4511 North Himes Ave., Suite 250
Tampa, FL 33614

(800) 717-3117
(813) 872-7835
Fax: (813) 873-7838

info@obesityaction.org
www.obesityaction.org

Statement of the Obesity Action Coalition (OAC) before the Meeting of the Food and Drug Administration's (FDA) Endocrinologic and Metabolic Drugs Advisory Committee Regarding the Role of Cardiovascular Assessment in the Pre-approval and Post-approval Settings for Drugs and Biologics Developed for the Treatment of Obesity

March 28 & 29, 2012

On behalf of the OAC, I am pleased to present the following comments to the March 28-29 meeting of the Food and Drug Administration (FDA) Advisory Committee regarding the role of cardiovascular assessment in the pre-approval and post-approval settings for drugs and biologics developed for the treatment of obesity. The OAC applauds the FDA for calling this hearing given the high risk of individuals affected by obesity to develop severe cardiovascular disease.

We agree that safety is paramount, but any discussions surrounding risk and benefit must also factor in the risk of doing nothing – especially in light of the other areas where obesity pharmacotherapy can make a meaningful difference in an individual's life:

- Prevent diabetes
- Lessen impact of osteoarthritis
- Improve sleep apnea
- Improve physical function and ameliorate disability
- Address urinary incontinence
- Sexual function and other quality of life issues
- Address infertility
- Reduced risk of Fatty liver
- Reduced risk of cancer
- Reduce depression and enhance self-esteem

For these reasons, the OAC has been working closely with Dr. Janet Woodcock and her staff at FDA's Center for Drug Evaluation and Research (CDER) as the agency carefully reviews the safety and efficacy of three new obesity drugs. During this process, we believe that there has been significant progress in educating the FDA regarding the risk/benefit analysis when it comes to review and approval of pharmaceutical treatments for those affected by obesity.

However promising though these past 18 months of dialogue have been between the obesity community and the FDA, we are still wary of the ever-present double standard when FDA and its appointed advisory committees review either current or pending obesity drugs for treating those affected by obesity – a serious multi-factorial chronic disease.

For example, last month's advisory committee hearing to review a new obesity drug did not include a single clinical obesity medicine specialist on this FDA-appointed panel. Such a situation would never stand in the case of reviewing a new drug to treat cancer or cardiovascular disease. And while we were pleasantly surprised that this panel overwhelmingly voted 20-2 to recommend FDA approval of QNEXA, we remain cautious in our optimism pending final FDA action later this year.

In addition to the near unanimous vote of the advisory committee, the OAC found the discussion and debate among panel members equally encouraging. Two issues that continued resurfacing throughout the discussion revolved around the

Obesity Action Coalition

4511 North Himes Ave., Suite 250
Tampa, FL 33614

(800) 717-3117
(813) 872-7835
Fax: (813) 873-7838

info@obesityaction.org
www.obesityaction.org

risk/benefit analysis surrounding QNEXA's 10 percent weight-loss in clinical trials and application of a balanced and fair Risk Evaluation & Mitigation Strategy (REMS) as compared to other chronic disease drugs.

Regarding the former, we believe that upcoming advisory committee panels charged with evaluating other new obesity drugs, such as Lorcaserin and Contrave, must remember that both medications (though not achieving 10 percent weight-loss) have also met or exceeded FDA's 2007 draft guidance for approval of weight-loss drugs – currently the only goal post placed on the field by the agency for drug companies to kick toward. FDA and its advisory committee panels must apply risk/benefit analysis to obesity drugs in the same fashion as drugs for other chronic disease – which are often approved because of their incremental benefit, or even ability to stabilize progression of the disease in the drug's targeted population.

In terms of the latter, we were pleased that FDA staff urged the panel to evaluate how REMS programs have been applied for other drugs, such as topirimate – one of the two currently approved FDA drugs on the market, which make up QNEXA. In the case of topirimate, we would note that FDA has not initiated any real restrictive and burdensome steps to ensure that pregnant women, taking topirimate for migraines, are "protected" from the same perceived danger of birth defects that FDA suggests are associated with the significantly lower dose of the drug contained in QNEXA. For example, pregnant women are not required to purchase topirimate through special pharmacies nor are women of child-bearing age currently taking topirimate mandated to submit to monthly pregnancy tests – two suggested REMS programs for QNEXA.

The OAC believes that new evidence-based treatment approaches for obesity should be subject to, and judged by, the same safety and approval criteria as new treatments for the evaluation and management of other chronic diseases such as heart disease or diabetes.

Setting up additional hurdles to treatment, or viewing those affected by obesity as less-intelligent than other patient groups, cannot continue. The OAC implores the FDA to address this double standard by treating obesity with the respect, urgency and action it deserves!

ABOUT THE OAC:

The OAC is a National nonprofit charity dedicated to helping individuals affected by obesity. The OAC was formed to bring together individuals struggling with weight issues and provide educational resources and advocacy tools.