FDA U.S. FOOD & DRUG ADMINISTRATION

Insights from FDA Listening Session with Transgender Youth

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FDA Patient Listening Session Program

Overview

What is an FDA Patient Listening Session?

- One way that patients & advocates can **share their experience** about a disease, condition, or health experience
- Participants can **talk directly with FDA** scientific staff
- A **resource** for FDA's medical product Centers to **quickly engage** with patient or advocacy community
- Starting point to **inform regulatory decision-making** & early-stage R&D
- In collaboration with National Organization for Rare Disorders **(NORD)** and the **Reagan-Udall Foundation** for the FDA
- **40+ Listening Sessions held** since late 2018
- Can be **requested by FDA or the patient community**

Understanding FDA's Patient Listening Sessions

What do Listening Sessions look like?

ARE

- **Non-public, non-advisory** discussions between FDA staff and **patients, their caregivers, and/or their advocates**
- **1 to 1.5 hour** meetings
- Via **phone, in person** at FDA or a **mix of the two**
- Meant to facilitate **expeditious sharing of patient or advocate perspectives** on:
  - Disease burden
  - Treatment burden
  - Impact on daily activities
  - Priorities to consider in medical product development programs

Are NOT

- Open to **industry**
- Avenues for the endorsement of **specific medical products**
- Able to guarantee **representative or comprehensive perspectives** on disease or treatment burden
- Meant to take the place of **other patient input and engagement processes**, e.g., the FDA Patient Representative Program, Patient-Focused Drug Development (PFDD) Meetings

Healthcare Challenges & Unmet Medical Needs in the Transgender Community

FDA-requested Listening Sessions with adults & adolescents

Transgender Health Listening Sessions

- **FDA-wide interest** in topic
  - Request from Center for Drug Evaluation and Research (CDER)
  - Center for Devices & Radiological Health (CDRH) & Center for Biologics Evaluation & Research (CBER)

- **Transgender adults (18+)** and **adolescents (13-17)** who are contemplating, currently undergoing, or have already **transitioned to their affirmed gender**
  - Hormone or hormone blocking therapies; gender-affirming surgeries

- **2 sessions:** June 1 (adults) & June 29 (teens)

- Objectives are to better understand:
  - **barriers to obtaining healthcare**
  - areas of **unmet medical need**
  - **goals related to gender (medical) transition**

Considerations – trans youth

- Education: the importance of using **affirming language & terminology**
  - **Pronoun usage; gender identity**
- Communications:
  - Language on **website & communications materials** (E.g. - health-related experiences and needs)
  - **Age-appropriate** language
  - Communication with parents
- **Written consent** for youth participation: Consulted with FDA Office of the Chief Counsel
- Outreach: **building & leveraging relationships**; social media; word-of-mouth

Insights

- Teens were articulate, well-prepared, & provided insightful comments
- Confident & **assured about identity** at a young age
- **Need more information**/resources aimed at teens
- **Representation** in pop culture/media is important
- Suicidal ideation & attempts, depression, **mental health**
- **Fear** and physical and emotional **safety**
- Transitioning is "life or death" – willing to risk severe adverse events in order to live/present as their affirmed gender
- A **good support system** is crucial (family, friends, therapist)
- Inadequacy in healthcare system (**lack of provider knowledge**, costs), **laws**, and gov't
- Session will be used to educate review staff; inform guidance development & regulatory decisions.

Youth-Focused Listening Sessions: Future Considerations

- More youth-based contacts – schools, youth organizations
  - Underrepresented communities
  - Relationship/trust-building
- Leverage social media platforms preferred by Gen Z (TikTok, Instagram) for outreach
- Time of the Listening Session: time of year; time of day
- Communication via text messaging vs. phone calls and emails
- Online platforms (Zoom) vs. teleconferences
- Consent: e–signed form; communications
- Flexibility in planning

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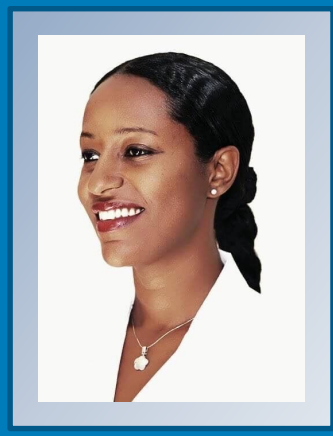
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