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

The purpose of this virtual meeting was to discuss the Reagan-Udall Foundation’s recent report outlining strategies for improving public understanding of FDA-regulated products. This meeting also included a review of the PEC’s recent meetings and activities and an opportunity for PEC members who will be ending their terms this year to share their highlights from participating in the PEC.

Strategies for Improving Public Understanding of FDA-Regulated Products

- The Reagan-Udall Foundation for the FDA released a report on “Strategies for Improving Public Understanding of FDA-Regulated Products” outlining their findings on how people find, consume, and perceive health information – especially regarding FDA-regulated products.

- According to research from the report, sound science, sound policy, and sound communication are the three most fundamental pieces to the FDA’s success.

- The Reagan-Udall Foundation’s research identified three key strategies for combatting misinformation and building public trust: “Prebunking” health misinformation, delivering credible information directly to consumers, and maintaining a clear and humble tone. The Reagan-Udall Foundation believes that everyone at the FDA – not just professional communicators – has a role to play in improving public understanding of FDA-regulated products.

Year in Review

- Over the past couple years, the PEC has welcomed several speakers and opportunities for learning, including presentations on the importance of the patient voice at the FDA. Topics included an overview the FDA orphan drug designation process, understanding the FDA Center for Biologics Evaluation and Research (CBER), an introduction and discussion on the FDA Guidance
Snapshots pilot program, the value of CTTI's diversity recommendations, and PEC member presentations on the impact of direct-to-consumer advertising on social media, and the importance of including adolescents and young adults in clinical trials.

- PEC members also engaged with members of the European Medicines Agency’s (EMA) Patients’ and Consumers’ Working Party (PCWP) in two annual joint meetings in 2022 and 2023, sharing communications and engagement lessons learned from the COVID-19 pandemic and perspectives on decentralized clinical trials.

- Over the past two years, some of the key topics and challenges discussed by members of the PEC included increasing awareness of existing engagement mechanisms among patients and patient groups, reaching patients who aren’t engaged with patient advocacy groups, investing in patients’ education to empower them to act as representatives of their broader community, improving communications between the FDA and patients, and ensuring that FDA resources are accessible to lay audiences.

- The eight PEC members who will be ending their terms this year discussed some of their highlights from participating in the PEC, including getting to meet with other patient groups, getting more connected with the FDA, hearing from a broad range of speakers and learning about various topics related to drug development and patient engagement, being able to contribute their unique voices and perspectives, and connecting with the PCWP to discuss improving patient care on a global scale.

**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. An orientation for new PEC members will be held in January 2024, and the next full PEC meeting will be held in February 2024.