

FDA Advises RIGT on Pathway for Federal Approval of Gender Affirming Therapy

The Research Institute for Gender Therapeutics (RIGT), a non-profit pharmaceutical organization, and 501(c)(3) public charity, has gained feedback from the U.S. Food and Drug Administration (FDA), in a formal Type B meeting, that would pave the way for federal approval of a gender-affirming hormone therapy.

RIGT proposed to FDA a development plan for estradiol as a feminizing agent for the treatment of gender incongruence. The goal of this development program is a stand-alone form of estradiol with a singular indication for people with gender incongruence. The program would be the most advanced ever conducted for gender-affirming care and would be a historic first.

“The FDA’s recognition of our proposal and provision of an acceptable program is an acknowledgement of the essential medical care that gender-affirming hormones provide. Our next step is to secure funding to conduct our program with estradiol as outlined by FDA,” said Nicole J. LaRocque, Founder and Chief Operating Officer of RIGT.

Through its discussions with RIGT, FDA has officially recognized the medical appropriateness of a formal development program for gender-affirming care, marking a significant milestone for the gender-diverse community.

Estradiol, the focal point of this initiative, is one of the primary therapeutics recommended for use as a feminizing agent in the management of gender incongruence. Backed by a robust body of evidence compiled over more than four decades, treatment for gender incongruence is associated with improved mental and physical health for transgender individuals.

This is a critical step in RIGT’s larger mission to research, develop, and gain FDA approval for therapeutic options for gender incongruence. Gender incongruence, sometimes called gender dysphoria, is when the gender identity of a person does not align with the gender assigned at birth. Gender incongruence is recognized by every major U.S. medical association and the World Health Organization as a serious medical condition, and untreated gender incongruence is associated with mental health concerns such as depression, psychological distress, and suicidal ideation and attempts.

This groundbreaking work will reshape healthcare access for gender-diverse populations and promote important representation for this underserved community.

About The Research Institute for Gender Therapeutics

The Research Institute for Gender Therapeutics (RIGT) is a registered 501c3 public charity that was founded to address the significant unmet medical and social needs of gender diverse individuals. The clinical treatment of gender diverse individuals is often stigmatized, under-researched, and there are no treatments specifically approved by the FDA to treat gender incongruence. RIGT was established to address these issues and has recruited a team of world-renowned experts in gender care and drug development to guide our organization and help support a world where the treatment of gender diverse individuals is broadly accessible and accepted as standard medical practice.

For more information, or to donate, please visit www.rigt.org

Contacts

Leo Caldwell

Director of Communications

Lncaldwell@rigt.org

The Research Institute for Gender Therapeutics, Inc.

Rigt.org