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## United States Senate

COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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June 6, 2023

### VIA ELECTRONIC TRANSMISSION

The Honorable Lawrence Tabak  
Acting Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Acting Director Tabak:

On January 19, 2023, the *New England Journal of Medicine* published the results of a study funded by the National Institutes of Health (NIH) entitled “Psychosocial Functioning in Transgender Youth After 2 Years of Hormones.”<sup>1</sup> The study consisted of a cohort of 315 youth who identified as transgender or non-binary and were receiving hormone treatment, over 75 percent of whom were under the age of 18.<sup>2</sup> According to the article, hormone treatment resulted in “increases in positive affect and life satisfaction and decreases in depression and anxiety symptoms.”<sup>3</sup> Tragically, however, two participants died by suicide during the study, and eleven participants reported experiencing suicidal ideation.<sup>4</sup>

We are shocked and deeply troubled that two young people died by suicide and eleven youth experienced suicidal ideation while participating in a study funded with taxpayer dollars. The article does not identify the age of the participants who died or contemplated suicide, nor does it explain what measures, if any, the researchers took to prevent these tragic deaths. According to the article, the researchers intend to continue “following this cohort to see whether gains in functioning are sustained over a longer follow-up period.”<sup>5</sup>

NIH should take all available steps to ensure the safety and wellbeing of research participants in any study it funds, especially minors such as those included in this cohort, who may

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<sup>1</sup> Diane Chen et al., *Psychosocial Functioning in Transgender Youth After 2 Years of Hormones*, 383 NEW ENGL. J. MED. 240–49 (Jan. 19, 2023), <https://www.nejm.org/doi/full/10.1056/NEJMoa2206297>.

<sup>2</sup> *Id.* at 241.

<sup>3</sup> *Id.* at 240.

<sup>4</sup> *Id.* at 243.

<sup>5</sup> *Id.* at 249.

already experience significant mental health challenges.<sup>6</sup> Given that the researchers are continuing to follow this cohort, we are extremely concerned that there are insufficient safeguards in place to ensure that no further tragedies occur in the course of this study—or any other study funded by NIH. In order to understand NIH’s decision to fund this study and the steps NIH has taken to prevent any future tragedies, we request you answer the following questions, on a question-by-question basis, by **close of business on June 20, 2023**.

1. Please explain in detail NIH’s process for approving this study and the number of NIH employees who were involved in the decision to approve it. With respect to NIH funding, please also provide the specific dollar amount spent on this study as of the date of this letter. Please also provide an estimate for the amount of money NIH anticipates spending on this study moving forward, if any. Finally, please provide an itemized list of expenditures of NIH funds for each of the four study sites.
2. With respect to NIH’s decision to fund studies involving mental health issues and the terms and conditions NIH applies to such funding, please explain in detail the steps NIH takes to work with the investigators and Institutional Review Boards to ensure that there are appropriate protocols in place to identify potential mental health risks of study participants and provide research participants with appropriate treatment upon enrollment and during the study.
3. Has NIH funded any additional studies on the effects of medical intervention intended to facilitate the transition of transgender and non-binary minors? If so, please provide (1) the specific dollar amount spent on each study as of the date of this letter, (2) the specific dollar amount spent on any future studies that have been approved to receive NIH funds, (3) a brief description of every such study, and (4) the names of all investigators and institutions affiliated with each study.
4. Please provide the age of both participants in the study who died by suicide. Was NIH made aware of the two deaths described in the study? If so, please describe when and how NIH first learned of the deaths and any action the agency took in response, in coordination with the investigators and the Institutional Review Board.
5. Please provide the age of the participants in the study who experienced suicidal ideation. Was NIH made aware of these experiences? If so, please describe when and how NIH first learned that the participants experienced suicidal ideation and any action the agency took in response, in coordination with the investigators and the Institutional Review Board.
6. With respect to NIH-funded studies of transgender youth, please describe in detail what safeguards, if any, NIH requires of investigators in order to prevent deaths by suicide, suicide attempts, or suicidal ideation by study participants.

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<sup>6</sup> See Rina Torchinsky, *Nearly Half of LGBTQ Youth Seriously Considered Suicide, Survey Finds*, NPR (May 5, 2022, 6:46 PM), <https://www.npr.org/2022/05/05/1096920693/lgbtq-youth-thoughts-of-suicide-trevor-project-survey>.

7. Please explain what processes and procedures, if any, were in place for the investigators to communicate and share information with the clinics where the participants were enrolled in the study. Were the investigators required to share with the clinics any potential concerns regarding the safety and wellbeing of the participants? If not, why not?
8. For participants experiencing serious mental health issues, did the investigators or clinics provide any supportive services for the participants? If not, why not?

Thank you for your prompt attention to this matter.

Sincerely,

*Bill Cassidy, M.D.*

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Bill Cassidy, M.D.  
Ranking Member  
U.S. Senate Committee on Health,  
Education, Labor, and Pensions



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Tommy Tuberville  
Senator