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FDA engages patient communities through listening session initiative

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The Food and Drug Administration (FDA) recognizes the importance of empowering patients and enhancing their role in medical product development. The FDA has had a longstanding commitment to working with patient communities, and since the HIV/AIDS crisis in the 1980s has established many formal avenues to include the patient voice in its regulatory work.

Among those avenues is the agency's Patient Listening Sessions initiative, which allows FDA staff to hear directly from patients and caregivers about their experiences living with and managing a disease or condition.

Listening sessions are small, nonpublic discussions held at the FDA headquarters or virtually. Participants share their experiences living with a disease, insights into risk tolerance and preferences related to clinical trial participation. Specific regulatory issues are not discussed during the sessions. Listening sessions can be requested by patient organizations or by FDA staff.

Led by the Patient Affairs Staff in the Office of the Commissioner, the FDA has hosted 30 listening sessions since the initiative's inception in 2018, including sessions for pediatric diseases such as neurofibromatosis, childhood cerebral adrenal leukodystrophy and Hunter syndrome.

Patient Affairs Staff believe the informal, intimate nature of the listening sessions allows patients and caregivers to feel more comfortable sharing their personal experiences, particularly when children are involved.

FDA staff have described these interactions as "eye-opening," and the listening sessions have garnered significant interest within and outside the agency. Information shared has helped the FDA better understand what is important to patient communities. The FDA also has used the information to prepare for public meetings and to inform guidance document development, medical product development and regulatory decision-making.

Patient listening sessions provide opportunities for patient communities to have a seat at the FDA's table.

Resources

- Information on Patient Listening Sessions
- Information on listening sessions on neurofibromatosis
- Information on listening sessions on childhood cerebral adrenal leukodystrophy Information on listening sessions on Hunter syndrome
- Additional FDA Update columns