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November 17, 2010

Margaret McCabe-Janicki
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave., Bldg. 66, rm. 1535 Silver Spring, MD 20993-0002

Dear Ms. McCabe-Janicki:

The Obesity Action Coalition (OAC), a national non-profit organization dedicated to helping those affected by obesity, respectfully submits the following written statement to the Food & Drug Administration's (FDA's) Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

The OAC represents nearly 19,000 members – the majority of which have been personally affected by obesity. Our membership includes adults who are overweight, obese, morbidly obese and those who have successfully addressed their obesity, parents of children who are affected by childhood obesity as well as concerned members of the public. In addition, our membership includes more than 1,000 healthcare providers who care for those afflicted with the disease of obesity. Our strong belief is that obesity, like other diseases, must be both prevented and treated. Those either currently obese, or at risk for developing obesity, and are ready to make a change in their lives, should have expanded access to both prevention and treatment avenues.

Patients and Their Healthcare Providers Need an Arsenal of Treatments

Today, the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee will examine the benefits and risks of expanding the indication for use of an adjustable gastric banding system to include weight reduction in patients with a body mass index (BMI) of at least 35 kg/m² or a BMI of at least 30 kg/m² with one or more co-morbid conditions, such as type 2 diabetes, hypertension, sleep apnea and others.

Treating or addressing obesity among those already affected by the disease is difficult. This is clearly demonstrated by the more than 34 percent of Americans who are currently affected by obesity. However challenging though, efforts must be made to both prevent and treat obesity at all stages and in all age groups. Treatment approaches should include the following: school and community-based programs; lifestyle interventions; educational programs; drug, diet and physician-supervised programs; and bariatric surgery.

Patients and their healthcare providers need an arsenal of treatments -- as any one treatment may not work for every individual. Furthermore, patients must have access to this comprehensive treatment approach through reasonable means and this access to care should not be hindered by undue tests or prerequisites on the part of the patient.

Quality and Outcomes Must be Monitored and Tracked

For these reasons, as well as the fact that the potential for bariatric surgery to address obesity related co-morbidities is so great, the OAC believes that the FDA should approve utilization of the LAP-BAND[®] System for the above population provided that these procedures are performed by qualified bariatric surgeons in multidisciplinary environments that encourage data collection on outcomes and complications.



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Monitoring of such requirements has precedent as seen with the already existing center designation requirements for participation in the Medicare bariatric surgery program. These mandate establishment of detailed protocols for patient selection, preparation for surgery, surgical volume and multidisciplinary team requirements. Such an approach would be consistent with the requirements set up by the American Society for Metabolic and Bariatric Surgery (ASMBS) and the American College of Surgeons (ACS), such as the ACS Bariatric Surgery Center Network Accreditation Program and the outcomes data housed in the College's National Surgical Quality Improvement Program; the ASMBS Bariatric Surgery Center of Excellence Program; and the Surgical Review Corporation's Bariatric Outcomes Longitudinal Database (BOLD™).

Multiple large epidemiologic studies have demonstrated that increasing BMI, particularly above 30 is associated with an increased risk of death or premature mortality. This relationship holds for various age groups, ethnic and minority populations and in different geographic locations. In addition, obesity is associated with multiple co-morbidities, which are either caused or worsened by the disease. Furthermore, these co-morbid conditions are expected to improve or resolve if effective weight-loss is achieved.

More than 20 such conditions have been identified, some of which are known to be associated with premature mortality and play a role in mediating the premature mortality associated with obesity. Included are type 2 diabetes, hypertension, dyslipidemia, pulmonary disease (obstructive sleep apnea and restrictive lung disease) and multiple cancers. Additional co-morbid conditions include renal and liver disease, musculoskeletal disease, gastroesophageal reflux disease, pseudotumor cerebri and a variety of psychosocial conditions.

While health insurance plans generally provide coverage for a comprehensive treatment approach for many of the above-mentioned chronic diseases, the same is not true regarding obesity. The OAC believes that obesity is too often misconstrued as a cosmetic problem and/or a personal failure. However, many individuals affected by obesity often deal with physical, emotional and social issues that can hinder them from addressing their weight issues. Obesity is not a condition of personal choice.

Individuals affected by obesity frequently struggle with not only the health and physical consequences of their disease, but also with workplace and other social consequences. Discrimination against individuals affected by obesity occurs in schools, workplaces, doctors' offices and more. No person should be discriminated against based on their size or weight.

For far too long, treatment avenues to address the disease of obesity have come under a different microscope than treatment modalities for other disease states. The OAC believes that new evidence-based treatment approaches for obesity should be subject to, and judged by, the same approval criteria as new treatments for cancer, heart disease or diabetes.

In closing, we would like to reiterate that no one prevention or treatment approach will solve the obesity epidemic as a wide variety of actions is necessary to address the complex and chronic condition of obesity.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joe Nadglowski, Jr.', is written over a light blue circular stamp.

Joseph Nadglowski, Jr.
OAC President and CEO