



AAFA Oral Comments

FDASIA 907 Public Meeting: Progress on Enhancing the Collection, Analysis and Availability of Demographic Subgroup Data

February 29, 2016

Good morning/afternoon.

My name is Meryl Bloomrosen, and I am the Senior Vice President of Policy, Advocacy, and Research at the Asthma and Allergy Foundation of America (www.aafa.org), or AAFA. AAFA is a not-for-profit organization working to improve the lives of people with asthma and allergic diseases, through advocacy, education, and research. Thank you for the opportunity to bring AAFA's perspective, and the perspective of the more than 60 million Americans with asthma and allergic disease, to this meeting today.

I will provide brief comments on what we believe are critical issues to consider about communication strategies and methods – one of the questions you posed. We will submit more detailed written comments via the public docket.

We know that asthma and allergic diseases are life threatening chronic conditions that disproportionately affect demographic subgroups, such as the medically underserved, minorities and children.¹ Asthma is more common and more severe among children, women, low-income and inner-city residents, and among African-American and Puerto Rican communities.² Allergic conditions are among the most common medical conditions affecting US children³ and they are of concern among the elderly⁴. Individuals with asthma and allergic diseases must manage multiple behavioral, socioeconomic and environmental factors that can trigger or exacerbate their symptoms, and must also adhere to a regimen of medications to keep their conditions well-controlled. There are ongoing, significant and increasing financial burdens for individuals living with asthma and allergies, including out of pocket costs associated with care, medications, treatments, trigger avoidance, and in the case of food allergies, additional and increased costs for safe allergen free food.

We also know that demographics in the US are shifting – the populations of the elderly and certain ethnic minorities are growing. Therefore, it is imperative that we take deliberate steps to enhance the inclusion of and communications with diverse populations in clinical trials and other research efforts.

The patient community needs research including clinical trials that is:

- **Better.** Patients and families need clinical trials that will result in options and innovations that are an improvement from current treatments.



- **Effective.** The treatment needs to work in the real world and in a patient's day-to-day life, not just in clinical trials.
- **Relevant.** Research (clinical trials) should be specific and focused on issues that matter most to patients. For example, patient centered outcomes should include metrics that address symptom control, quality of life, and functional status.
- **Safe.** Therapies need to be carefully tested in a controlled environment.

Patients need information that is communicated in ways that are:

- **Available.** Provide and disseminate information in forms and formats, and in places that are accessible to patients where they live, work and play.
- **Trustworthy.** Find new ways to communicate about evidence and risk. Enhance public awareness by developing and refining messaging and channeling them to target audiences through trusted intermediaries such as patient advocacy organizations. Disseminate messages via appropriate, efficient channels and by using credible user-friendly, subpopulation-and culturally- appropriate messengers.
- **Understandable.** Provide resources and information for patients in patient friendly, plain language messages which can be readily understood. Design FDA communications materials and information to reach people with various levels of literacy and health literacy.
- **Usable.** Assure that information for patients addresses what is most important to patients, their families and caregivers. Provide opportunities for patients to identify and prioritize what they want to know about and which topics impact and affect them the most.

We urge the FDA to continue to expand and better integrate the role of the patient and consideration of the patients' perspectives in the agency's work. 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.⁵ AAFA is ready to work with the FDA and other stakeholders on patient focused medical product, device, and drug development, precision medicine, and during legislative and regulatory discussions.

AAFA can bring the voices of individuals with asthma and allergic diseases, through the online and real world communities that we support. And we have the opportunity to assist the FDA, to build greater awareness, participation and expertise in the patient community. AAFA is ready to partner with the FDA, and others, who recognize as we do the opportunity



to advance clinical trials and the evidence that we have, more consistently and more effectively, and for diverse subpopulations with asthma and allergic diseases.

Our goal is to bring the voice of patients with asthma and allergic disease—with high fidelity and with force—to the conversations that are shaping and re-shaping healthcare. Thank you for the opportunity to be part of today's conversation.

¹ Ethnic Disparities in the Burden and Treatment of Asthma <http://www.aafa.org/page/burden-of-asthma-on-minorities.aspx>

² Coordinated Federal Action Plan to Reduce Racial and Ethnic Asthma Disparities.

http://www.epa.gov/sites/production/files/2014-08/documents/federal_asthma_disparities_action_plan.pdf

³ <http://www.cdc.gov/nchs/data/databriefs/db121.htm>

⁴ Cardona, V., Guilarte, M., Luengo, O., Labrador-Horrillo, M., Sala-Cunill, A., & Garriga, T. (2011). Allergic diseases in the elderly. *Clinical and Translational Allergy*, 1, 11. <http://doi.org/10.1186/2045-7022-1-11>

⁵ Bloomrosen M, Sennett C. Patient engagement: challenges and opportunities for physicians. *Ann Allergy Asthma Immunol*. 2015 Dec;115(6):459-62. doi:10.1016/j.anai.2015.09.005. Epub 2015 Oct 6.

[http://www.annallergy.org/article/S1081-1206\(15\)00591-8/abstract](http://www.annallergy.org/article/S1081-1206(15)00591-8/abstract)