



18 U.S.C. 208(b) (3) and 712 Waivers to Allow Participation in a
Food and Drug Administration Advisory Committee

DATE: April 19, 2012

TO: Jill Hartzler Warner, J.D.
Associate Commissioner for Special Medical Programs (Acting)
Food and Drug Administration

THROUGH: Vince Tolino _____ /S/
Director, Ethics and Integrity Staff
Office of Management Programs
Office of Management

Michael F. Ortwerth, Ph.D. _____ /S/
Director, Advisory Committee Oversight and Management Staff
Office of Special Medical Programs

FROM: Jayne E. Peterson _____ /S/
Director, Division of Advisory Committee and Consultant Management
Office of Executive Programs
Center for Drug Evaluation and Research

Name of Voting Member: Daniel Bessesen, M.D.

Committee: Endocrinologic and Metabolic Drugs Advisory Committee Meeting

Meeting date: May 10, 2012

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of the Financial Interest(s):

Daniel Bessesen, M.D., is a consultant on the Drug Safety Monitoring Board (DSMB) for _____ (b) (4). This consulting involves a competing product for an indication that is related to the product to be discussed by the committee and the agency's actions regarding NDA 22-529, described below, could impact _____ (b) (4) willingness or ability to continue its consulting relationship with Dr. Bessesen.

The magnitude of personal financial interest: \$0 – \$5,000 per year

Description of the Particular Matter to Which the Waiver Applies:

The committee will discuss the safety and efficacy of new drug application (NDA) 22-529 (lorcaserin hydrochloride) tablets, manufactured by Arena Pharmaceuticals, as an adjunct to diet and exercise for weight management in patients with a body mass index (BMI) equal to or greater than 30 kilograms (kg) per square meter or a BMI equal to or greater than 27 kg per square meter if accompanied by weight-related co-morbidities.

Additional Facts: None

Basis for Granting the Waiver:

According to the Division of Metabolism and Endocrinology Products, the need for Dr. Bessesen's expertise is essential to this meeting and greatly outweighs the potential for a conflict of interest.

Lorcaserin hydrochloride is a new molecular entity being developed for the treatment of obesity. This is the second advisory committee meeting for this product; Arena Pharmaceuticals received a complete response letter on their application for this product after the first meeting because of marginal weight loss efficacy and concern regarding carcinogenicity risk in rats.

Daniel H. Bessesen, M.D. is Head, Section of Endocrinology at Denver Health Medical Center and Professor of Medicine in the Division of Endocrinology, University of Colorado, School of Medicine. In addition, he is Associate Director for Research Training, Colorado Center for Human Nutrition, Co-Director of the Metabolism Course at University of Colorado School of Medicine, and the Fellowship Program Director of the Fellowship Training Program in Endocrinology, Metabolism and Diabetes, at University of Colorado School of Medicine.

Dr. Bessesen is a clinical endocrinologist who treats patients with diabetes mellitus, lipid disorders, and obesity. He is a member of the Obesity Society, the Endocrine Society, the American Society for Nutrition, and the Society for the Study of Ingestive Behavior. He is on the Obesity Guideline committee for the Colorado Department of Public Health and serves on the external advisory committee to the Minnesota Obesity Research Center.

Dr. Bessesen also conducts basic science research on obesity and insulin resistance and has over 50 original papers and review articles on relevant topics such as fatty acid and glucose metabolism, eating behaviors, dietary composition, body composition, energy expenditure, and weight loss in clinical trials. He is currently chair of the NIH-NIDDK Clinical Investigations in Diabetes and Obesity study section.

Dr. Bessesen's combined clinical and scientific expertise is needed at this meeting.

Eleven obesity experts were invited to this meeting. Six were unable to attend due to schedule conflicts or conflicts of interest. The remaining are able to attend with Dr. Bessesen requiring a waiver.

It is essential to have several obesity experts with clinical expertise (specifically physicians who treat obese patients) for the discussions at this advisory committee meeting. In addition to clinical expertise, a breadth of knowledge in the science of obesity management, the treatment of obesity, and clinical trials is necessary. Including Dr. Bessesen, there will be five obesity experts attending, each bringing a different perspective and experience. Four have clinical experience, including two endocrinologists (including Dr. Bessesen), one is a bariatrician and one is a pediatric endocrinologist. The additional obesity expert attending is an epidemiologist. Thus, Dr. Bessesen's clinical and scientific expertise in obesity is essential to this meeting in order to have an adequate number of obesity clinicians and experts for a full discussion.

Accordingly, I recommend that you grant a waiver for Dr. Daniel Bessesen, a temporary voting member of the Endocrinologic and Metabolic Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a) as well as the conflict of interest prohibitions of section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

Certification:

- The individual may participate, pursuant to 18 U.S.C. 208(b)(3) – The need for the individual’s services outweighs the potential for a conflict of interest created by the financial interest involved.
- The individual may participate, pursuant to 21 U.S.C. 379d-1 – The individual’s service is necessary to afford the advisory committee essential expertise.

Limitations on the Regular Government Employee’s or Special Government Employee’s Ability to Act:

Non-voting

Other (specify):

Denied – The individual may not participate.

_____ /S/	_____ 4/25/2012
Jill Hartzler Warner, J.D. Associate Commissioner for Special Medical Programs (Acting)	Date