EXHIBIT 171

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Bethesda, Maryland 20892

May 23, 2019

Michael K. Laidlaw, M.D.
Endocrinology, Diabetes, and Metabolism
The Kelsey Coalition
4770 Rocklin Road
Suite 1
Rocklin, California 95677

Dear Dr. Laidlaw:

Thank you for providing Alex M. Azar II, Secretary of Health and Human Services (HHS), and Dr. Francis Collins, Director of the National Institutes of Health (NIH), with a copy of your letter to Dr. Jerry Menikoff, Director of the Office of Human Research Protections (OHRP) at HHS. Your letter outlined your concerns regarding an NIH-funded study (R01 HD082554-01A1: *The Impact of Early Medical Treatment in Transgender Youth*). The study, which is in the fifth and final year, is funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). As the Director of NICHD, I have been asked to respond to your letter. An important part of NICHD's scientific mission is to ensure that every person is born healthy and that all children have the chance to fulfill their potential to live healthy and productive lives.

Upon learning of the concerns of the Kelsey Coalition, NIH shared all pertinent grant materials, including the protocols, consent forms, and assent forms, with OHRP. OHRP is currently reviewing these materials for an assessment of the risk to human subjects and the adequacy of the consent process.

The application was originally submitted in response to a Funding Opportunity Announcement (PA12-111) entitled: "Research on the Health of LGBTI Populations." Prior to award, the application went through a rigorous peer review process, receiving a highly meritorious score in the study section, indicating that the scientific community considered that the proposed work would have a high impact on the medical community. The application was also reviewed by NICHD's Advisory Council. My predecessor at NICHD, Dr. Alan Guttmacher, made the final funding decision. To ensure that appropriate progress is being made and appropriate patient protections are in place, NICHD scientific staff have rigorously reviewed the grant each year.

The main purpose of this observational study is to gather evidence on the hormonal treatment of transgender youth to inform the medical community of potential yet unknown benefits or risks that may lead to changes in current treatment guidelines for such individuals. This multicenter study is the first in the United States to evaluate longitudinal outcomes of medical treatment for transgender youth. Children with gender dysphoria are brought to endocrine clinics by their

parents and often referred by their local primary care physician. Physicians at the funded academic centers follow current guidelines for the therapy of transgender youth.[1] Independent of the administration of hormonal therapy, each transgender child and their parent/guardian, who are willing to enter the study, sign an assent or consent for further evaluation by the study investigators. The transgender youth and their parent/guardian sign the protocol consent only if they wish to participate in the NIH-sponsored observational study to allow study personnel to follow their progress. Therefore, study personnel collect data on both treated and untreated children who seek advice and therapy for gender dysphoria.

Notably, these research participants and their parents sought and obtained the hormonal therapies independent of the protocol. Therefore, termination of the protocol would not end the treatments; rather, it would only end the compilation of data needed to advance scientific understanding of the risks and likely outcomes of those treatments. The parents and transgender youth sign consent/assent for the study investigators to monitor outcomes to help them assess the effects of hormonal therapy, including medical risks, and physical and psychological outcomes. As there are few studies to inform physicians about care for this patient population, these data are critical to assure improved outcomes. *Nature Reviews Endocrinology* has published an excellent review[2] of this topic.

Thank you again for writing and for your continued interest in the research activities supported by NIH and NICHD.

Sincerely,

Diana W. Bianchi MD

Diana W. Bianchi, M.D.
Director, NICHD

[1] Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline J Clin Endocrinol Metab 2017 Nov 1;102(11):3869-3903. doi: 10.1210/jc.2017-01658.

[2] Kreukels BP, Cohen-Kettenis PT. Puberty suppression in gender identity disorder: the Amsterdam experience. Nature Rev Endocrinol. 2011 May 17;7(8):466-72. doi: 10.1038/nrendo.2011.78. Review.

The Kelsey Coalition
Working to change the systems that failed our kids

April 5, 2019

Jerry Menikoff, M.D., J.D.
Director
Office for Human Research Protections
1001 Wootton Parkway, Suite 200
Rockville, MD 20852

Re: "The Impact of Early Medical Treatment in Transgender Youth"
NIH Project #1R01HD082554-01A1
Application # 8965408

Dear Dr. Menikoff:

We request that the Office for Human Research Protections (OHRP) place an immediate moratorium on the above-referenced study, *The Impact of Early Medical Treatment in Transgender Youth,* while investigating whether informed consent laws have been violated. We make this request on behalf of the Kelsey Coaliton, a new and rapidly growing national group of hundreds of parents whose children suddenly began identifying as transgender.

In 2015, the National Institutes of Health awarded a five-year, $5.7 million dollar grant to a consortium of four pediatric gender clinics for an observational study that purportedly will "evaluate longitudinal outcomes of medical treatment for transgender youth and will provide essential evidence-based data on the physiological and psychosocial effects and safety of treatments.[1] Given the numerous deleterious side effects of these medications that we will describe, and the lack of FDA approval for cross-sex hormones even in adult populations, the likelihood of serious harms accruing in these young patients is very great.

The medical protocol for this study involves treating transgender-identifying children who are otherwise perfectly healthy with powerful drugs that radically modify their endocrine systems, and indeed, their entire young bodies. Children in early puberty are given "puberty blockers"; older children are given cross-sex hormones. These treatments negatively impact fertility, sexual function, cardiovascular health, bone health, and brain development.[2] [3] This study has no control group and is not randomized. It is simply an observational experiment on otherwise unremarkable, healthy children with confusion about their sexed bodies. Fertility and sexual functioning will certainly be impacted, as hypogonadotropic hypogonadism is being

[1] NIH Grant: The Impact of Early Medical Treatment in Transgender Youth., Project No. 1R01HD082554-01A1. SF 424 (R&R) 05/2015.

iatrogenically induced by GnRH agonists such as Lupron. This puberty blockade is being used on children as early as Tanner Stage 2, before fertility is established. When these children go on to cross-sex hormones and then gonadectomy, they will be permanently sterilized.[23]

Due to our concerns regarding possible ethical violations, the lack of ability of children or their parents to consent to the serious side effects of this therapy, and potential violations of laws protecting human subjects, we submitted a FOIA request to the NIH to examine the research protocol and progress reports.

After multiple attempts, we were unable to obtain the blank templates used for the informed consent forms used in this study (which was clearly listed as being in Appendix B of the protocol).[4]

But what we recently discovered from the 2017 progress report was alarming: the minimum age for cross-sex hormone inclusion was decreased from age 13 to age 8.

> "the minimum age for the cross-sex hormone cohort inclusion criteria was decreased from 13 to 8 to ensure that a potential participant who could be eligible for cross-sex hormones based on Tanner Staging [meaning stage of puberty] would not be excluded due to age alone."[5]

Furthermore, the 2018 progress report shows that 19 children were recruited in the new 8-12 year-old group to receive harmful cross sex hormones.

> "To date we have recruited...19 of the 60 participants and they make up 6.8% of the CSH [cross sex hormone] cohort."[6]

This means potentially that girls as young as eight years old are being given testosterone to simulate a false puberty of the opposite sex. Boys as young as nine are being given estrogen to attempt to crudely mimic female puberty. The doses given are far in excess of the normal range for their respective sexes. Cross-sex hormones have already been shown to lead to an

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[2] Laidlaw MK, Van Meter QL, Hruz PW, Van Mol A, Malone WJ. Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline". The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 3, 1 March 2019, 686–687, https://doi.org/10.1210/jc.2018-01925

[3] Laidlaw MK, Cretella M, Donovan K. "The Right to Best Care for Children Does Not Include the Right to Medical Transition". The American Journal of Bioethics. Volume 19. Published online 20 Feb 2019. 75-77. https://doi.org/10.1080/15265161.2018.1557288.

[4] NIH Grant: The Impact of Early Medical Treatment in Transgender Youth., Project No. 1R01HD082554-01A1. SF 424 (R&R) 05/2015, p.1.

[5] 2017 Progress Report. "The Impact of Early Medical Treatment in Transgender Youth". NIH Project #1R01HD082554-01A1. p.23 F.2.

[6] 2018 Progress Report. "The Impact of Early Medical Treatment in Transgender Youth". NIH Project #1R01HD082554-01A1. P.19 F.2.

increased risk of myocardial infarction and death due to cardiovascular disease in adult males and females.[7]

The basis for inclusion in the study is little more than a child's self-identification as transgender. There are no blood tests, genetic tests or imaging to prove this "identity." Indeed, increasing evidence shows that many underlying factors[8] influence transgender identities: mental health issues, autism, ADHD, trauma, sexual confusion, as well as peer and media influences.[9]

It is impossible to predict whether these children in the study will change their minds, or if these hormonal interventions will be regretted after they have already caused serious irreversible harms, including infertility.

We contend that neither children, nor their parents, can meaningfully consent to permanent infertility, or other potentially serious medical harms, to treat a non-medical condition. We question whether these parents were fully informed of the health risks, or the possibility of tragic regret, before allowing their children to be treated with dangerous hormones for five years, and quite likely, much longer.

Thus, we believe that this trial violates Department of Health and Human Services (HHS) regulations protecting human subjects, specifically the general requirements and documentation required for informed consent, 45 CFR § §46.116-17.

Because this study poses irreversible medical harms (including infertility) to children, we request an immediate moratorium and investigation. Thank you for your prompt attention to this important and urgent matter.

Sincerely,

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[7] Irwig MS.Cardiovascular health in transgender people .Rev Endocr Metab Disord. 2018;19(3):243–251.

[8] Holt V, Skagerberg E & Dunsford M. (2014). Young people with features of gender dysphoria: Demographics and associated difficulties. Clinical child psychology and psychiatry. 21. 10.1177/1359104514558431.

[9] Littman L (2019) Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLOS ONE 14(3): e0214157.

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Attachments:

(1) Grant-Protocol-r_R01HD082554-01A1.pdf
(2) Olson-NIH-Progress-Report-2018.pdf
(3) Olson-NIH-Progress-Report-2017.pdf
(4) ajob-affirmative-care-Laidlaw-Cretella-Donovan-final.pdf
(5) JCEM-letter to ed-laidlaw-et-al.pdf