SMG 9006

FDA Staff Manual Guides, Volume IV – Agency Program Directives

General or Multidiscipline

Public Engagement Staff FDA Patient Listening Sessions

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1. Purpose.

The purpose of this document is to describe the procedures for the management of cross-Center FDA Patient Listening Sessions (PLS) led by the Public Engagement Staff (PES) in the Office of External Affairs (OEA) in the Office of the Commissioner (OC). Cross-Center refers to sessions that involve more than one Center, typically to include the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH) and OC. As needed, the Center for Food Safety and Applied Nutrition (CFSAN), Center for Tobacco Products (CTP), and others may be included. This Staff Manual Guide (SMG) outlines the standardized processes for cross-Center PLS, organized and executed by PES, to enable efficient and effective planning for all internal and external stakeholders involved.

2. Background.

The FDA has made significant efforts to broaden its engagement with patients and ensure that patients and caregivers are actively engaged in the medical product regulatory process, and their voice is considered as a part of the FDA's regulatory work.

Several key programs across the medical product centers support patient-related mandates included in User Fees Acts (UFA) and the 21st Century Cures Act. The PES PLS builds on these efforts. The Food Drug and Safety Innovation Act (FDASIA) and the fifth Prescription Drug User Fee Agreement (PDUFA V) enacted in 2012, directed the FDA to develop and implement strategies to solicit the views of patients to inform medical product development and regulatory decision activities. The 21st Century Cures Act enacted in 2016, the sixth Prescription Drug User Fee

Agreement (PDUFA VI), and the Medical Device User Fee Amendments (MDUFA) of 2017 built upon previous efforts by advancing the collecting, analyzing, interpreting, and integrating patient disease experiences into medical product development and regulatory decision-making processes.

The PES FDA PLS are one of several programs across the Agency that support these patient-related mandates. Through these sessions, the FDA staff have the opportunity to ask questions directly to patients and caregivers about their experience related to their health or a disease and/or condition. PLS provide a unique opportunity for the FDA to gain insight to patients' perspectives on the burdens of a disease, current treatments if any, its impact on the patients' and caregivers' daily activities and quality of life, as well as ultimately what is important to patients when new products are to be developed. A key component of medical product review and regulation is shared learning and incorporating input directly from patients and/or caregivers.

A PLS is a cross-Center, informal, non-binding meeting, (the meeting is herein referred to as a "Session"). The Sessions are generally not intended to be focused on a specific medical product. The Session is typically 60 or 90 minutes in length and are recommended to have no more than 7 patient perspectives participating in the Session[1]. The Sessions can either be requested by patients/advocates (externally) or by the FDA (internally). External sessions are initiated by patients or advocate groups while internal Sessions are initiated by the FDA staff who are looking to gain information from the patient community. These two types of Sessions are known as Patient-Led Listening Sessions and FDA-Requested Listening Sessions. Sessions are not open to the public however, high-level summary documents may be posted publicly online after the PLS has occurred.

The goals of PLS include:

1. To educate the FDA review staff about diseases, conditions, and health-related experiences and perspectives that are important to patients, caregivers, advocates, and community representatives;

2. To broaden the FDA's awareness of unmet patient needs and to better contextualize the patient experience;

3. To help the FDA better understand what is most important to different communities and individuals who have specific health, medical, and treatment needs;

4. To inform regulatory decision-making, e.g., for a specific product or application, benefit/risk trade-offs, developing guidances;

[1] The FDA Patient Listening Sessions are exempt from the Paperwork Reduction Act (PRA) under 21st Century Cures Act Section 3003.

5. To inform the FDA of patient preferences related to clinical trials, including endpoints, benefit-risk acceptance, outcome assessment tools, etc.; and

6. To help patients and their advocates understand the FDA's mission and work, e.g., generating awareness around the FDA's role in the medical product development process and review.

PLS were developed, piloted, and refined with standardized procedures for planning and executing a Session to ensure that they provide value while not adding excessive burden to the FDA and patient stakeholders. Based on the outcomes of the pilot and the internal and external stakeholder feedback, the procedures were implemented and are outlined in this SMG.

3. Responsibilities.

A. Public Engagement Staff: Located in the Office of External Affairs in the Office of the Commissioner, the primary FDA staff responsible for executing PLS that involve more than one Center.

B. Lead Review Division: The FDA division(s) with the primary interest in the PLS topic and who are typically an expert in the therapeutic area.

C. Lead Division Point of Contact: An individual in the lead review division(s) who will serve as PES' main point of contact for planning a FDA-requested PLS.

D. Interested Staff and Divisions: The FDA divisions other than the lead review division who have an interest in participating in the PLS in listening mode only. The Patient Engagement Leads from each Center assist with identifying interested staff and divisions.

E. Patient Engagement Lead: A Center representative who serves as PES' point of contact for their Center or program.

F. Patient Community: The patients, caregivers, patient advocates, or community representatives encompassing the patient community who attend the PLS and provide insight into their experience and answer questions.

G. Patient Advocacy Group: The individual or groups of individuals who are patients, caregivers, or patient advocates who act as the representative for the patient community, when applicable.

4. Procedures.

The procedures for planning and executing a PLS in brief:

A. Evaluation

1. The FDA staff or patients/advocacy groups submit a request for a FDA-Requested PLS or Patient-Led PLS, respectively, to PES. The request should include:

    a. Disease/condition name or issue relevant to a specific community
    b. Desired meeting goals and objectives
    c. Listening session topics or discussion questions
    d. Proposed draft agenda

2. PES reviews the request and considers whether a PLS is the appropriate avenue for communication between review staff and patients, caregivers, or their advocates. Some of the criteria used by PES to accept and prioritize a request include:

    a. No prior interactions and no currently planned interactions with the FDA on the same set of agenda topics

    b. Anticipated broad impact from the Session (e.g., Session will be attended by staff from two or more Centers)

    c. Reviewing division verifies that the Session will aid in regulatory decision-making at that time

    d. There is not another avenue that could better meet needs of the request

3. PES engages relevant stakeholders, including the lead review division, patient engagement leads, interested staff and divisions, and the patient community to solicit additional context or feedback that can help clarify the appropriateness of the Session.

    a. PES, in consultation with the review divisions, decides if a Session should be scheduled. PES informs the requester whether a Session is appropriate and potential next steps. If not appropriate or an alternative avenue preferred: (I) PES directs the requester to an alternative contact, (ii) suggests alternative timing, (iii) provides feedback that would enhance the appropriateness of request, or (iv) provides feedback about the reason for the request being declined/turned down.

B. Preparation

1. Requester refines the agenda and participant criteria.

2. PES hosts preliminary call(s) with the requestor as appropriate. Preliminary calls may occur with relevant FDA staff and/or the patient community. Preliminary calls will:

b. Help orient stakeholders to the logistics associated with organizing and running a Session

c. Develop or refine the agenda and, when applicable, define the participant selection criteria

d. Create a facilitation plan for the Session, including what questions or topics will be addressed and their intent

Preliminary calls can occur at different stages of planning with attendance determined based on necessity and availability.

3. PES schedules a date and time for the Session and sends invitations to all pertinent stakeholders.

   a. PES provides materials to aide in the preparation for the Session, which could include expectations documents, logistics details, and a refined agenda or discussion questions.

   b. As necessary, PES schedules additional preliminary calls to refine details of the Session.

4. PES and/or the patient community or patient advocacy group identify potential patients/caregivers to participate.

   a. For Patient-Led PLS, the patient community or advocacy group identifies patients/caregivers to participate in the Session.

   b. For FDA-Requested PLS, PES will either identify the participants, or will work with advocacy groups to identify participants. Identification is often completed through a survey tool.

5. For FDA-Requested PLS, the lead review division reviews the deidentified list of participants to better tailor their discussion questions. When there are more interested participants than slots available for the Session, the lead review division selects the deidentified participants based on the deidentified information they shared in the survey or other tool.

6. PES (FDA-Requested PLS) or the patient advocacy group (Patient-Led PLS) reaches out to selected and waitlisted patients and/or caregivers via phone to 1.) share information about the Session, 2.) determine that the patient or caregiver has first-hand familiarity with the subject matter and 3.) confirm the willingness of the patient or caregiver to participate in the Session and share their personal experiences. PES or the patient advocacy group addresses any questions or concerns the patient or caregiver may have.

7. PES develops a facilitation guide for PLS. For FDA-Requested PLS, PES collaborates with the requester to develop discussion prompts and questions, which will be asked to the patient/caregiver participants. For Patient-Led PLS, PES works with the requester to ensure their planned presentation and agenda will meet the needs of the FDA attendees and the objectives of the PLS. Information commonly requested by the FDA staff includes but is not limited to willingness to participate in clinical trials, the most meaningful symptom/disease improvement, the level of risk patients are willing to assume, and barriers to clinical trial participation.

8. PES manages logistics, including identifying a Session date and time, scheduling the meeting, and when applicable, reserving a conference room and providing directions to people coming to campus. PES distributes background documents and agendas to attendees prior to the session. Sessions typically are scheduled for either 60 or 90 minutes, depending on the number of participants and level of detail required to achieve the objectives of the Session.

C. Listening Session

1. All participants dial-in via phone or connect to the meeting via Zoom,

2. PES opens the conference call line at least ten minutes early and monitors it as participants enter the Session. PES ensures all lead review division and patient/caregiver participants attendees have joined and can hear/be heard.

3. PES initiates the Session with opening remarks. These include:

    a. PES introducing the meeting facilitators and explaining if and why “silent observers” are present

    b. Explaining what PLS are, sharing the Session objectives, and setting attendee expectations

    c. Reading a financial disclosure statement, and

    d. Reading a disclaimer.

4. After PES’ opening remarks, the PLS follows the prepared agenda and/or discussion prompts and questions.

    a. In FDA-Requested PLS, PES is the primary facilitator, and the lead division point of contact(s) are secondary facilitators. PES leads a discussion in which patients and caregivers are guided through a series of prepared questions. The lead division point of contact(s) ask follow on

questions as needed. PES is responsible for interjecting if the conversation deviates from the lead review division's intended agenda and to ensure that all planned questions are asked to patient and/or caregiver attendees in the allotted Session time.

b. In Patient-Led PLS, the patients/advocates who requested the session are the primary facilitators and PES are secondary facilitators. The patients/advocates present their planned remarks. After their remarks, approximately 15 minutes are allocated for an open discussion between the patient community and the FDA. PES facilitates the open discussion during which the FDA staff are encouraged to ask questions.

5. When there are approximately 5 minutes left, PES provides closing remarks. PES thanks the participants for their time, reviews next steps and action items, and concludes the Session.

D. Codification and Communication

1. PES thanks the patient community participants for their time via email. PES collects feedback about the session and identifies procedural improvements via surveys sent to the patient community and the FDA staff.

2. As applicable, the lead review division and interested staff and divisions follow up on any outstanding questions that were raised during the Session and provide responses to PES.

3. A summary document is developed, and a link is posted on the FDA's website.

   a. In FDA-Requested PLS, PES develops a high-level summary document that highlights the key takeaways discussed for each question asked to participants. The summary document is subsequently shared with the lead review division for their input and approval of the content. When approved, the FDA posts the summary on the FDA's website.

   b. In Patient-Led PLS the patient community is encouraged to develop a high-level summary document that highlights the key takeaways discussed during the Session. PES requests to review the summary before it is made available to the public and provides a disclaimer statement that should be included in the summary. The FDA will post the link to the advocacy group's summary on the FDA's website.

5. Effective Date.

The effective date of this guide is May 10, 2022.

6. Document History - SMG 9006, "Public Engagement Staff FDA Patient Listening Sessions"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	10/10/2019	N/A	OC/OCPP/PAS	Nina Hunter, Director, Office of Clinical Policy and Programs
Revision	05/05/2022	N/A	OC/OCPP/Patient Affairs	Andrea Furia-Helms, Director, Office of Patient Affairs Jodi Black, Director, Office of Clinical Policy and Programs
Change	01/15/2025	Patient Affairs to Public Engagement Staff	OC/OEA/PES	Andrea Furia-Helms, Public Engagement Staff Dayle Cristinzio, Director, Public Engagement Staff Leah Hunter, Associate Commissioner for External Affairs

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