



June 12, 2017

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted Electronically via regulations.gov

RE: FDA-2017-N-0455; Enhancing Patient Engagement Efforts Across the Food and Drug Administration

To Whom It May Concern:

The Epilepsy Foundation appreciates the opportunity to comment about the establishment of the Office of Patient Affairs at the Food and Drug Administration (FDA). We are encouraged by the FDA's willingness to improve the way that patients and advocates engage with the agency, and that the agency is elevating the importance of the patient as a core aspect of its mission. The FDA was established to serve the public by ensuring safe and effective therapies are available to patients, and it is thus critical that the patient voice is considered in the drug development and review process. The Epilepsy Foundation also expresses our support for the comment that we have joined offered by a large group of patient groups including the American Cancer Society Cancer Action Network and the National Organization for Rare Disorders (NORD). **If structured and staffed with a focus on true engagement, the Office of Patient Affairs could be a key bridge for the FDA and patient/voluntary health agency community.**

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of more than 3 million Americans with epilepsy and seizures. We foster the wellbeing of children and adults affected by seizures through research programs, educational activities, advocacy, and direct services.

The Epilepsy Foundation encourages the FDA to ensure that the patient voice is integrated into the conversations from the beginning, and that it continues to be considered throughout the review process and post-market. The proposed FDA Office of Patient Affairs will help build on the successful patient engagement that the agency has already conducted in recent years. Engaging patients leads to better outcomes and more satisfaction in our overall health care system. The FDA can build trust and confidence by keeping communication channels open and transparent.

We are supportive of the FDA's stated goals for the Office of Patient Affairs including:

- Developing a better understanding of the patient experience of a disease;
- Determining what is clinically meaningful to patients;
- Assessing attitudes towards benefit-risk and tolerance of uncertainty; and
- Enhancing the science of eliciting and integrating patient input.

The Office of Patient Affairs will also be able to share best practices and help to spread awareness about opportunities for patients to engage with the FDA. Having a central, direct resource at the agency will be a significant advantage for the patient community. We welcome the Office of Patient Affairs as a resource to help patients and advocates understand and navigate the regulatory process at the FDA. Increased communication between patients and advocates and the FDA will always be beneficial and well-received.

We strongly encourage the FDA to structure the mission of its Office of Patient Affairs so that the staff team is proactive in reaching out to the patient advocacy community. It will be critically important that the Office of Patient Affairs have strong connections with the various divisions at FDA, and be looking for opportunities to connect patients to advisory committees, regulatory reviews, work on future PDUFA, MDUFA, GDUFA agreements, and engaging with the patient community to determine their needs and ideas for FDA.

Due to the unmet medical need in epilepsy, and devastating impact of seizures, the epilepsy community places a high value on a strong FDA with leaders focused on innovation and patient engagement. Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions. For the majority of people living with epilepsy, medication is the most common treatment for controlling and/or reducing seizures. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime. While many significant advances have been made in epilepsy over the past several years, including the development of innovative medications, medical devices, and surgical options, unfortunately, the number of people with epilepsy who are still experiencing seizures, despite being treated for the condition, has not changed. No cure currently exists for epilepsy, and one third of people with epilepsy live with uncontrollable seizures and many more experience significant side effects from available therapies; thus, research and innovation are a priority for the epilepsy community.

In the development of a new Office of Patient Affairs at the FDA, we are hopeful that patient engagement will be enhanced, amplified, and strengthened. The patient perspective needs to be considered by everyone at the FDA. We hope that this office will facilitate conversations overall between the FDA and patients, aid in navigating the agency's existing patient initiative, and ensure that each Center is making the most of the patient perspective. **We strongly suggest that the Office of Patient Affairs include staff with experience in the patient advocacy and voluntary health agency community, including key staff with experience in FDA advocacy for the patient community.**

Further, the Office of Patient Affairs should not usurp the authority of each Center to plan and implement its own patient engagement initiatives; instead, it should assist at a high-level with coordinating and facilitating. Lastly, we are also hopeful that the office will be able to support research and integration of patient data into the FDA review process, as we view this broader initiative as exceptionally important.

The Epilepsy Foundation thanks the FDA for its efforts to advance and improve patient-focused drug development, and we are supportive of the Office of Patient Affairs. If you have any questions or concerns, please contact Angela Ostrom, Chief Legal Officer & Vice President Public Policy at aostrom@efa.org or 301-918-3766.

Sincerely,



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President & CEO
Epilepsy Foundation