programs focused on disadvantaged groups in the name of eliminating ideology will only harm American patients and the administration's stated goals of "Making America Healthy Again."

FDA staffing cuts: Impacts on safety and efficacy

At the FDA, the Trump administration has made staff cuts ↗ across the entire agency, including the support staff for the facility inspection programs and the lab staff that tests samples from batches of Active Pharmaceutical Ingredients (APIs), the components that generate drugs' impacts on disease. The cuts come against a background of long-term inadequate staffing at that agency. The Government Accountability Office (GAO) recently reported that the FDA's volume of inspections was not sufficient even before the new Trump administration and had not been since 2018 ↗. The inspection cuts will particularly affect the agency's ability to regulate the quality of generic drugs, which constitute 90% of the drugs ↗ dispensed in the United States. With staffing and funding limited, fewer inspections will happen in places like China and India, where production of APIs for generic drugs is concentrated ↗ and thereby risks harming American patients.

The job cuts have also affected reviewers of new drug applications for near-generic biological products, such as biosimilars. The FDA has a widely admired record of testing the safety of the drug supply ↗. Its long and successful regulatory history has been a key factor in the growth of the generic industry. Americans have come to believe, with good reason, that an FDA-approved drug has met safety and efficacy standards and that an approved generic drug will work as effectively and safely as its counterpart, a branded drug.

Underfunding and understaffing can have two very negative effects in this context. First, drug manufacturing is a complex process, and safety and quality lapses do happen. Reduced facility inspections and product testing will increase the likelihood of unsafe products reaching American consumers, which will both harm people directly and ultimately undermine the public's confidence in FDA-approved products. Evidence from other countries with less well-respected regulatory agencies suggests that reduced confidence will have a particularly negative effect on the acceptability of generic drugs. Second, slower approval of new drugs will impede the development of

competitive, lower-priced products—me-too drugs and biosimilars—that, along with generic drugs, will work against efforts to reduce drug costs. While President Trump's recent executive order ↗, "Lowering Drug Prices by Once Again Putting Americans First," aims to lower prices, these actions at the FDA are more likely to increase them.

Conclusions

America's infrastructure for the development and testing of new technologies has long been the envy of the entire world. Scientific advances produced through this infrastructure have been the source of extraordinary improvements in life expectancy and health for over 75 years. Ideologically driven cuts at the NIH and a misaligned view of efficiency at the FDA threaten that infrastructure and further progress. They contradict President Trump and Secretary Kennedy's own stated aspirations and are a dangerous mistake. Administration officials should reconsider its proposed budget cuts for the next fiscal year.

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