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August 2, 2016

Robert M. Califf, MD  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Califf,

We, the undersigned, represent a large portion of national and international clinicians, researchers, and advocates for individuals with eating disorders. We have come together to present a united front in light of our deep concern about a recent device approved by your agency: the AspireAssist. We are asking the Food and Drug Administration (FDA) to reconsider its support of this device, which we believe to be unsafe.

As you are aware, the AspireAssist includes a tube placed inside the user's stomach to drain a portion of the content after every meal. It is a device that is intended to simulate purging and is marketed as a tool to treat obesity. We are shocked that one of the clinical criteria for bulimia nervosa (purging behavior) has actually been turned into a form of medical treatment for obesity.

As experts in the field of eating disorders, we believe that this device is dangerous and represents a truly disturbing incidence of technology serving to perpetuate pathology. Eating disorders have the highest mortality rate of any psychiatric illness and are marked by chronic courses. Individuals in the overweight or obese range are particularly at risk for developing disordered eating, and many others are suffering from an active eating disorder that has gone undiagnosed. The AspireAssist may further increase these individuals' risk of a lifelong, potentially deadly disorder.

On behalf of The Academy for Eating Disorders (AED), a global professional association committed to leadership in eating disorders research, education, treatment, and prevention, AED president, Eva Trujillo, MD, FAED stated, "Such a device may carry very serious physical and mental health consequences, including life-threatening situations, and should not be approved by the FDA. This will likely prove to be yet another in a long list of misguided, unsuccessful, and dangerous products for losing weight. We need to stop subjecting people in larger bodies to unsafe procedures and insisting they are a problem to be fixed."

Though the FDA has stated that this product is not intended for use on people with eating disorders, we consider this disclaimer to be woefully inadequate due to the under-diagnosis of people with eating disorders, specifically binge eating disorder and higher weight anorexia nervosa. These often-missed eating disorders carry a similarly high rate of medical and psychological consequences and elevated mortality rates as classic anorexia nervosa and

bulimia nervosa. Further, this warning does not address those individuals who may not have an eating disorder at present, but for whom the AspireAssist may serve to trigger the development of such a disease. For individuals of any size and especially those in larger bodies who may be seeking remedies to reduce size or restrict food intake, this device can compound unhealthy, potentially life-threatening eating disorder-related behaviors.

We call for the FDA to revoke its approval of the AspireAssist, and to truly live up to its stated goal of “Protecting and Promoting *Your* Health.”

Sincerely,

Academy for Eating Disorders  
Alliance for Eating Disorders Awareness  
Australia & New Zealand Academy for Eating Disorders  
BingeBehavior.com  
Binge Eating Disorder Association  
Center for Eating Disorders, Ann Arbor  
Comenzar de Nuevo Foundation  
Eating Disorders Coalition  
Families Empowered and Supporting Treatment of Eating Disorders  
Hispano Latino American Chapter of the Academy for Eating Disorders  
Icelandic Eating Disorder Association  
International Association of Eating Disorder Professionals Foundation, Inc.  
International Eating Disorder Action  
Mexican Association of Eating Disorders Professionals  
National Eating Disorders Association  
Residential Eating Disorders Consortium  
Strategic Training Initiative for the Prevention of Eating Disorders  
Trans Folx Fighting Eating Disorders  
World Eating Disorders Action Day

c: Jeffrey Shuren, MD, JD, Director of the Center for Devices and Radiological Health  
William Maisel, MD, MPH, Deputy Director for Science and Chief Scientist, Center for Devices and Radiological Health  
Anne T. Hawthorn, JD, Communications Liaison (Acting), Office of Device Evaluation  
Elizabeth Everhart, MSN, RN, ACNP, Health Programs Coordinator, Office of Health and Constituent Affairs, Office of External Affairs  
Mary (Peper) Long, Senior Advisor, Center for Devices and Radiological Health