



November 20, 2015

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

Re: FDA-2015-N-3166 Establishment of the Patient Engagement Advisory Committee;
Establishment of a Public Docket; Request for Comments

Submitted electronically via <http://www.regulations.gov>

Dear Letise Williams,

On behalf of the Asthma and Allergy Foundation of America (AAFA, www.aafa.org), I am pleased to submit comments in response to the above referenced request for comments. AAFA, a not-for-profit organization founded in 1953, is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. AAFA is dedicated to improving the quality of life for people with asthma and allergic diseases through education, advocacy and research.

AAFA applauds the Food and Drug Administration's (FDA) announcement of the establishment of a Patient Engagement Advisory Committee. We appreciate the FDA's intent to obtain advice [from patients] on issues relating to medical devices, regulation of devices, and their use by patients. However, we are extremely concerned and disappointed about the FDA's proposed approach and the suggested Committee composition.

AAFA believes that if the FDA is committed to establishing a Patient Advisory Committee, the Committee must be comprised of patients and/or patient advocates, and each needs to be a voting member of the Committee with equal rights and responsibilities. The only people qualified to represent the primary care patient experience(s) and health care needs of patients are patients. Committee members should have experience as patients, families or caregivers of patients from a wide and broad array of conditions (such as acute, chronic, prevalent, rare, infectious, and non-infectious conditions) and at different stages of their diagnosis, treatment and management. Patients have different preferences regarding approaches to device innovation and to specific devices. Thus, FDA would benefit from assuring that diverse patients are actively involved in this effort. The FDA's proposed approach undermines the value of patient opinions, feedback and input. Unfortunately, the FDA proposal implies that non-patients can represent the patient perspectives.

However, the FDA seems intent on selecting and convening people with experience running professional organizations, with experience using methodologies for eliciting patient



preferences, or with knowledge of strategies for communicating benefits, risks and clinical outcomes to patients and research subjects. If the FDA is interested in determining patient preferences or seeks to understand how to communicate with patients, then ask patients. If the FDA wishes to obtain information about patient preferences regarding devices or to understand what is important to patients, then ask patients.

Further, AAFA is disappointed that the FDA notice seems to imply that there *may* be consideration given to “*one consumer representative*” who is a technically qualified member, selected by the Commissioner or designee, identified with consumer interests, and is recommended by either a consortium of consumer oriented organizations or other interested persons.” The FDA wording is vague and ambiguous. It is not clear if the FDA is using the terms “consumer” and “patient” interchangeably nor what the FDA means by “consumer interests” or “other interested persons”. The FDA proposal implies that the perspective of “one consumer” adequately and appropriately represents the perspectives of all types of consumer (patients?).

Patients are critical members of the healthcare, research and policy making team, and they must be given the opportunity to work side by side as equal partners with clinicians, researchers, and policymakers in order to achieve the outcomes that are most important to them. Solving the challenges and problems of living with diseases requires active engagement of patients, families, and caregivers, in all issues relating to medical devices, regulation of devices, and their use. AAFA strongly urges the FDA to revise its proposed approach so that it reflects diverse patient perspectives based on their circumstances, needs, treatment and life goals.

AAFA thanks the FDA for providing the opportunity to offer comments. Please do not hesitate to contact me at Csenett@aafa.org or Meryl Bloomrosen, AAFA’s Senior Vice President for Policy, Advocacy and Research at mbloomrosen@aafa.org for further information.

Regards,

Cary Sennett, MD, PhD
President and CEO