



Obesity Community Statement on the Future of Obesity Drugs

During March and May of 2012, two separate Food and Drug Administration (FDA) advisory committees voted overwhelmingly to recommend that the FDA approve two new obesity drugs. Additionally, the agency appears close to finalizing approval of a third drug to treat the disease of obesity. The Obesity Action Coalition, The Obesity Society, and the American Society for Metabolic and Bariatric Surgery – members of the Obesity Care Continuum (OCC) are pleased with the great progress that the FDA has made regarding obesity drugs throughout the last 12 months. This is extremely promising news as we are now closer than ever to approval of our first obesity drugs in more than a decade.

As FDA moves forward in expanding patient access to numerous new obesity treatment tools, the obesity community urges the agency to adopt strong and fair risk management strategies that encourage both physician and patient education to ensure that appropriate patients, who understand both the risks and benefits of treatment, are prescribed these medications by appropriately trained physicians. In addition to strong Risk Evaluation and Mitigation Strategies (REMS), the obesity community believes that the FDA should utilize careful drug indication labeling, which focus on the long-term benefits that these drugs offer for the management of the chronic disease of obesity.

While cognizant of the need for careful strategies for distribution of these new obesity drugs, the FDA must also recognize that those affected by obesity are no different than the millions of other Americans affected by chronic diseases. In short, individuals who struggle with their weight are no less intelligent than those who struggle with maintaining their blood pressure or blood sugar. Therefore, FDA should not adopt REMS programs for obesity drugs that it is not prepared to adopt for other drugs.

The current obesity drugs under review have all met the FDA's February 2007 draft "Guidance for Industry Developing Products for Weight Management." And while none of these medications are without some risk, we strongly encourage the agency to move forward by allowing these drugs to reach the marketplace by restricting patient populations and indications and rigorous control of access. Such an approach, coupled with post marketing safety-trials, would be congruent with how the agency has approached new medication approval for other diseases and conditions.

We are at a critical juncture in how our country will treat the millions of Americans affected by obesity. Will we continue to stigmatize those affected and throw up unnecessary roadblocks to new treatments or will we take a serious approach to treating a serious chronic disease? We hope it's the latter!