

United States Senate

WASHINGTON, DC 20510

December 5, 2024

VIA ELECTRONIC TRANSMISSION

The Honorable Monica M. Bertagnolli, M.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Director Bertagnolli:

Last year, multiple Republican senators wrote to the National Institutes of Health (NIH) raising concerns about an NIH-funded observational study in which two children who identified as transgender or non-binary and were receiving hormone treatment died by suicide.¹ This study, “The Impact of Early Medical Treatment in Transgender Youth,”² has two arms: one observing a cohort of older youth receiving hormones (the “older cohort”) and the other observing a cohort of younger youth with an average age of 11 years old receiving puberty blockers (the “younger cohort”). While the study is ongoing, to date, researchers have published 29 papers related to this study, including one paper, the focus of our 2023 letters, that summarized the first two years of outcomes for the older cohort.³ None of these papers have so far summarized outcomes for the younger cohort.

In September 2023, NIH responded to Ranking Member Cassidy and Senator Tuberville’s letter stating that this population is “understudied in biomedical research.”⁴ Similarly, during your Senate confirmation process, you emphasized the need to get more data about this population and the impact of related medical interventions. It has recently been revealed, however, that NIH-funded researchers are withholding the results of their research on the younger cohort for political reasons.

On October 23, *The New York Times* (NYT) reported that a lead researcher for this study, Dr. Johanna Olson-Kennedy, delayed publishing results from the younger cohort, likely due to lackluster data that do not support her political agenda.⁵ Dr. Olson-Kennedy told NYT that the data shows puberty blockers did not lead to mental health improvements among the younger

¹ Letter from Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions, & Sen. Tommy Tuberville to Lawrence Tabak, Acting Dir., Nat’l Insts. of Health (June 6, 2023), https://www.help.senate.gov/imo/media/doc/nih_trans_letter.pdf; letter from Sen. Ted Budd, Sen. Rand Paul, & Sen. James Lankford et al. to Lawrence Tabak, Acting Dir., Nat’l Insts. of Health (May 9, 2023), https://brecheen.house.gov/uploadedfiles/brecheen-budd_letter_to_nih.pdf.

² *The Impact of Early Medical Treatment in Transgender Youth*, NIH REPORT, <https://reporter.nih.gov/project-details/8965408> (last visited Oct. 28, 2024).

³ See Diane Chen, Ph.D. et al., *Psychological Functioning in Transgender Youth after 2 Years of Hormones*, 388 NEW ENG. J. MED. 240 (2023), <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2206297>.

⁴ Letter from Tara A. Schwetz, Acting Principal Deputy Dir., Nat’l Insts. of Health, to Sen. Bill Cassidy, Ranking Member, S. Comm. on Health, Educ., Lab., & Pensions (Sept. 14, 2023) (on file with Committee).

⁵ See Azeen Ghorayshi, *U.S. Study on Puberty Blockers Goes Unpublished Because of Politics, Doctor Says*, THE N.Y. TIMES (Oct. 23, 2024), <https://www.nytimes.com/2024/10/23/science/puberty-blockers-olson-kennedy.html>.

cohort, but justified the findings by saying they were most likely because the children were already doing well when the study began.⁶ However, as NYT noted, this conclusion seemingly contradicts an earlier finding from Dr. Olson-Kennedy and her colleagues that 28.6 percent of the younger cohort had “elevated depression symptoms” and 23.6 percent reported suicidal ideation at some point in their lifetime before receiving treatment.⁷ Dr. Olson-Kennedy stated that she has not published the data because she “do[es] not want our work to be weaponized,” and is afraid the results could be used in court to argue that puberty blockers should not be used on transgender adolescents.⁸ But the refusal to publish data surprised even her colleagues, with a coauthor of papers associated with the study, Dr. Amy Tishelman, saying, “I understand the fear about it being weaponized, but it’s really important to get the science out there.”⁹

Under the NIH-funded study, the researchers set out to try to validate the findings of an earlier study out of the Netherlands that found that giving puberty blockers to children with persistent gender dysphoria led to some psychological improvements.¹⁰ However, similar efforts undertaken by researchers in the United Kingdom were not able to replicate the Dutch findings. Specifically, their results found that puberty blockers did not change the children’s well-being, including rates of self-harm.¹¹ According to news outlets, results from the British study were not published until 2020, years after puberty blockers were adopted as the standard of care, and the researchers withheld their underlying data from England’s High Court of Justice during related litigation.¹²

Following the publication of the results from the British study, and a subsequent independent review led by Dr. Hilary Cass, who found the evidence surrounding these procedures to be “weak,” England’s National Health Service (NHS) changed its standard of care to no longer prescribe puberty blockers to children at gender identity clinics.¹³ Citing the independent review’s findings that there was “not enough evidence” that puberty blockers are safe or effective, NHS determined that they could only be prescribed as part of clinical research trials or in “exceptional circumstances.”¹⁴

⁶ *Id.*

⁷ Diane Chen, Ph.D. et al., *Psychosocial Characteristics of Transgender Youth Seeking Gender-Affirming Medical Treatment: Baseline Findings from the TYC Study*, 68 J. ADOLESCENT HEALTH 1104 (2021), [https://www.jahonline.org/article/S1054-139X\(20\)30453-5/abstract](https://www.jahonline.org/article/S1054-139X(20)30453-5/abstract).

⁸ Azeen Ghorayshi, *U.S. Study on Puberty Blockers Goes Unpublished Because of Politics, Doctor Says*, THE N.Y. TIMES (Oct. 23, 2024), <https://www.nytimes.com/2024/10/23/science/puberty-blockers-olson-kennedy.html>.

⁹ *Id.*

¹⁰ See Annelou L.C. de Vries, M.D. et al., *Puberty Suppression in Adolescents With Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. OF SEXUAL MED. 2276 (2011), <https://academic.oup.com/jsm/article-abstract/8/8/2276/6843977?redirectedFrom=fulltext>.

¹¹ See Polly Carmichael et al., *Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK*, PLOS ONE (Feb. 2, 2021), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0243894>.

¹² Hannah Barnes & Deborah Cohen, *Tavistock puberty blocker study published after nine years*, BBC (Dec. 11, 2020), <https://www.bbc.com/news/uk-55282113>; Azeen Ghorayshi, *U.S. Study on Puberty Blockers Goes Unpublished Because of Politics, Doctor Says*, THE N.Y. TIMES (Oct. 23, 2024), <https://www.nytimes.com/2024/10/23/science/puberty-blockers-olson-kennedy.html>.

¹³ Josh Parry, *NHS England to stop prescribing puberty blockers*, BBC (Mar. 12, 2024), <https://www.bbc.com/news/health-68549091>; *Independent review of gender identity services for children and young people: Final report*, THE CASS REV. (Apr. 2024), <https://cass.independent-review.uk/home/publications/final-report/>.

¹⁴ Josh Parry, *NHS England to stop prescribing puberty blockers*, BBC (Mar. 12, 2024), <https://www.bbc.com/news/health-68549091>.

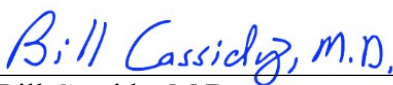
According to Dr. Cass, the delays from the American and British research groups have led the public to believe that puberty blockers improved mental health, even though there was little scientific evidence to support that conclusion.¹⁵ England and four other European countries have limited puberty blockers and/or hormone treatments for children in the wake of the British findings. Yet here in the United States, we lack results from similar federally funded research that could better inform doctors and parents.

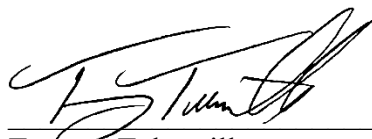
To be clear, we oppose taxpayer funding going toward gender transition interventions for minors. While we recognize that this particular study is observational, we remain concerned that minors lack the ability to fully understand the lifelong outcomes of the interventions studied in this project and provide their consent. Further, taxpayers have the right to know the outcomes of the research they fund, particularly when the intervention studied has life-altering impacts. The events in England serve as a warning about the dangers of researchers withholding their findings for political or ideological reasons. In this case, it is particularly concerning because of the lack of data on this population that you yourself highlighted, and the potential health impact of puberty blockers when used on children. Ranking Member Cassidy's May 2024 white paper on modernizing NIH highlighted the need for more data access among scientists to improve the quality of biomedical research.¹⁶ This means sharing *all* data, even when they do not support the researchers' original hypothesis. Though NIH has taken steps to ensure data access for future studies through its Data Management and Sharing Policy,¹⁷ we are concerned about the transparency of previously funded studies.

In order to ensure transparency in medical research, we ask that you produce each annual progress report submitted to NIH for "The Impact of Early Medical Treatment in Transgender Youth," project number 5R01HD082554-08 (formerly 2R01HD082554-06), no later than **December 19, 2024**.

We look forward to your prompt reply.

Sincerely,


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


Tommy Tuberville
United States Senator

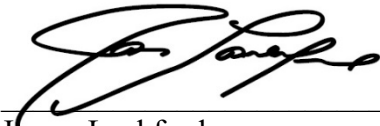
¹⁵ Azeen Ghorayshi, *U.S. Study on Puberty Blockers Goes Unpublished Because of Politics, Doctor Says*, THE N.Y. TIMES (Oct. 23, 2024), <https://www.nytimes.com/2024/10/23/science/puberty-blockers-olson-kennedy.html>.

¹⁶ See *NIH in the 21st Century: Ensuring Transparency and American Biomedical Leadership*, S. COMM. ON HEALTH, EDUC., LAB., & PENSIONS (May 9, 2024), https://www.help.senate.gov/imo/media/doc/nih_modernization_5924pdf.pdf.

¹⁷ *Final NIH Policy for Data Management and Sharing*, NAT'L INSTS. OF HEALTH (Oct. 29, 2020), <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html>.



Ted Cruz
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