



August 30, 2010

Paul T. Tran, R.Ph.
Food and Drug Administration
10903 New Hampshire Avenue
WO31-2417
Silver Spring, MD 20993-0002

RE: NDA 22-529

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) Advisory Committee on Endocrinologic and Metabolic Drugs. On behalf of our more than 16,000 members throughout the United States who are personally affected by all forms of obesity, the OAC is pleased that today's Advisory Committee meeting – the second of three hearings over a six-month period where the FDA will examine three new pharmaceutical treatment avenues for those who struggle with their weight.

First and foremost, the OAC believes that the goals laid out for those who have chosen to address their obesity should focus less on total weight-loss and more on health improvement. We believe such an approach may encourage more consistent and continued individual participation in programs to address obesity – highlighting realistic outcomes and expectations for those affected by obesity.

Treating or addressing obesity among those already obese 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 surgery.

Working toward this goal, the OAC is pleased that today marks the second of three advisory committee meetings that will separately focus on three new obesity drugs, which are pending final market approval. We are excited because if any of these new drugs meet FDA's strict approval criteria, it will mean more treatment options for the nearly two-thirds of people in our country who are affected by overweight or obesity.

This point is extremely critical because 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.

Multiple large epidemiologic studies have demonstrated that increasing body mass index (BMI), particularly above 30 (defined as obesity), 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 obesity. Furthermore, these co-morbid conditions are expected to improve or resolve if effective weight-loss is achieved.

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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, psedotumor cerebri and a variety of psychosocial conditions.

While many pharmaceutical and biomedical agents have been developed for the 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 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 will be necessary to address the complex and chronic condition of obesity. Today's advisory committee meeting represents the FDA's interest and commitment to fairly evaluating the latest pharmaceutical and biomedical advances in the treatment of obesity.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joe Nadglowski, Jr.', written in a cursive style.

Joseph Nadglowski, Jr.
President and CEO