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May 29, 2007

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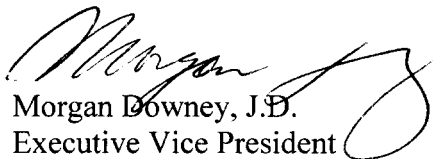
RE: Docket No. 2007N-0090
Endocrinologic and Metabolic Drug
Advisory Committee

Dear Sir:

Attached are the comments of The Obesity Society on the above noted docket.

If you have any questions, please do not hesitate to contact me.

Sincerely,


Morgan Downey, J.D.
Executive Vice President

2007N-0090

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**Statement on Rimonabant
Endocrinologic and Metabolic Drugs Advisory Committee
Of the Food and Drug Administration
The Obesity Society
Rockville, MD
June 13, 2007**

Good afternoon. I am Caroline Apovian, M.D. representing *The Obesity Society*, formerly known as NAASO. Before proceeding to our comments, we wish to make known that *THE OBESITY SOCIETY* has received unrestricted financial contributions from sanofi-aventis, which manufactures rimonabant as well as from competing pharmaceutical and non-pharmaceutical companies.

THE OBESITY SOCIETY is the preeminent scientific society in North America that has obesity as its focus. Our nearly 2,000 members include clinicians, educators, and scientists from academia, government, industry. We are committed to improving the understanding of the causes, consequences, and management of obesity. The Society has worked with the Food and Drug Administration to modernize the guidances to industry on the development of future pharmacological treatments for obesity.

THE OBESITY SOCIETY is supportive of the development and approval of products for obesity treatment, prevention, and amelioration when the safety and efficacy of those products are well-supported by rigorous scientific evidence.

In any decision making about potential approval of obesity agents, *THE OBESITY SOCIETY* believes the following statements, all of which are well-supported by substantial empirical evidence, define the context and merit consideration.

- The causes of obesity are complex and multifactorial, involving genetic, behavioral, and environmental factors that are only partially understood.
- Obesity is a chronic condition that significantly impairs the quality of life and reduces life expectancy.
- Obesity increases the risk for heart disease, type 2 diabetes, atherogenic lipid problems, hypertension, non-alcoholic liver disease, sleep apnea, and several other serious conditions. Obesity and its related comorbidities, in particular, type 2 diabetes, represent one of the major threats to the long-term health and wellbeing of the United States population.

- Obesity is related to increased healthcare utilization, higher healthcare costs, greater absenteeism from work, and increased rates of disability.
- The management of obesity is of increasing concern as the proportion of persons with obesity in the US rises. The prevalence of obesity is at an all time high and is currently estimated to affect nearly 1/3rd of the US adult population. Obesity has also increased substantially in children and adolescents.
- Obesity has now exceeded malnutrition, that is undernutrition, as the most prevalent nutritional problem in the world and the continuing obesity epidemic is exacting a huge personal and health care burden on our society.
- Among obese people, weight loss achieved in the context of medically recommended programs improves quality of life, functionality, most of the weight-related biomarkers signaling increased disease risk, and reduces the risk of developing future disease.
- Achievable weight losses, as small as 5-10% of initial body weight, appear to be sufficient to confer important health benefits.
- Current treatment options, including pharmacotherapies, for obesity are limited. With the exception of bariatric surgery, available treatments are associated with modest efficacy and all have side-effects that, for some individuals, are intolerable. Additional agents targeted at new mechanisms are potentially useful and very much needed expansions of the treatment armamentarium.
- Lifestyle modification remains a key component of treatment for obesity. Unfortunately, programs of intensive lifestyle changes are difficult to implement in clinical practice and for many patients.
- Given that weight regain rates are high among obese people in the absence of long-term pharmacotherapy or surgery, effective and safe medications to assist people to lose *and maintain* weight and improve health gains are needed.
- As with people with type 2 diabetes where lifestyle therapy and adjunctive drug treatment are current standards of care, obese people with health problems deserve similar access to health care delivery.
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- Recently published evidence-based clinical practice guidelines on the management of obesity recommend that pharmacotherapy and bariatric surgery should be offered to selected obese individuals.

Obesity is long been associated with enormous social stigma. As scientists, we recognize that 'blame' has no role in our discussions. Obesity is the result of long-term energy balance, which can include behavioral components and is influenced by genetic and environmental factors. As clinicians, we recognize that persons with obesity deserve our care, our compassion, and our help. Obese people deserve access to safe and effective medications that can be reviewed in the same manner as are medications for other chronic conditions.

We applaud the FDA for undertaking a rigorous review of the safety and efficacy data on rimonabant. The clinical and patient community expects the drug review process to protect them against dangerous and ineffective products. We can expect that many physicians are eager to have an additional tool to help their patients. And we can expect many patients will be eager to find support for their weight management efforts. We expect that the FDA will review the data on this drug by the same standards it employs for products of other similar conditions and will make its decision as expeditiously as possible.

Thank you for this opportunity to present our views.

Carolina Apovian, M.D.
On Behalf of The Obesity Society