

Patient Engagement Collaborative (PEC) Meeting Summary

October 5-6, 2020

OVERVIEW

This virtual meeting built upon prior Patient Engagement Collaborative (PEC) discussions of a potential patient outreach and education program, focusing on discussing informational needs from the broad range of patient communities that may be addressed in an initial set of written fact sheets in development by FDA. Working titles/topics for these educational resources include: Welcome to the FDA, FDA: Myth vs. Fact, FDA Patient Engagement Opportunities, and Medical Product Approval Overview. Discussion emphasized the latter two topics, as well as progress toward launching the pilot outreach and education program, and refining a vision for the future of the PEC. The FDA's Dr. Anand Shah provided opening remarks to the PEC highlighting the importance of the patient voice in medical product development.

EDUCATIONAL RESOURCES – DISCUSSION THEMES

- Different audiences may need and desire differing levels of detail
- Ensure resources build trust among patient communities
- Convey why the patient perspective is important in FDA's work, potentially with examples
- Emphasize the range of opportunities for patients to engage with FDA (shorter- to longer-term, individually and via patient groups, in-person and remotely), along with information about how to participate
- Clarify common FDA terminology, and also clarify terms FDA does not use but that are often used in private company consumer advertisements and similar
- Convey FDA's role in the broader medical product development process, including what is outside of FDA's scope (but commonly perceived otherwise)
- The medical product development and review process is particularly challenging for the general patient community to understand, in part because even simplified explanations tend to make extensive use of unfamiliar jargon

FUTURE VISION FOR THE PATIENT ENGAGEMENT COLLABORATIVE (PEC) – DISCUSSION THEMES

- Consider developing a metric to assess success
- In terms of both PEC membership and topics addressed, emphasize:
 - Diversity, including racial, ethnic, sociodemographic, age, gender, geography, and other factors
 - Engaging teenagers and young adults, and learning from experiences with broader range of communications approaches

- Enhancing caregiver engagement
- Continue exploring opportunities for FDA to enhance:
 - Engagement with individual patients, including feedback mechanisms for individual patients to understand their impact.
 - FDA outreach to the patient community for feedback (as contrasted with patients feeling they have to ‘knock on the door’)
- Members also discussed suggestions to:
 - Increase partnership within and across FDA
 - Identify opportunities for patients to be more deeply ‘embedded’ in agency activities, in order to provide first-hand knowledge that could be shared within their communities
 - Explore as many communication mechanisms as possible for educating and engaging with patients and the public, including face-to-face

CONCLUSION AND NEXT STEPS

PEC member’s ideas, insights and information shared during this meeting will help inform ongoing efforts by FDA’s Patient Affairs Staff (PAS) to develop educational resources for a pilot program. This program is envisioned as an approach to:

- Support two-way communication between patients and FDA;
- Educate patient communities about FDA’s activities; and
- Inform patients and caregivers about how they can provide their experiences and perspectives to enhance and strengthen FDA’s public health work.

DISCLAIMER

The views expressed in this meeting summary represent the individual perspectives of the attendees and do not necessarily represent the official views of the FDA or CTTI or of any organization with which the attendees are affiliated. Discussions and responses are not intended to establish binding agreements pertaining to medical product development programs or to discuss proprietary information pertaining to specific development programs under FDA review.