

Patient Engagement Collaborative (PEC) Meeting Summary

September 11, 2019
Rockville Hilton
1750 Rockville Pike, Rockville, Maryland

OBJECTIVES

- Complete discussions of how to enhance FDA website content for the patient community.
- Define vision, scope, and objectives for an FDA Ambassador program.
- Initiate work on Ambassador program, including discussions of audiences, ambassador characteristics, and supporting tools/resources.

KEY TAKEAWAYS

Over the course of the day's discussion, PEC members came to several key takeaways for further consideration:

- Before the FDA launches its enhanced website geared toward patient engagement, FDA representatives may want to consider consistency of content, different methods of visual organization, and using images of real people. The FDA's goal is to launch the website in late 2019 or early 2020 and then disseminate the website as discussed with the PEC.
- Underrepresented populations need to be considered throughout development processes, both for the website and the pilot FDA Ambassadors program. Content could be developed in other languages, especially in Spanish, in tandem with the English versions. If a phased approach is necessary, FDA could release a potential timeline for when translations will be completed.
- Patients are receptive to (or motivated by) personal stories of successful patient engagement with the FDA and examples of PEC members' experiences developing materials with the FDA.
- The FDA Ambassadors program could respond to a wide range of challenges, from clearing up confusion about the FDA's role in regulatory processes to alleviating distrust of FDA in certain communities.
- A sustained, long-term engagement effort is needed to truly build trust in a community and relationships between target audiences. Bidirectional communication and a continuous feedback loop can benefit both parties.
- There are a broad range of options for potential audiences for the FDA Ambassadors program. Audiences could include not only patients, but also clinicians and industry partners so they can partner to help patients engage with the FDA.

SESSION I: COMPLETE PEC DISCUSSION OF WEBSITE UPDATES

Viewing a Mockup of the Website Redesign

FDA's Patient Affairs Staff (PAS) presented PDF mockups to give PEC members a sense of the website's new look and feel. The enhanced high traffic pages of the website should be built out by late 2019 or early 2020. The goals of the enhanced website include:

- Creating an environment that is welcoming, engaging, and transparent.
- Building a structure that is clear and easy to navigate.
- Ensuring visual organization by separating information into sections/buckets.
- Demonstrating responsiveness for use across all devices.

By incorporating PEC feedback gleaned over several months of phone calls, the FDA made several improvements:

- Making sure that the themes of patient engagement and ways to engage are front and center by including text developed during prior PEC meetings.
- Incorporating accordions so that text expands once a user clicks on a specific section.
- Including more photos and white space so the webpages don't look overwhelming and text-heavy.

PAS discussed the enhanced website with PEC. They exchanged several ideas:

- Accordions are not always the best solution, as they are not good for search engine optimization (SEO) and make it harder to locate information; consider a long scroll and separate sections with gray and white bands instead, as well as an index/menu in which users could click to immediately navigate to a certain section on a page.
- The text may be too small. Ensure text is large enough to allow for onscreen reading and printing. Some patients will need to print out pages to accommodate their health needs, so an easily accessible, printer-friendly version of materials is important.
- Use photos of real people where possible; avoid graphics or stock images.
- Consider user-friendly ways to present dense information.
- Consider creating an FAQ page, which would help people find information easily while also helping with SEO.
- The website will probably need to be available in other languages as well, especially Spanish.

Developing a Dissemination Plan

The PEC discussed potential avenues to inform patients, caregivers, and patient advocates that the FDA has an enhanced patient-engagement-focused website. A beta test is included in the current project plan. After PAS gathers feedback from end users, staff will refine the website and launch. It will be important to gather feedback from patients who were not involved in the website's creation.

Once the website is launched, potential communication targets could include:

- National disease organizations that could link to the website from their homepages.
- Colleges of pharmacy across the U.S. Often pharmacists are the first link to patients, so they should be aware of engagement opportunities with the FDA.
- Upcoming conferences in which the FDA could hold sessions to highlight the updated website as a resource for patients and the public.
- Social media templates or potential language to send to disease organizations and patient advocacy groups. Social media posts should highlight important areas of the website and calls to action for patients, rather than just announcing there is a new website.
- Instructors at universities and research centers so that engagement opportunities can be discussed in classes.
- Other federal agencies that engage with patients through research, such as the NIH.
- Industry sponsors that engage with patients through research.

Additional considerations for website dissemination include:

- The PEC and/or PAS staff could create a few slides so that representatives could present on the website updates at events, conferences, etc.
- People follow stories. Ideas for potential stories include:
 - A perspective piece from a PEC member: "I am a member of the PEC, and this is how patient engagement can improve because of our work to revamp the FDA's website."
 - Stories or examples from people who successfully engaged with the FDA, and how it was beneficial for them. This could be included either in the website dissemination plan or in the Ambassadors program.
- One marketing/awareness push is not sufficient; ongoing communication is critical to build use of the website.

SESSION II: DEFINE PEC AMBASSADOR PROGRAM VISION, SCOPE, OBJECTIVES

Roadmap for a Pilot Program

PAS introduced the five stages of the “roadmap” that PAS developed for the creation of a pilot Ambassador program. The name of the Ambassador program could change based on the PEC’s discussion. The meeting focused mostly on the first two stages of the roadmap.

The five stages of the roadmap are as follows:

1. Define
 - Delineate program scope, as well as goals and objectives
 - Outline characteristics that would make an effective program Ambassador
 - Decide on target audiences
2. Develop
 - Set measurable criteria for evaluating program success
 - Define a timeline for the pilot program
 - Develop ideas for materials associated with the program
 - Create an outreach plan
3. Design
 - Create materials associated with the program
 - Have target audiences review materials and gather feedback
 - Refine materials based on feedback
4. Deliver
 - Conduct the pilot program
 - Track progress
 - Ensure target audiences are being reached
5. Evaluate
 - Assess the pilot program and delivery process
 - Identify areas for improvement
 - Revise methods and materials

Building from the PEC’s March 2019 in-person meeting, the group discussed current barriers to patient engagement with the FDA. The FDA Ambassadors program is intended to address the following challenges:

- Lack of knowledge in community about regulatory decision making
- Mistrust in community about the role the FDA plays
- Lack of minority representation in regulatory work conducted by the FDA

To begin determining scope for a pilot Ambassador program, PEC discussed the following questions:

- Who are the FDA Ambassadors?
- Who is the intended audience?
- What are the FDA Ambassadors educating their audience about?

Who are the FDA Ambassadors?

The PEC discussed the need for a diverse set of Ambassadors. This includes diversity in race and ethnicity, profession, socioeconomic status, and age (the PEC also considered the idea of involving pediatric Ambassadors).

The PEC also mentioned that effective Ambassadors need to be well-informed and enthusiastic about their mission. It would also be beneficial to involve individuals who have had multiple touchpoints with the FDA so that they can speak to many different areas of engagement. Therefore, an initial group of ambassadors could possibly even be drawn from PEC members.

Who is the intended audience?

One of the PEC members asked whether the Ambassadors program and its associated materials would be available in Spanish. Several PEC members agreed that the updated website and Ambassador program materials should be available in Spanish whenever possible. The members also noted that the PEC does not currently have enough Latino representation, and that it would be beneficial to embed representation in the program development process, especially because distrust of government entities such as the FDA is higher in minority populations.

To further define the audience for the pilot program, members discussed initially focusing on patient communities in which medical products or drugs are available or in development, as these communities may have the most immediate opportunities to engage with the FDA.

In addition, the PEC discussed the potential to expand target audiences from patients to academic investigators and industry sponsors, who also need to be informed so that they can partner with the FDA to help patients engage.

What are the FDA Ambassadors educating their audience about?

The PEC considered some ultimate goals of the Ambassador program, which could include creating an open and trusting relationship between Ambassadors and patient communities. This could lead to a long-term, two-way relationship that can build trust and understanding between patient communities and the FDA.

Members mentioned that many people would like to be involved with medical product development but don't know how, so they rely on traditional patient advocates to be their voice. This program could provide understanding and empower people to engage on behalf of their own health and wellness. The PEC suggested that it would like to see more people involved so the FDA hears some new patient perspectives.

However, before patients can engage, it will be important that patients are educated on what the FDA does and does not do. Many people do not have a good understanding of the FDA and its purview, and lack of understanding, as well as mistrust, leads to lack of patient participation. FDA Ambassadors will need to communicate that the work of the FDA does apply to individual patients, as well as raise awareness about the opportunity to engage and why the FDA cares about patient engagement. PEC members suggested the ambassador program materials include an "FDA 101" explanatory video or graphic.

INVITED PRESENTATION: YALE CULTURAL AMBASSADOR PROGRAM

Overview of the Yale Cultural Ambassador Program

To inform the PEC's discussions, presenters from the Yale Cultural Ambassador Program were invited to discuss their work and ongoing collaboration with the FDA's Office of Minority Health and Health Equity. The [program](#) launched in 2012 with the goal of increasing diverse representation in clinical research.

The COO and deputy director of the Yale Center for Clinical Investigation talked through the inception of the program and the work that has been accomplished in the years following. She shared materials from a "Help Us Discover" campaign that Yale launched in 2012 to engage patients in the research process. She noted that three versions of this campaign exist: a generic version, one targeted toward African Americans, and one targeted toward Latinos.

Yale held focus groups to better understand the barriers to participation in clinical research. When the program leaders learned that trust was an issue, they knew they would need to partner with trusted members of the community to achieve their goals; this included partnering with local churches to reach African Americans and with a Latino-focused nonprofit called Junta.

Comments from Cultural Ambassadors

Two pastors who partner with Yale and serve as Cultural Ambassadors offered insight as to why they chose to participate in the program. The first pastor said that although he was initially hesitant to get involved, Yale's team presented him with valuable information that made him think twice. He eventually realized that involving his congregation could help future generations. The second pastor spoke in a similar vein. He grew up in a community in which people feared and mistrusted doctors, but he also saw people in his community dying because they didn't participate in research or receive the right medications. This insight helped him understand that it was important to partner with the entities that have information that could help.

Presenters discussed that the Yale ambassadors have about 40 hours of face-to-face training and participate in ongoing training. It was emphasized that a long-term commitment is critical to build trust, and that any relationship established with audiences should be bidirectional.

SESSION III: INITIAL DEVELOPMENT OF AMBASSADOR PROGRAM

The PEC split into two groups to brainstorm ideas for the Ambassador program. Each group was tasked with addressing five questions:

1. Who is your specific target audience?
2. What does your target audience need to know?
3. What is the desired outcome?
4. How will you share the information with your audience?
5. Who are the best ambassadors to share the information?

PAS said staff hoped to generate some learnings and let everyone's ideas be heard.

Reporting Back on Group Discussions

A representative from each group summarized their small group's discussion for the entire PEC.

Group 1: Minority Populations with Chronic Pain

The first group suggested that its target audience could be minority populations, with an emphasis on those who experience chronic pain. The group discussed that Ambassadors needed to promote messages that explain what the FDA is and combat myths surrounding the FDA. This information would be shared at casual, face-to-face conversations over coffee in an effort to help the community feel comfortable and empowered to engage with the Ambassadors.

The group also discussed the importance of knowing their audience; for example, messages would differ for rural and urban audiences. It is also important to keep in mind that audiences have their own expectations, so the Ambassadors program must try to deliver information that aligns with those expectations.

The group suggested that the best Ambassadors would be engaged, have insight into what the FDA does, and have their own experiences interacting with the FDA so that they can better connect to and relate with their audience. Because of the high level of engagement that is needed, the group suggested that for the pilot program, current PEC members would be the best Ambassadors. This approach would be paired with a point person from the FDA that the Ambassadors could contact if they face challenges or need additional answers.

Group 2: Minority Populations with Health Issues

The second group focused on a similar, but slightly broader, target audience: racial or ethnic minorities who are currently facing health issues, along with their caregivers. This group desired to educate their audience about how they can participate in FDA programming and why it matters, as well as the risks of their nonparticipation.

This group wished to see a demographically appropriate percentage of minorities engaging and participating across all FDA programming, and for their audience to understand the importance of diverse participation in clinical trials and the medical product development process.

The group also suggested it would be critical for the target audience to trust the communicator, and that information should be shared face-to-face. Approaches discussed included use of mass media, churches, and advisory boards. The best Ambassadors would be people who are already trusted individuals in the target audience's community, and who are of the same race or ethnicity as the target audience. When appropriate, the group decided, the FDA Ambassador program could work with patient advocacy groups and leaders to help spread their message.

There was also conversation around which mode of delivering information to the audience would be most effective and well-received. The group mentioned that focus groups to test this would be beneficial. These focus groups would also be convened by trusted leaders within the community.

Conclusion and Next Steps

The FDA concluded the meeting by thanking the PEC members for their work and their commitment to the PEC. PAS plans to launch the enhanced website in late 2019 or early 2020 and then disseminate the website as discussed with the PEC. The PEC will continue brainstorming ideas and developing the FDA Ambassador program in upcoming teleconferences/meetings. The name of the Ambassador program, as well as implementation plans, is still being discussed and may evolve as discussions proceed.

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.

MEETING AGENDA

- 8:15 a.m. Welcoming Remarks
- 8:30 a.m. Session I: Complete PEC Discussion of Website Updates
- 10:00 a.m. Break
- 10:15 a.m. Session II: Define PEC Ambassador Program Vision, Scope, & Objectives
- 11:30 a.m. Lunch
- 12:30 p.m. Invited Presentation: Yale Cultural Ambassador Program
- 1:30 p.m. Break
- 1:40 p.m. Session III: Initial Development of Ambassador Program
- 3:15 p.m. Wrap Up
- 3:30 p.m. Adjourn