



*Lupus ends with Us!*



## **Lupus Community Shares Views with FDA at Historic Patient-Focused Drug Development Meeting**

Top decision makers at the U.S. Food and Drug Administration (FDA) heard from over 550 people impacted by lupus this week at an unprecedented in-person meeting and live webcast about what it's really like to live with the disease and what they need most from new treatments.

Three organizations – the Lupus and Allied Diseases Association, the Lupus Foundation of America, and the Lupus Research Alliance – organized the meeting as part of the FDA's externally-led Patient-Focused Drug Development (PFDD) Initiative. The PFDD was created by the FDA to allow regulators to better understand the perspectives of people with diseases such as lupus so they can better assess the risks and benefits of drugs under review.

The meeting featured two panels of people with lupus and family members and speakers that included clinicians, representatives from the FDA, and a community representative. Audience members also provided input throughout the day on symptoms and treatments. Dr. Anca Askanase, director of the Lupus Center at Columbia University Medical Center described the unpredictability and individuality of lupus with symptoms ranging from extremely debilitating pain and fatigue to serious organ damage. She detailed the inadequate treatments for lupus, describing their varying effectiveness and challenging side effects.

Director of FDA's Center for Drug Evaluation and Research Dr. Janet Woodcock urged participants to share the burdens of treatment as well as the burden of the disease. Participants answered her request with poignant accounts of how lupus and lack of symptom relief has robbed them of dreams for school, careers, and children.

"I no longer had control over my life," said one panelist, while another observed, "Every day I feel I'm putting on a show when all I want to do is cry." A former nurse said she finds lupus fog is the worst impact on her life and profession, affecting her memory and ability to think. Of the numerous symptoms mentioned throughout the day, extreme fatigue was identified by nearly all as having the greatest impact on their day-to-day life. Virtually all participants shared how friends, family, and colleagues often think they're "faking" because lupus is an "invisible" disease without obvious symptoms.

Meeting participants also spoke about the difficulties of managing treatment for this heterogeneous and unpredictable disease, including the side effects of many medications. As one attendee said, "Treatments are short-term decisions that have long-term implications. We must weigh the risks and benefits with little information about long-term risks to guide our decision." Another woman, who has been living with lupus for decades, voiced "What's really upsetting is there's not much more to offer today than there was to me fifty years ago. ...I'm very excited that this [meeting] is finally taking place, where all the lupus organizations are together, and put together, you can do something positive."

Throughout the meeting, attendees demonstrated their resilience in the face of lupus and expressed the urgent need to develop new treatments. As speaker and lupus community representative Kathleen A. Arntsen noted, "Today marks a new era in drug development for lupus. It is imperative that the next generation of people with lupus have a better quality of life and the opportunity to pursue their dreams. After all, lupus ends with us."

Next step – a comprehensive *Lupus: Patient Voices* report will be sent to the FDA summarizing all the feedback from the meeting, online participation, and surveys from more than 2,000 people with lupus. We welcome your comments about your experiences with lupus and what you would like to see in future treatments. Comments submitted via email to [info@lupusPFDD.org](mailto:info@lupusPFDD.org) by October 6 will be used to inform the report. Additional information, including a recording of the meeting, can be found at <https://lupuspfdd.org/meeting/>. To view the meeting by individual sessions visit [our YouTube channel](#).

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