



January 14, 2011

Margaret Hamburg, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hamburg,

Our nation is in the grip of a public health problem unlike any it's seen before, with a widespread and devastating impact on health and life. More than two-thirds of US 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.¹ 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 and overweight have been estimated at \$270 billion annually, including direct medical costs and indirect costs such as absenteeism and productivity losses.² On an individual level, recent data indicated 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.³

Surprisingly, given the terrible toll obesity takes on U.S. public health, we currently have very few clinical options available to treat this condition and reduce its damage. There is 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 obese individuals turn to fad diets and untested dietary supplements which may further damage their health.

The Obesity Society (TOS), American Association of Clinical Endocrinologists (AACE), American Society for Metabolic and Bariatric Surgery (ASMBS), and Obesity Action Coalition (OAC) would like to call to your attention to several pervasive myths about obesity that are common even within the medical and scientific community:

Myth #1: Obesity is just a lifestyle problem.

Reality: Obesity is a chronic, relapsing, neurochemical disease with a genetic basis. Just telling an obese person to "eat less and exercise more" is overly simplistic and demonstrably ineffective. For many people, the extent of long-term calorie reduction and exercise enhancement necessary for adequate weight loss is not feasible for a multitude of biological and environmental reasons we are only beginning to appreciate. Lifestyle changes such as diet and exercise are obviously key elements of any obesity treatment plan, but just like other chronic conditions that have a lifestyle component (e.g. hypertension and diabetes), there are strong bio-regulatory networks working to defeat weight

loss efforts and sustain obesity. Thus, for many patients, obesity treatment requires lifelong interventions in addition to healthy lifestyle change. Ignoring this need ignores the human and financial costs of the condition. Obesity deserves serious treatment.

Myth #2: Obese people lack willpower and are over-indulgent.

Reality: Pervasive weight bias is a major impediment to providing people who suffer from obesity with the treatment they need. Biased attitudes toward obese patients have been documented among the general public and health care providers. Such attitudes can obscure the need for serious intervention options for this condition. Obesity is a chronic neurochemical disease, not a character flaw. As such, it requires an array of effective treatment tools.

Myth #3: Obese patients need to lose lots of weight to achieve health benefits

Reality: A 5-10% weight loss produces clinically significant reductions in blood pressure, lipids, blood glucose and other health parameters -- illustrating that the goals laid out for those who have chosen to address their obesity should focus less on total weight-loss and more on health improvement. And, while there are clear clinical benefits associated with significant excess weight loss that accompany surgical intervention, weight loss surgery can not be the only treatment tool that healthcare providers have in their arsenal -- as any one treatment may not work for every individual.

Last year in the *New England Journal of Medicine*, you and Dr. Joshua Sharfstein of the FDA, discussed the role of the FDA as a “public health agency”.⁴ In your article, you state “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.” TOS, AACE, ASMBS, and OAC urge the FDA to 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.

There has been some expression of concern about the abuse of new obesity drugs, particularly their use by non-obese people seeking weight loss for purely cosmetic reasons. TOS, AACE, ASMBS, and OAC all agree that there is a need to properly educate the doctors who prescribe any obesity treatments to ensure appropriate use. Such education must include a) selection of appropriate patients who need to lose weight for medical benefit, b) recognition of the importance of using medication in conjunction with a healthy diet and exercise regimen, and c) communication of realistic expectations concerning the amount, rate and ease of weight loss. Nonetheless, withholding effective medications from tens of millions of people whose health is otherwise imperiled because of concerns that these medications might be misapplied by a few ill-informed or unethical prescribers seems inconsistent with a balanced public health risk-benefit analysis.

Additionally, we are concerned about access to treatment issues that could result from requiring cardiovascular outcomes/endpoints in pre-approval clinical trials as this approach would delay drug delivery, impact innovation and likely not improve the safety profiles of the drugs. Instead we recommend strict and transparent post-approval surveillance of new obesity medications.

Obesity subjects more than a third of US adults to widespread illness, disability, and premature death. If we don't increase the current limited range of treatment options, we cannot hope to decrease the current toll of obesity on the nation's public health.

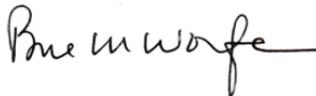
Sincerely,



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