



August 31, 2011

Dr. Janet Woodcock  
Director, Center for Drug Evaluation and Research  
Food & Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Dr. Woodcock,

In prior discussions with the Food & Drug Administration (FDA), the member groups of the Obesity Care Continuum (OCC) have found much common ground, including a deep concern about the public health impact of the obesity epidemic; an abiding commitment to develop and use obesity medications to bring the health benefits of weight loss to many in our population who struggle with losing weight; and an appreciation for the importance of balancing the risk inherent in taking a medication with the benefit of modest weight loss. The upcoming review of agents for the treatment of obesity provides an opportunity for the OCC to comment with regard to several issues, in particular ones where we have engaged FDA representatives in discussion.

**What is the appropriate patient profile for prescribing drugs for weight loss? Clearly, this question is best answered by understanding the risks that obesity imposes and the benefits of modest weight loss.**

The benefits of modest weight loss are well documented in studies of individuals with symptoms (e.g. functional limitations, joint pain), abnormal risk factors (e.g. lipid abnormalities, elevated CPK, abnormal glucose or impaired glucose tolerance, metabolic syndrome, or diseases associated with obesity (e.g. hypertension, diabetes, sleep apnea, urinary incontinence, arthritis). All of these can improve with modest (5%-10%) weight loss. We think that individuals who are overweight or obese with symptoms of one or more obesity-related risk factors or co-morbid conditions are appropriately included in obesity pharmacotherapy treatment paradigms, because the risk they face and the symptoms they incur justify pharmacotherapy intervention.

However, in clinical practice, we can identify individuals who are overweight or obese who do not have symptoms, abnormal risk factors or diseases associated with obesity, and in those patients there is little to show in the way of improvement with modest weight loss. Individuals who are "healthy" but overweight and obese, particularly in class I obese category, do exist albeit uncommonly, but without manifestations of risk or symptoms, obesity treatment must be considered preventive in these categories.

### **Who is at greatest risk for side effects?**

Still, some individuals who meet the profile described above (with obesity associated symptoms, risk factors or diseases) should be excluded from treatment because of increased risk of adverse events they might encounter with a specific medication. For example, medications with a pressor effect should not be given to those with uncontrolled hypertension or with a history of cardiovascular disease (e.g. MI, coronary surgical procedure, stroke). Similarly, individuals taking some antidepressants should not receive drugs that might increase risk for serotonin syndrome and individuals with a history of seizures should not receive medications which potentiate seizures. Thus, an important part of the equation to identify appropriate patient profiles for obesity medication is to exclude those who might be at increased risk for side effects and adverse events.

### **What is the best way to assure that the appropriate patient is prescribed obesity medications in an appropriate way?**

Assuring appropriate prescription and use. Modern REM programs insure that risks can be mitigated by limiting prescription rights to certified physicians, utilization of central pharmacies to limit unapproved dispensing of drugs and requiring documentation of an appropriate patient profile and response pattern for prescription renewal. We endorse the use of these modern techniques to assure that obesity medications are not used for cosmetic purposes but that allow patients who are most likely to benefit to have access to them.

### **What is the benefit to the public health of access to obesity medications under appropriate circumstances described above?**

In the face of an epidemic of overweight and obesity and the health risks that are associated, it is imperative that physicians have access to medications to help their patients. Lifestyle change is foundational to weight loss and medications work through biologic means to reinforced behavioral attempts at changing lifestyles. Obesity medications can help more patients achieve significant (5-10%) weight loss and achieve meaningful health benefits. The obesity epidemic and the twin epidemic of type 2 diabetes are a call to action to physicians to help their patients achieve lifestyle change.

Sincerely,



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With a combined membership of over 100,000 healthcare professionals and patient advocates, the Obesity Care Continuum is dedicated to promoting access to, and coverage of, the continuum of care surrounding the treatment of overweight and obesity. The OCC also challenges weight bias and stigma oriented policies – whenever and wherever they occur. The OCC is a coalition of the Obesity Action Coalition (OAC), the Obesity Society (TOS), the American Dietetic Association (ADA), and the American Society for Metabolic and Bariatric Surgery (ASMBS).