Obesity Action Coalition

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April 21, 2011

The Honorable Darrell Issa
Chairman, House Oversight and Government Reform Committee
2157 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Issa,

On behalf of the 25,000 members of the Obesity Action Coalition (OAC), I am pleased to submit the following statement for the record for today's hearing of the House Oversight and Government Reform Committee regarding "Federal Policies Affecting Innovation and Job Growth in the Biotech and Pharmaceutical Industries." We appreciate the opportunity to submit comments regarding this critical issue and its specific impact on development of new pharmaceutical treatments for those affected by obesity.

The OAC is deeply concerned that the Food and Drug Administration (FDA) continues to utilize an unbalanced and unfair approval process in evaluating new and promising medications (Contrave, Locaserin and Qnexa) to help treat Americans affected by obesity. During 2010, the agency made critical decisions regarding three new drug applications for the treatment of the disease of obesity. Unfortunately, in each case, the FDA chose to either reject its own draft guidance or establish unreasonable pre-market approval trials, before the agency would provide its blessing to allow these new drugs to enter the market – even under strict indications and dosing requirements for those seeking access to these promising new drugs.

Our nation is in the grip of a public health epidemic unlike any it's seen before, with a widespread and devastating impact on health and life. More than two-thirds of U.S. adults are overweight or obese, and as a result are either present or potential victims of the damaging health consequences of obesity. One out of every eight deaths in America is caused by an illness directly related to obesity. Research has clearly documented the harmful health effects of excess body weight, which increases risk for conditions such as diabetes, hypertension, sleep apnea, hip and knee arthritis, low back pain and depression.

Costs attributable to obesity have been estimated at nearly $150 billion annually, including direct medical costs and indirect costs such as absenteeism and productivity losses. On an individual level, recent data indicate that due to increased health and work-related expenses, the excess cost associated with being obese is $4,879 for women and $2,646 for men annually.

Risk vs. Benefit

Surprisingly, given the terrible toll obesity takes on our country's public health, we currently have very few clinical options available to treat this condition and reduce its damage. There is currently only one approved obesity medication on the market and few new options on the horizon -- perhaps due in part to what are perceived by many obesity researchers as daunting regulatory hurdles unlike those that face new medications for any other disease. In the absence of approved medical treatments, given the physical and emotional costs of obesity, millions of individuals affected by obesity turn to fad diets and untested dietary supplements which may further damage their health.

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During 2010, FDA Secretary Margaret Hamburg discussed the role of the FDA as a "public health agency" in an article that was published in the New England Journal of Medicine. In that article, Secretary Hamburg stated:

"A public health approach recognizes that the potential good of a new medical product or policy must be balanced against the potential harm. Some benefits are not worth the risk; some risks are worth taking. Key considerations are the severity of the illness at issue, the availability of alternative treatments or preventive interventions, and the current state of knowledge about individual responses."

Frankly, we can't agree more with Dr. Hamburg's view and wonder why the agency that she leads is not applying this same reasoning when evaluating new drug therapies for those affected by obesity. The FDA must give objective consideration to the urgent need for more effective treatments for this severe, chronic disease, and to balance the significant benefits of weight losses of 5-10% with the risks of any potential drug therapy.

Hitting a Moving Target

While the OAC does not consider itself an organization that specializes in research or product development surrounding new pharmaceutical treatments, we do possess a sound understanding of the importance and fairness of the federal government establishing a level playing field regarding the drug approval process. We are deeply troubled that the FDA has yet to finalize its February 2007 draft "Guidance for Industry Developing Products for Weight Management."

This point is especially problematic given that the latest group of companies to bring new obesity drugs before the FDA during 2010 all achieved the standards of approval laid out in the 2007 draft guidance document. Despite this fact, the FDA chose to reject all three drugs and set up new additional hurdles for these small biotech companies to meet before the agency would allow their new drugs to enter the marketplace – even under extremely restricted patient population indications and dosing requirements.

In one case, the FDA decided to even ignore its own advisory committee, which voted 13 to 7 to approve Contrave during the panel's December 7, 2010 hearing. During this hearing, advisory committee members even discussed recommending premarket approval studies for Contrave but stated that such a move should be rejected because A.) the company had met the approval criteria laid out in the FDA's 2007 draft guidance; and more importantly, B.) how such a suggestion would be extremely unfair to the company as it would effectively be changing the rules in the middle of the game.

Intervention is Needed Now!

New evidence-based treatment approaches for the disease of obesity must be subject to, and judged by, the same approval criteria as new treatments for other major diseases. Unfortunately, there are relatively few treatment options available for those impacted by obesity even though obesity is an epidemic in our country. In failing to approve any of these three new obesity medications, we believe that the FDA has chosen a double standard for evaluating and approving treatment options for this disease.

If this outcome is allowed to stand, it will leave even fewer treatment options for those who struggle with obesity and will likely further discourage any research and development in the area of obesity ever again. We have already witnessed the withdrawal of the major pharmaceutical companies from this market given the lack of clear

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predictability surrounding FDA's approval process. We are now seeing the same result in the small biotech market and truly wonder who will fill this void in the absence of any firm drug approval guidance from the FDA.

Therefore, we urge the Committee to encourage the FDA to follow its own 2007 drug approval guidance and allow these drugs to reach the marketplace under strict patient population indications and rigorous dosing requirements. Such an approach, coupled with post market trials, would be congruent with how the agency has approached new medication approval for other diseases or conditions.

Sincerely,

Joe Nadglowski, OAC President and CEO