The Food and Drug Administration (FDA) recently held a listening session with transgender adolescents to learn about their health care challenges and unmet medical needs.

The small, nonpublic meeting was part of the FDA's Patient Listening Session program, which allows the agency to hear patient and caregiver perspectives on living with diseases and conditions, perceptions of risk tolerance and unmet medical needs, and preferences related to clinical trial participation. The listening sessions are among the ways the FDA includes the voices of patient communities in medical product development and the regulatory process, particularly communities that have been historically underrepresented.

Adolescents’ perspectives on transgender health are important, as many transgender teens begin hormone therapies and hormone-blocking therapies around puberty.

During the listening session, adolescents ages 13 to 17 years said the most important outcome is for their body (gender presentation) to match their internal identity. In discussing benefit-risk tradeoffs related to medical transition, adolescents described a willingness to accept risks associated with surgeries and treatments to achieve their goals related to gender transition and presentation.

The adolescents also discussed their experiences with mental health concerns, gender dysphoria, challenges accessing gender-affirming medical care, the need for age-appropriate educational resources for gender-affirming care and barriers to accessing health care due to state laws and discrimination.

This was the first listening session that included only adolescent participants. Therefore, the FDA addressed privacy concerns by seeking parental consent for minor participation. It also took care to use gender-affirming language and age-appropriate communications.
The Patient Listening Session program is managed by the Office of Patient Affairs in the Office of the Commissioner. The Office of Patient Affairs hopes to continue to bring patient voices to the FDA, including those of youths in underrepresented populations.

The FDA’s Office of Pediatric Therapeutics (OPT), Office of Patient Affairs (OPA), Division of Pediatric and Maternal Health (DPMH) and Division of Urology, Obstetrics and Gynecology (DUOG) contributed to this article. OPT and OPA reside in the Office of Clinical Policy and Programs in the Office of the Commissioner. DPMH and DUOG reside in the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine within the Office of New Drugs in the Center for Drug Evaluation and Research.

Resources

- Summary of the transgender adolescent listening session
- FDA Patient Listening Session webpage
- FDA Patient Listening Session summary page

Copyright © 2021 American Academy of Pediatrics