



The Obesity Care Continuum (OCC) is pleased to provide the following comments before the Food and Drug Administration's (FDA) Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee regarding the premarket application (PMA) for the Maestro® Rechargeable System sponsored by Enteromedics, Inc.

The past two years have been very exciting and promising for the obesity community and those developing new treatment avenues for the millions of Americans affected by obesity. We have seen the FDA approve two drugs for the treatment of the disease of obesity – after a 13-year hiatus in this space. This is a tremendous proactive step in ensuring obesity treatment availability and we are pleased that the FDA's actions have encouraged other companies to pursue other drug and device solutions for treating this chronic disease. Obesity is a serious medical disease and our patients deserve additional treatment options. We urge the agency and its reviewers to consider the urgent need for more treatment options as you review this application.

While we are excited for the recent round of obesity drug approvals, it is important that we not lose sight of the overarching goal to increase obesity treatment options across the spectrum from medically managed weight-loss to metabolic and bariatric surgery. As obesity carries with it many root causes, which often coincide, such as emotional, environmental, physical, behavioral, genetic and more, it is important that we continue to strive for an increase in all FDA-approved obesity treatments.

If we look at any other disease state, the armamentarium used to treat that disease is vast and impressive; however, obesity, which affects more than 93 million Americans, is often limited to very few options. Treating obesity is not a simple science. If it were, we would not have an epidemic on our doorstep at this time.

For these reasons, the OCC is hopeful that the advisory committee will provide a fair and balanced review of the Maestro® Rechargeable System. The implantable device is a neuromodulator, which delivers high frequency (5000 Hertz), controllable electrical pulses to the intra-abdominal vagus nerve trunks. The effect of VBLOC therapy is reported to suppress neural signals carried by the vagus nerve trunks, resulting in decreased hunger, decreased digestive enzyme secretion and calorie absorption, and increased satiety.

The proposed indication for use for the Maestro® Rechargeable System, as stated in the PMA, is as follows: The Maestro® Rechargeable System is indicated for use in weight reduction in adult patients with obesity that have a Body Mass Index (BMI) of at least 40 kilograms per square meter (kg/m^2), or a BMI of at least 35 kg/m^2 with one or more obesity-related comorbid conditions, and have failed a more conservative weight reduction alternative.

In closing, as future obesity treatments come up for FDA review in the coming months and years, we strongly encourage the FDA to continue displaying the proactive mindset used throughout the past two years. For the first time in history, we have seen the first glimpse of treating obesity as a disease with a full spectrum of tools. It is imperative that we keep this positive momentum moving forward with the future approval of obesity treatment options.

About the Obesity Care Continuum

The leading obesity advocate groups founded the Obesity Care Continuum or “OCC” in 2010 to better influence the healthcare reform debate and its impact on those affected by overweight and obesity. Currently, the OCC is composed of the Obesity Action Coalition (OAC), the Obesity Society (TOS), the Academy of Nutrition and Dietetics (AND), the American Society for Metabolic and Bariatric Surgery (ASMBS) and the American Society for Bariatric Physicians (ASBP).

The purpose of the OCC is to pool the resources of its member groups and better coordinate Federal and state advocacy efforts to secure access to, and coverage of, the continuum of care surrounding the treatment of overweight and obesity. With a combined membership of more than 125,000 patient and healthcare professional advocates, the OCC covers the full scope from nutrition, exercise and weight management through pharmacotherapy to device and surgery. The coalition is a major force in the continuing debate regarding the critical need to both prevent and treat the disease of obesity.