# FDA and CTTI Patient Engagement Collaborative Meeting

May 11, 2023 | 12:30 – 2:30 pm ET | Zoom Virtual Meeting

***Disclaimer:*** *The purpose of this meeting was to facilitate a discussion of ideas, and as such, not all of the content below will be within the scope of the FDA or PEC. The views and opinions expressed in this meeting are those of the individual speakers and participants and do not necessarily reflect the official views of their organizations, the FDA, or CTTI.*

### Meeting Overview

A representative from the FDA Center for Biologics Evaluation and Research (CBER) presented an overview of their center and patient engagement opportunities with CBER. Next, PEC members provided high level feedback on potential content updates for the FDA's Patient Listening Sessions webpages. Lastly, a PEC member presented her patient organization's research on how direct-to-consumer pharmaceutical advertising on social media and lack of representation in clinical trials affect adolescents and young adults.

### Overview of FDA Center for Biologics Evaluation and Research (CBER)

- The Center for Biologics Evaluation and Research (CBER) regulates biological products for human use, including extracts used to test allergies, human tissues and cellular products, gene therapies, vaccines, and devices related to biologics.
- CBER is active in patient engagement and collaborates with other centers and offices across the FDA on patient engagement efforts.
- CBER patient engagement activities include:
    - participating in agency initiatives like the PEC and cross-center patient experience listening sessions
    - providing patients, caregivers, and advocates with information about regenerative medicine therapies and opportunities to advance product development through their #RegenMedEd educational workshop and webinar series
    - holding patient-focused drug development (PFDD) meetings and sending CBER staff to externally-led PFDD meetings

*Discussion*

- *CBER will continue the #RegenMedEd program, addressing common questions that came up in previous sessions.*
- *Patient engagement staff at CBER and other FDA centers meet regularly to coordinate and share information on patient engagement.*

### Review of Proposed Updates for FDA Patient Listening Sessions Web Pages

*The FDA is planning to update the Patient Listening Sessions web content and asked PEC members for their input on proposed changes and suggestions for additional information that would be helpful to include for patients and patient advocacy groups.*

PEC members suggested including:

- A way for FDA to connect patient group representatives, who have participated in an FDA Patient Listening Session, with patient groups who have not, so they can share advice and perspectives on their experience.
- Information about FDA-Requested Listening Sessions versus FDA Patient-Led Listening sessions, the purpose of FDA Patient Listening Sessions, the kinds of topics they can cover, the ideal time to organize them, opportunities for patient groups to collaborate, and the outcomes of listening sessions.
- Information to help patients and patient advocacy groups identify the FDA engagement opportunities that would best fit their needs.

**PEC Member Presentation:** Generation Patient

- Direct-to-consumer (DTC) pharmaceutical advertisements on social media platforms like TikTok and Instagram can go viral, allowing them to reach a much larger audience.
- The FDA Office of Prescription Drug Promotion (OPDP) has oversight of advertisements for prescription medications. The landscape of DTC advertising on social media has changed significantly since their DTC guidance was updated in 2014.
- Young adults are often grouped with older adults in clinical trials and treated similarly in clinical care, despite growing evidence that young adults experience different outcomes.
- Identifying and reporting on subgroups of adolescents and young adults could improve study data on the safety and efficacy of medical products.

*Discussion*

- *Social media could be an effective way to recruit young adults and increase their representation in clinical trials. However, there aren't many examples to follow and there are significant ethical issues to consider in using social media to recruit participants.*
- *Social media influencers driving health misinformation/disinformation are from many different backgrounds, including healthcare. Many people, especially young people, find it difficult to identify trusted sources of health information.*

**Conclusion and Next Steps**

The FDA and CTTI will review the discussion points and ideas generated during this meeting. The FDA will share comments from this meeting with agency departments to facilitate engagement with patient communities and PEC members. The third annual joint meeting between the PEC and the European Medicines Agency's (EMA) Patients' and Consumers' Working Party will be held on July 20.

The PEC is a public-private partnership between the FDA and the Clinical Trials Transformation Initiative (CTTI) that is not intended to advise or direct the activities of either organization. The PEC is primarily a forum to facilitate the exchange of information between patient community representatives and the FDA on areas of common interest, including regulatory discussions and strategies to increase patient engagement. Public summaries of all PEC meetings are available on the PEC website.