## Congress of the United States

## Washington, DC 20510

November 19, 2025

The Honorable Mr. Robert F. Kennedy, Jr. Secretary U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dr. Jay Bhattacharya, M.D., Ph.D. Director National Institutes of Health 9000 Rockville Pike Bethesda, MD 20892

Dear Secretary Kennedy and Dr. Bhattacharya,

We write to express deep concern regarding the impact of the funding lapse, commonly referred to as a government shutdown, on the development of and access to lifesaving, groundbreaking bio-innovation. We request that the Department of Health and Human Services ("the Department") take steps to ensure that clinical trials access is not interrupted in any future government shutdown. We further request answers regarding what delays in grant review and clinical trial enrollment resulted from the government shutdown and what steps the Department is taking to ensure that patients' access to care is fully restored.

If funding lapses for the National Institutes of Health (NIH), as it did on September 30, 2025, NIH is unable to process new grant applications or award new grants. NIH's investment in research at university and research hospitals is critical for advancing the science that drives treatments and cures to patients. Researchers at universities warned that without NIH funding, they may have to close their labs and lay off their staff. Additionally, while extramural researchers could continue to draw down funds from existing grants, they were not able to get technical or administrative support from furloughed extramural NIH employees. Meanwhile, NIH-employed researchers conducting basic or translational research were not able to continue

<sup>&</sup>lt;sup>1</sup> Information for the NIH Extramural Community During the Lapse of Federal Government Funding, National Institutes of Health (Oct. 1, 2025), <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-004.html">https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-004.html</a>.

<sup>&</sup>lt;sup>2</sup> Phie Jacobs, *As U.S. shutdown drags on, 'it's just one blow after another'*, Science (Oct. 14, 2025), <a href="https://www.science.org/content/article/u-s-shutdown-drags-it-s-just-one-blow-after-another">https://www.science.org/content/article/u-s-shutdown-drags-it-s-just-one-blow-after-another</a>.

<sup>&</sup>lt;sup>3</sup> National Institutes of Health, *supra* note 1.

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their research during the shutdown.<sup>4</sup> We are concerned that delays in NIH grant reviews and awards delayed advances in biomedical research for years to come.<sup>5</sup>

Furthermore, we are concerned about the ramifications of the government shutdown on patient access to clinical trials. NIH did not process new clinical trial registrations or enrollments during the shutdown. At the NIH's Clinical Center, often referred to as the "House of Hope," no new protocols were able to begin and new patients were not admitted (with few exceptions). For patients seeking to enroll in trials outside of NIH's Clinical Center in Bethesda, Maryland, Clinicaltrials.gov, the NIH-operated clinical trials database for trials occurring in all 50 states and over 200 countries was not being updated during the shutdown. This prevented clinical trials sponsors from registering new clinical studies for enrollment and prevented new patients from enrolling in clinical trials. During the government shutdown in 2013, following a *Boston Globe* article on the matter, the NIH recalled furloughed workers to update the database. We expected the Department to update ClinicalTrials.gov during the federal shutdown to facilitate access to clinical trials for patients and their families.

These delays in patient access to promising new treatments, therapeutics, and care resulting from the government shutdown are unacceptable.

As such, we ask that you respond in writing to the following questions by December 4, 2025. Please provide the following:

- 1. The number of NIH grant submissions that were received but unable to be reviewed during the government shutdown,
- 2. The number of clinical trials that were scheduled to begin that were not able to during the government shutdown,
  - a. The number of patients who would have been eligible to participate in these clinical trials, and
- 3. The number of NIH-employed researchers who were furloughed and unable to conduct research during the government shutdown and the subject matter of their research.

<sup>&</sup>lt;sup>4</sup> National Institutes of Health (September 25, 2025), <a href="https://www.hhs.gov/about/budget/fy-2026-nih-contingency-staffing-plan/index.html">https://www.hhs.gov/about/budget/fy-2026-nih-contingency-staffing-plan/index.html</a>.

<sup>&</sup>lt;sup>5</sup> Science News Staff, *U.S. Scientists gird for yet another government shutdown*, Science (Sept. 30, 2025), <a href="https://www.science.org/content/article/u-s-scientists-gird-yet-another-government-shutdown">https://www.science.org/content/article/u-s-scientists-gird-yet-another-government-shutdown</a>.

<sup>6</sup> *Id.* 

<sup>&</sup>lt;sup>7</sup> Clinicaltrials.gov's banner reads: "Notice: Because of a lapse in government funding, the information on this website may not be up to date, transactions submitted via the website may not be processed, and the agency may not be able to respond to inquiries until appropriations are enacted. The NIH Clinical Center (the research hospital of NIH) is open. For more details about its operating status, please visit cc.nih.gov. Updates regarding government operating status and resumption of normal operations can be found at opm.gov. Clinicaltrials.gov, National Library of Medicine (n.d.), <a href="https://clinicaltrials.gov/">https://clinicaltrials.gov/</a>.

<sup>&</sup>lt;sup>8</sup> Federal Government Shuts Down After Congress Fails to Pass FY26 Funding Bill: ASCO members asked to share their stories, American Society on Clinical Oncology (Oct. 1, 2025, updated October 21, 2025), <a href="https://www.asco.org/news-initiatives/policy-news-analysis/federal-government-shuts-down-congress-fails-pass-FY26-funding-bill">https://www.asco.org/news-initiatives/policy-news-analysis/federal-government-shuts-down-congress-fails-pass-FY26-funding-bill</a>.

<sup>&</sup>lt;sup>9</sup> Jocelyn Kaiser, *Tales From the Shutdown: Clinicaltrials.gov Gets Exemption*, Science (Oct. 4, 2013) <a href="https://www.science.org/content/article/tales-shutdown-clinicaltrialsgov-gets-exemption">https://www.science.org/content/article/tales-shutdown-clinicaltrialsgov-gets-exemption</a>.

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Thank you for your attention to this important matter. We look forward to your response.

Sincerely,

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Member of Congress

Røbin L. Kelly Member of Congress Lori Trahan

Member of Congress

Andre Carson

Member of Congress

Eleanor Holmes Norton

Member of Congress

Valerie P. Foushee

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Jesús G. "Chuy" García

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James P. McGovern Member of Congress Shri Thanedar Member of Congress

Mary Gay Scanlon Member of Congress Stephen F. Lynch Member of Congress

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Dwight Evans

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