



**Before the Department of Health and Human Services  
Food and Drug Administration  
[Docket No. FDA-2009-N-0664]**

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory  
Committee

Statement of the Asthma and Allergy Foundation of America

**Re: Alair Bronchial Thermoplasty System sponsored by Asthmatx, Inc.**

October 28, 2009

I am Charlotte Collins, Director of Public Policy & Advocacy for the Asthma and Allergy Foundation of America (AAFA). AAFA employs me and paid my expenses to participate in this meeting. AAFA discloses that it receives both unrestricted contributions and grants for specific sponsored programs from a number of funders, like the American Academy of Allergy, Asthma, and Immunology, the American College of Allergy, Asthma and Immunology, Asthmatx, AstraZeneca, Genentech, Novartis, Pfizer, Sanofi-Pasteur, Schering-Plough, Teva and Vistakon. However, no corporate sponsor has underwritten my compensation or any other expenses of my participation in this meeting. AAFA also receives federal funding for its programs, and donations from thousands of asthma and allergy patients.

Founded in 1953, AAFA is a national public foundation dedicated to serving the more than 60 million Americans with asthma and allergic diseases. AAFA provides free information to the public, offers educational programs to consumers and health professionals, leads efforts to improve patient care and supports research to find better treatments and cures. AAFA conducts outreach to patients in the form of online surveys, advocacy training and focus groups.

As I listened to asthma patients talk about their experiences during a recent focus group we conducted, I was struck by their sense of frustration. I heard that people who suffer from severe asthma operate in a different reality than those who have mild or moderate asthma. Other people underrate the impact of their condition. The sitcom characters who cough and wheeze for laughs belittle the real burden that severe asthma sufferers carry.

This debilitating disease can interfere with basic human functions across a range of activities that most of us take for granted. In a recent online survey we conducted, one third of severe asthma patients said that asthma “tremendously hinders” their daily activities. They risk the deleterious side effects of asthma medications that they have trouble affording, and still their asthma may not be well controlled. Only half of the respondents to our survey said that they find any of their asthma medications effective. Severe asthma also means facing the real threat of being hospitalized during cold and flu season. In our survey, over three-quarters of severe asthma respondents have been in the emergency department once due to asthma; fourteen percent have been more than twenty times.



AAFA supports new and meaningful treatments for those who suffer from all allergies and asthma. We would like to see safe alternatives for those with severe asthma. We support a thorough and data-driven process to determine the safety and value of innovative new interventions for patients. Bronchial thermoplasty is a new and meaningful intervention that may offer hope for a limited subset of asthma patients whose conditions are so severe that they are not well managed by other options. It may offer them a way to gain better control of their severe asthma and reduce the burden of intensive care hospitalizations and emergency hospital visits.

AAFA urges that you recommend approval of this procedure if you find that it offers both safety and efficacy. If approved, we hope that the procedure will be affordable and that it will be covered by health plans. We caution FDA to take steps to assure that this procedure be exceptional, targeted to only the most severe asthma patients for whom other less invasive treatments offer little relief or dramatic side effects. While we are concerned that patients will want the treatment even if non-invasive treatments are more appropriate, we think that appropriate guidelines and responsible marketing will reassure us.

Thank you.