ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States

House of Representatives COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

Majority (202) 225-3641

Minority (202) 225-2927

July 7, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Secretary Becerra,

We write raising serious concerns about your failure to follow the law and ensure accountability for billions of dollars in taxpayer funding at the National Institutes of Health (NIH). As detailed below, it has become apparent that you, as Secretary of Health and Human Services (HHS), did not reappoint a number of Institute and Center (IC) Directors at the NIH. Your failure could have grave implications for the validity of actions taken by 14 NIH IC Directors during their unlawful tenure, including former National Institute of Allergy and Infectious Disease (NIAID) Director Dr. Anthony Fauci.

Appointment of NIH IC Directors

Congress passed the 21st Century Cures Act with overwhelmingly bipartisan support in 2016. Under Article II, Section 2 of the Constitution of the United States, NIH IC Directors are inferior officers of the United States. Further, section 2033 of the 21st Century Cures Act, titled *Increasing Accountability at the National Institutes of Health*, lays out the framework by which NIH IC Directors must be appointed and reappointed. Specifically, it requires the Secretary of HHS to reappoint NIH IC Directors, including those who were serving at the time of the law's enactment when their five-year terms expired on December 12, 2021.

The Secretary of HHS is traditionally involved in senior level appointments at the department and operating divisions. In past administrations, the Secretary has approved the appointments or reappointments of NIH IC Directors. When section 2033 of the 21st Century Cures Act became law, it made the requirement explicit and set a term limit; the Secretary must

¹ 21st Century Cures Act, Pub. L. 114–255, § 2033, 130 Stat. 1033, 1057 (2016).

² *Id*.

appoint and reappoint the NIH IC Directors on December 13, 2021.³ As noted by a National Academy of Science report: "Most [IC] directors chose to move into the Title 42 program, so they are, in fact, already subject to 5-year renewable terms. Under this system, the Secretary of Health and Human Services retains approval authority for appointments.⁴ **Thus, the NIH Director can only recommend, but not appoint, senior leadership in the agency.**" *(emphasis added)*

Investigation and Findings

It has become increasingly clear that you never appointed or reappointed the 14 NIH IC Directors in December of 2021. HHS and the NIH repeatedly assured the Committee that the NIH IC Directors were validly reappointed but did not produce proper supporting documentation. For example, in its first response to the Committee on April 5, 2022, the NIH claimed "[a]ll current IC Directors who were serving as of December 13, 2016, have undergone review and have been reappointed to new 5-year term appointments," and submitted a chart showing that the NIH Director was the official who made the reappointments of the NIH IC Directors, which even if true, is contrary to what the law requires. 6

A May 5, 2023, letter from HHS Assistant Secretary Melanie Egorin, in response to our April 21, 2023, letter, correctly identified the HHS Secretary as the approving official for NIH IC Director appointments but did not respond to the Committee's questions about the reappointments. Her letter did not provide any documents establishing the HHS Secretary had made the appointments and reappointments. HHS staff also declined to confirm the reappointments in discussion with Committee staff while again referring the above-mentioned chart as evidence of the reappointments.

On June 20, 2023, HHS finally produced documents, titled "Ratification of Prior Selection and Prospective Appointment: Appointment Affidavit" (herein after "Appointment Affidavit"), and signed by you, purporting to show that some of the NIH IC Directors at issue were reappointed. However, the Appointment Affidavits were signed on June 8, 2023, and June 15, 2023 – not December 13, 2021. Critically, no appointment affidavits were produced for two NIH IC Directors, Dr. Fauci and Dr. Roger Glass, who were serving in December 2016, but retired before June 2023.

³ *Id*

⁴ National Academies of Science, Engineering, and Medicine, Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges 112 (2003).

⁵ Id.

⁶ Letter from Dr. Tara A. Schwetz, Ph.D., Acting Principal Deputy Director, NIH, to the Hon. Cathy McMorris-Rodgers, the Hon. Morgan Griffith, and the Hon. Brett Guthrie (Apr. 5, 2022) (enclosed as attachment).

⁷ Letter from the Hon. Melanie Anne Egorin, Ph.D., Assistant Secretary for Legislation, HHS, to the Hon. Cathy McMorris-Rodgers, the Hon. Morgan Griffith, and the Hon. Brett Guthrie (May 5, 2023) (enclosed as attachment).

⁸ *Id*.

⁹ Letter from the Hon. Melanie Anne Egorin, Ph.D., Assistant Secretary for Legislation, HHS, to the Hon. Cathy McMorris-Rodgers, the Hon. Morgan Griffith, and the Hon. Brett Guthrie (June 20, 2023) (enclosed as attachment). ¹⁰ *Id.*, Appointment Affidavits, CMRAppts000004 to CMRAppts000027 (enclosed as attachment).

Based on the information provided to date, the Committee believes that you failed to reappoint the NIH IC Directors listed below after their terms expired on December 13, 2021. Instead, the NIH handled the reappointments as an internal matter, signed by an NIH human resources director, whose name was redacted by HHS. Only after multiple investigative letters and extensive discussion with the Committee did you apparently attempt to reappoint these NIH IC Directors in a series of signed appointment affidavits issued on June 8, and 15, 2023, some eighteen months after their terms expired. 11 In total 14 current and former NIH IC Directors are impacted:

Dr. Anthony Fauci	National Institute of Allergy and Infectious Disease (NIAID)
Dr. Richard Hodes	National Institute on Aging (NIA)
Dr. Nora Volkow	National Institute on Drug Abuse (NIDA)
Dr. Roger Glass	Fogarty International Center (FIC)
Dr. Griffin Rodgers	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Dr. Eric Green	National Human Genome Research Institute (NHGRI)
Dr. Gary Gibbons	National Heart, Lung, and Blood Institute (NHLBI)
Dr. Jon Lorsch	National Institute of General Medical Sciences (NIGMS)
Dr. George Koob	National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Dr. Walter Koroshetz	National Institute of Neurological Disorders and Stroke (NINDS)
Dr. Elisio Perez-Stable	National Institute on Minority Health and Health Disparities (NIMHD)
Dr. Patricia Brennan	National Library of Medicine (NLM)

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Dr. Joshua Gordon National Institute of Mental Health

(NIMH)

Dr. Diana Bianchi National Institute of Child Health

and Human Development

 $(NICHD)^{12}$

The failure to reappoint the above NIH IC Directors jeopardizes the legal validity of more than \$25 billion in federal biomedical research grants made in 2022 alone. The 21st Century Cures Act requires NIH IC Directors "review and make the final decision with respect" to all competitive grant awards issued by their Institute or Center. Therefore, the final award decision rests with NIH IC Directors. As Assistant Secretary Egorin stated in her May 2023 letter to the Committee, this high level of responsibility, coupled with appointment by the Secretary, suggests that NIH IC Directors are inferior officers of the United States. The Committee concurs with this assessment.

The June 2023 appointment affidavits purport to ratify the *prior selection* of the NIH IC Directors and to *prospectively reappoint* them. Here *selection* refers to actions taken by the NIH Director to identify candidates to recommend to the Secretary for appointment. The appointment affidavits state that the reappointments are only *prospective*. ¹⁵ Thus, the June 2023 reappointments do not retroactively ratify the decisions that NIH IC Directors made while not lawfully appointed – those decisions occurring between December 14, 2021, and the June 2023 reappointments affidavits. A recent U.S. Court of Appeals decision also suggests that actions taken by NIH IC Directors while they were not lawfully appointed are legally invalid. ¹⁶

As stated above, HHS has produced no documentation showing that Dr. Fauci and Dr. Glass were reappointed as NIAID Director and Fogarty International Center Director, respectively. Both retired prior to the issuance of the June 2023 appointment affidavits. Given his central role in the COVID-19 response, the Committee is particularly concerned about the failure to reappoint Dr. Fauci. Without reappointment, Dr. Fauci continued to serve as NIAID Director until his retirement on December 31, 2022. ¹⁷ If Dr. Fauci was never reappointed, every action he took is potentially invalid.

During that time, Dr. Fauci also served as President Biden's Chief Medical Adviser. He regularly attended high-level meetings with Biden administration leadership and policy makers,

¹³ NIH Center and Institute Grant Awards and Funding Fiscal Year 2022 (on file with Committee).

¹² Supra, note 7.

¹⁴ Supra, note 1.

¹⁵ Supra, note 7.

¹⁶ Lucia v. Sec. & Exch. Comm'n, 138 S. Ct. 2044 (2018) (holding SEC ALJs are "Officers" subject to the Appointments Clause and that claimants are entitled to an independent decision issued by a different ALJ if a timely challenged ALJ decision is "tainted" by a pre-ratification ALJ decision); see also Cody v. Kijikazi, No. 21-3553, 2022 U.S. App. LEXIS 25355 (9th Cir. Sept. 8, 2022) ("An Appointments Clause violation is thus no mere technicality or quaint formality—it weakens our constitutional design. An appointment too far removed from the President or the head of an executive agency may, for example, erode political accountability").

¹⁷ Press Release, NIAID, Dr. Anthony Fauci to Leave NIAID at the End of December (Dec. 7, 2022) (https://www.niaid.nih.gov/grants-contracts/dr-anthony-fauci-leave-niaid-end-december#:~:text=At%20the%20end%20of%20this,positions%2C%20I%20am%20not%20retiring).

including the National Security Council and the intelligence community. ¹⁸ He was instrumental in crafting the administration's response to the pandemic and was an outspoken advocate for intrusive public health mandates. ¹⁹ Dr. Fauci, who remained the highest paid federal employee with an annual salary of \$480,654, also made controversial decisions at NIAID during 2022. ²⁰ He awarded a new grant to EcoHealth Alliance despite unanswered concerns raised by us and others about possible EcoHealth double-billing USAID and NIH for the same research expenses and their failure to produce laboratory notebooks and other records from the Wuhan Institute of Virology. ²¹ That he could have amassed and exercised all of this authority and influence without being duly reappointed as NIAID Director demonstrates how ineffective HHS is at managing its component agencies and how little accountability currently exists.

Your failure to follow the 21st Century Cures Act and reappoint 14 of the 27 IC Directors, which represents just over 50 percent of NIH IC Directors, is unacceptable. You have not complied with your oath to faithfully discharge the duties of your office. That HHS and the NIH spent 15 months obstructing the Committee to coverup your failure only makes matters worse. HHS and the NIH should have known within days of receiving the Committee's March 14, 2022, letter that the reappointments as legally required had not occurred. Rather than addressing the problem in consultation with the Committee, HHS and the NIH repeatedly misled the Committee, claiming "[a]ll current IC Directors who were serving as of December 13, 2016... have been reappointed to new 5-year term appointments." This misrepresentation calls into question the veracity of other representations made to the Committee by HHS and the NIH, particularly those made by their respective legislative affairs offices. ²²

The Committee needs to understand the consequences of your failure to reappoint NIH IC Directors on federal biomedical research and other related issues, such as potential violations of the "purpose" statute, 31 U.SC. 1301(a), that restricts appropriated funds to their authorized purposes and the Antideficiency Act. We also intend to get a full accounting of who at HHS and the NIH decided to mislead the Committee and why. HHS and the NIH's bad faith and failure to

¹⁸ Press Briefing, White House, Press Briefing by Press Secretary Karine Jean-Pierre, COVID-19 Response Coordinator Dr. Ashish Jha, and Chief Medial Advisor Dr. Anthony Fauci (Nov. 22, 2022) (<a href="https://www.whitehouse.gov/briefing-room/press-briefings/2022/11/22/press-briefing-by-press-secretary-karine-jean-pierre-covid-19-response-coordinator-dr-ashish-jha-and-chief-medial-advisor-dr-anthony-fauci/).

¹⁹ Brittany Bernstein, *Fauci: 'Inexplicable' That Americans See Forced Masking as Encroachment on Freedom*, National Review (Aug. 10, 2022) (https://www.nationalreview.com/news/fauci-inexplicable-that-americans-see-forced-masking-as-encroachment-on-freedom/).

²⁰ Justin Anderson, *Dr. Anthony Fauci is paid more than the president — here's how much he earns as he prepares to retire from public service*, Yahoo Moneywise (Sept. 5, 2022) (https://www.yahoo.com/video/dr-anthony-fauci-paid-more-130000506.html).
²¹ Ronn Blitzer, *NIH gives new grant to EcoHealth Alliance to research bat coronaviruses, despite concerns over*

Ronn Blitzer, NIH gives new grant to EcoHealth Alliance to research bat coronaviruses, despite concerns over Wuhan lab link, Fox News (Oct. 3, 2022) (https://www.foxnews.com/politics/nih-gives-new-grant-ecohealth-alliance-research-bat-coronaviruses-despite-concerns-wuhan-lab-link); see also HHS Office of the Inspector General, The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies (Jan. 2023) (https://oig.hhs.gov/oas/reports/region5/52100025.pdf); see also U.S. Gov't Accountability Office, GAO-23-106119, Federal Research: NIH Could Take Additional Actions to Manage Risks Involving Foreign Subrecipients (Jun. 2023).

²² Letter from the Hon. Melanie Anne Egorin, Ph.D., Assistant Secretary for Legislation, HHS, to the Hon. Cathy McMorris-Rodgers, the Hon. Morgan Griffith, and the Hon. Brett Guthrie (Apr. 26, 2023) (on file with Committee).

follow the law in this matter epitomizes why Americans no longer trust federal public health agencies. Not only did HHS and NIH ignore the law, it is also grossly unfair that Dr. Fauci — who unlawfully held his position after December 13, 2021 — could use his authority to push authoritarian mandates on the American people during the COVID-19 pandemic response. Greater accountability is needed.

Oversight is part of our constitutional responsibilities, and we expect you and your staff not to mislead the Committee but to work constructively with us and provide the requested documents and information. To assist our inquiry, pursuant to Rules X and XI of the U.S. House of Representatives, please provide by July 21, 2023, the following:

- 1. With regard to reappointments of NIH IC Directors, what criteria is used for reappointments?
- 2. What was the role of the NIH Director in the reappointments since December 13, 2016? Did the NIH Director make a recommendation for the reappointment or the termination for each applicable NIH IC Director? Please provide copies of all correspondence between the NIH Director and HHS officials mentioning the appointment or reappointment of the NIH IC Directors from June 2021 through today.
- 3. Did the HHS Secretary have any role in the NIH human resources actions taken in December 2021? If so, please explain your apparent lack of involvement?
- 4. Please provide copies of all correspondence between the Office of the Secretary and HHS officials that discuss, mention or reference the attempts at appointments and reappointments of the NIH IC Directors from June 2021 to today.
- 5. Upon realizing that none of the 14 NIH IC Director appointments had been made as required by the Constitution, did NIH or HHS consult the Department of Justice, including its Office of Legal Counsel, White House Counsel's Office, or outside legal counsel? If so, identify who was consulted and when.
- 6. Per 42 U.S.C. § 284 (a)(2) (F), "[a]ppointments and reappointments under this subsection shall be made on the basis of ability and experience as it relates to the mission of the National Institutes of Health and its components, including compliance with any legal requirement that the Secretary or Director of National Institutes of Health determines relevant." What information is used in the reappointments to determine ability and experience as relates to the NIH mission? Who decides on what information is used? Who decides on the appointments and reappointments? Please provide documentation showing that the reappointments were made on the basis of ability and experience.
- 7. Per 42 U.S.C. § 284(a)(2)(F), is there any legal requirement that you as the Secretary determined relevant to the reappointment of the NIH IC directors at the NIH? If so, please list the requirement(s) and why they were determined relevant.

- 8. Per 42 U.S.C. § 284(a)(2)(F), is there any legal requirement that the Director of the NIH determined relevant to the reappointment of the NIH IC Directors at the NIH? If so, please list the requirement(s) and why they were determined relevant.
- 9. Per 42 U.S.C. § 284(a)(2)(B), NIH IC Directors must be reappointed in accordance with standards applicable to the relevant appointment mechanism. What is the relevant appointment mechanism? What are the standards applicable to the relevant appointment mechanism?
- 10. Any internal guidance documents (policies, procedures, etc.) that address the appointment, reappointment, assessment, and termination of NIH IC Directors.
- 11. All documents related to the notification of NIH IC Directors about their reappointments, including notification of their Appointment Affidavits.
- 12. Explain in detail the clearance and approval process for the April 5, 2022, letter from NIH Acting Principal Deputy Director Tara A. Schwetz, including its attached chart, to then Ranking Members Rodgers, Griffith, and Guthrie. As part of your answer, identify every official, employee, or appointee of the NIH, HHS, the Executive Office of the President, including but not limited to the Office of Science and Technology Policy (OSTP), or the White House who drafted, reviewed, edited, or approved the letter.
- 13. Produce all communications and documents referring or relating to the March 14, 2022, letter from then Ranking Members Rodgers, Griffith, and Guthrie to Secretary Becerra.
- 14. Produce all communications and documents referring or relating to the April 5, 2022, letter from NIH Acting Principal Deputy Director Tara A. Schwetz, including its attached chart, to then Ranking Members Rodgers, Griffith, and Guthrie. For this request priority custodians include:
 - a. Dr. Lawrence A. Tabak;
 - b. Dr Tara A. Schwetz:
 - c. Adrienne Hallett;
 - d. Lauren Higgins; and
 - e. Jennifer Plank-Bazinet.

Please be advised that intentional misstatements or omissions in response to the above questions may constitute federal criminal violations under 18 U.S.C. §1001. In addition, the Committee believes that interviews from HHS and NIH officials and employees about this matter may be necessary.

Finally, this letter serves as a formal request to preserve all existing and future records and materials in HHS and the NIH's possession relating to the topics addressed in this letter. You should construe this preservation notice as an instruction to take all reasonable steps to prevent the destruction or alteration, whether intentionally or negligently, of all documents, communications, and other information, including electronic information and metadata, that are

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or may be responsive to this congressional inquiry. This instruction includes all electronic messages sent using official and personal accounts or devices, including records created using text messages, phone-based message applications, or encryption software.

If you have any questions, please contact the Majority Committee staff at (202) 225-3641. Thank you for your attention to this request.

Sincerely,

Cathy McMorris Rodgers

Chair

Energy and Commerce Committee

Asthur

Brett Guthrie

Chair

Subcommittee on Health

H. Morgan Griffith

Chair

Subcommittee on Oversight and Investigations

CC: The Honorable Frank Pallone, Ranking Member

The Honorable Anna Eshoo, Ranking Member, Subcommittee on Health

The Honorable Kathy Castor, Ranking Member, Subcommittee on Oversight and Investigations

Lawrence A. Tabak, D.D.S., PhD., Senior Official performing the duties of Director, National Institutes of Health

Dr. Richard Hodes, M.D., Director, National Institute on Aging (NIA)

Dr. Nora Volkow, M.D., Director, National Institute on Drug Abuse (NIDA)

Dr. Griffin Rodgers, M.D., M.A.C.P., Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Dr. Eric Green, Director, M.D., Ph.D., National Human Genome Research Institute (NHGRI)

Dr. Gary Gibbons, M.D., Director, National Heart, Lung, and Blood Institute (NHLBI)

Dr. Jon Lorsch, Ph.D., Director, National Institute of General Medical Sciences (NIGMS)

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Dr. Patricia Brennan, RN, Ph.D., Director, National Library of Medicine (NLM)

Dr. Anthony Fauci, M.D.

Dr. Roger Glass, M.D., Ph.D., MPH.

Attachments

Letter from Dr. Tara A. Schwetz, Ph.D., Acting Principal Deputy Director, NIH, to the Hon. Cathy McMorris-Rodgers, the Hon. Morgan Griffith, and the Hon. Brett Guthrie (Apr. 5, 2022). Letter from the Hon. Melanie Anne Egorin, Ph.D., Assistant Secretary for Legislation, HHS, to the Hon. Cathy McMorris-Rodgers, the Hon. Morgan Griffith, and the Hon. Brett Guthrie (May 5, 2023) (attachments included).

Letter from the Hon. Melanie Anne Egorin, Ph.D., Assistant Secretary for Legislation, HHS, to the Hon. Cathy McMorris-Rodgers, the Hon. Morgan Griffith, and the Hon. Brett Guthrie (June 20, 2023) (attachments included).