

Healthcare Challenges and Unmet Medical Needs of Transgender Adults - FDA-Requested Listening Session (Session #1)

June 1, 2021

Objectives of Session

- To gain a better understanding of the barriers to obtaining health care, areas of unmet medical need, and the most important goals of individuals who are contemplating, undergoing, or who have completed transition to their affirmed gender.

Discussions in FDA Listening Sessions are informal and not meant to replace, but rather complement, existing patient engagement opportunities in the Agency. All opinions, recommendations, and proposals are unofficial and nonbinding on FDA and all other participants. This report summarizes the input provided by persons from the transgender community at the meeting. To the extent possible, the terms used in this summary describe the health needs, perspectives, preferences and impacts reflect those of the individual participants. This report is not meant to be representative of the views and experiences of the entire transgender population or any specific group of individuals or entities. There may be experiences that are not mentioned in this report.

Summary of Discussion by Question

Round 1 – Perspectives related to gender transition

- **In thinking about where you are in your transition right now, what outcomes are most important to you in your transition? What are your ultimate goals with regard to your transition?**
 - Six of the participants stated that an important outcome for them in their transition is their body and voice matching their affirmed gender.
 - Participants mentioned various examples of gender affirmation procedures such as phalloplasty, hysterectomy, voice surgery, and hormones.
 - Three participants shared that an important outcome at this point in their transition is their safety and well-being.
 - Three participants noted that an important outcome is accessible, consistent, transparent, and qualified medical and surgical care.
 - Participants shared that many physicians do not have experience working with individuals who are contemplating, undergoing, or who have completed transition to their affirmed gender.
 - A participant shared that it is difficult for people undergoing their transition to find “good” (qualified) doctors covered by their insurance plans.
 - All participants mentioned that their ultimate goal in regards to their transition is to feel “at home” in their bodies and to feel as though they are accepted by society.
- **Follow up question from CDER’s Division of Urology, Obstetrics & Gynecology: This question is for those of you have mentioned completing transition and moving beyond transitioning and living a normal life as your affirmed gender. When would you consider your transition complete, or is there a “completion point” or point at which you feel your transition is acceptable to you?**
 - Three participants responded to this follow up question.

- All three participants mentioned that there is not a completion point in regard to their transition. All are on hormones and will be for the rest of their lives.
- One participant shared that physical transitioning does need to have an endpoint and access to affordable, accessible healthcare is important.
- Another participant stated that their transition stopped for them when they decided to finish making physical changes to their body, but their body is still undergoing changes.
- **FDA recognizes that surgeries, medical procedures, and treatments (such as hormone therapy) can involve potential risks. We are interested in understanding how you view these risks. What risks of treatment or surgeries are you willing to accept to achieve your goals related to your transition? For example, how do you view the potential for serious side effects of hormone treatment, such as strokes and heart attacks? How do you find (or learn about) information on the risks associated with these treatments or surgeries?**
 - All participants stated that they are willing to accept any risks related to surgeries, medical procedures, and treatments in order to achieve their goals.
 - Four participants mentioned that risks related to treatments, surgeries, or procedures are a better alternative than doing nothing which can lead to gender and body dysphoria and, ultimately, an increased risk of self-harm.
 - All participants shared they have experienced a lack of sharing information related to risks from healthcare providers.
 - One participant noted they have had doctors who are willing to explain potential risks.
 - One participant mentioned they are fortunate to have a degree in Public Health as it has allowed them to be knowledgeable about gathering information about risks and researching LGBTQ medical conferences and forums. The participant also works to develop a curriculum for the rest of their community in order to better train providers.
 - Two participants shared that they receive information on risks from elders and friends within the LGBTQ community.
 - Three participants stated they do their own research including finding information online.
- ***Follow up question from CDER's Division of Urology, Obstetrics & Urology: How do you feel about enrolling in clinical trials or being part of registry to collect information about surgical and medical treatment? Do you feel people would be excited about that to better study treatments/regimens/methods that have been shown to work better?***
 - Four participants responded to this question.
 - All four stated that they would be excited to participate in a registry or clinical trial.
 - One participant was clear that their participation would be dependent on the goal/endpoint of the registry. They noted that there isn't a common goal shared by people who identify as trans. One person's goal might not align with another's.
- ***Follow up question from CDER's Division of Psychiatry: Some risks are necessary, and some aren't. Involving transgender and non-binary folks in research could give us more info. We can educate physicians about not just hormone therapy but also therapies for a host of disorders transgender and non-binary people have. Labelling is gendered, very binary, doesn't include transgender and non-binary. This might affect what providers can do. How has that been***

addressed in your personal care? Is there a way that labeling changes (patient or physician) can make data we have more clear?

- Two participants responded to this follow up question.
 - Both participants mentioned binary labeling as a barrier to obtaining necessary medications.
 - One participant stated that they have experienced providers denying access to medications due to the binary labeling. If the person hoping to obtain a prescription does not fit the criteria listed on the medication label, then the provider won't prescribe the medication.
 - Another participant expressed the belief that the medical community wishes trans people would go away so that everyone fits into a binary labeling system.
- **What would you consider to be a significant or meaningful improvement to your quality of life (such as looking or feeling a certain way) that currently is not being addressed?**
 - Three participants stated they would like their insurance to provide higher quality coverage for gender affirmation procedures as well as covering physicians who are more experienced in regard to transgender healthcare needs.
 - One participant shared that they are unable to have surgeries they desire as the procedures are currently considered cosmetic and therefore, not covered by their insurer.
 - Another participant mentioned they'd like insurance companies to offer coverage for more holistic treatments and procedures.
 - One participant reiterated that it would be a significant improvement to their quality of life if they are able to more fully physically match or "pass" as the gender they identify with.
 - A participant noted that it would be meaningful to have access to some form of post-operation care following gender affirming procedures.
 - A participant stated that the approval of products that provide female-level testosterone levels would be a significant improvement to quality of life.
 - Better access to information and treatments for hair removal and hair regrowth were also mentioned as meaningful by a participant.
 - One participant shared that the most meaningful improvement to their quality of life would be acceptance.

Round 2 – Healthcare challenges, barriers & unmet medical needs

- **What barriers unrelated to costs or insurance coverage have you experienced accessing the healthcare that you need?**
 - Over half of the participants stated that they have experienced barriers obtaining medications. Specific barriers include difficulties obtaining testosterone due to its classification as a controlled substance, travel time to pharmacies that will fill prescriptions, and caps or restrictions on gender affirming medication.
 - Three participants mentioned they have experienced gatekeeping by physicians while accessing needed healthcare specifically regarding gender affirming surgeries and medications.
 - Three participants expressed that they have had issues with finding knowledgeable, qualified healthcare providers near their locations.

- **What healthcare-related products are your most important need? Are there certain unmet areas of need?**
 - Almost all of the participants stated that access to consistent hormones is their most important healthcare need.
 - Three participants noted that hair replacement/removal procedures are important. One of these participants also mentioned greater access to quality wigs.
 - One participant shared that for they would like easier access to gender affirming procedures such as a hysterectomy.
 - One participant added that medical-grade top binders are an unmet area of need.
 - A participant mentioned fillables as an alternative to surgeries for transgender women who are hoping to achieve a more feminine looking face.
 - Safe and realistic breast implants were mentioned by a participant as an important healthcare need.
- **Follow up question from CDER's Division of Psychiatry: One of the participants mentioned that treatment goals were very individual; could the participants comment on the range of treatment goals there might be for hormone therapy?**
 - One participant responded to this follow up question.
 - The participant shared theirs and their friends' experiences. Not all people undergoing hormone therapy have the same treatment goals. Some might want facial hair, others might not; some might want a lower voice, others might not; some might want their chest to be flat, others might not. The process is individual and requires a knowledgeable medical provider to achieve the individual's desired outcome/s.

Round 3 - Miscellaneous

- **How and where do you find support services, including those related to medical and mental healthcare, that you may need?**
 - This question was not asked during the session due to time constraints.
 - One participant did provide a written response to this question after the session. They mentioned they find support services through their local LGBTQ Center, online via Facebook and Reddit, as well as through National Trans-led organizations with mental health providers.
 - Regarding their mental healthcare, they noted that they pay out of pocket for these services as the local providers covered by their insurance are not trans-affirming and/or do not have knowledge or experience working with trans identified clients.

FDA Offices and Divisions in Attendance

- Office of the Commissioner
 - Office of Patient Affairs (*organizer*)
 - Attendees: Oncology Center of Excellence; Office of Clinical Policy & Programs; Office of Clinical Policy; Office of Orphan Products Development; Office of Pediatric Therapeutics; Office of Regulatory Science and Innovation; Office of Stakeholder Engagement; Office of Women's Health
- CBER
 - Attendees: Office of the Director

- CDRH
 - Attendees: Division of Health Technology III B; Division of Health Technology IV A; Office of Clinical Evidence & Analysis; Patient Science & Engagement
- CDER
 - Division of Urology, Obstetrics, & Gynecology (*requestor*)
 - Other Attendees: Compounding Branch 3; Division of Biometrics II; Division of Biometrics III; Division of Biometrics IV; Division of General Diabetes, Lipid Disorders & Obesity; Division of General Endocrinology; Division of Oncology I; Division of Oncology III; Division of Pediatrics & Maternal Health; Division of Psychiatry; Division of Rare Diseases and Medical Genetics; Division of Regulatory Operations for Rare Diseases, Pediatrics, Urology & Reproductive Medicine; Office of the Center Director; Office of Clinical Pharmacology

Non-FDA Attendees

- Reagan-Udall Foundation for the FDA
- European Medicines Agency

Participants Represented

- Seven participants participated in this session.
- Participants' ages ranged from 29-59.
- Participation in this session included people who were assigned female at birth as well as participants who were assigned male at birth.
- Participants identified as trans-male, trans-female, non-binary/agender/non-conforming, two-spirit, and a preference to self-describe.

Prior to the Listening Session, Participants Shared

- A majority of participants have already had or are currently having hormone therapy.
- A majority of participants shared that their biggest concern regarding their overall health and mental health is exclusion or denial to qualified, knowledgeable healthcare providers.

Financial Interest

Participants did not identify financial interests relevant to this meeting and are not receiving compensation for participation in this listening session.