



Waiver to Allow Participation in a Food and Drug Administration Advisory Committee

DATE: April 28, 2009

TO: Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy
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 Policy, Planning, and Preparedness

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

Name of Temporary Voting Member: Edward Pritchett, M.D.

Committee: Psychopharmacologic Drugs Advisory Committee

Meeting dates: June 9 - 10, 2009

Description of the Facts on Which the Waiver is Based:

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

Dr. Pritchett owns stock in two competing firms.

The magnitude of the total interests are: between \$25,000 to \$50,000.

Description of the Particular Matter to Which the Waiver Applies:

On June 9 and 10, 2009, the committee will discuss safety and efficacy issues for the following new drug applications (NDAs): 1) NDA 20-639/S-045 and S-046: Seroquel

(quetiapine fumarate), AstraZeneca Pharmaceuticals LP, for (a) the acute treatment of schizophrenia in adolescents (13-17 years of age), and (b) the acute treatment of bipolar mania in children (10-12 years of age) and adolescents (13-17 years of age); 2) NDA 20-825/S-032: Geodon (ziprasidone hydrochloride), Pfizer Inc., for the acute treatment of manic or mixed episodes associated with bipolar disorder, with or without psychotic features in children and adolescents ages 10-17 years; and 3) NDA 20-592/S-040 and S-041: Zyprexa (olanzapine), Eli Lilly and Company, for (a) the acute treatment of manic or mixed episodes associated with bipolar I disorder, and (b) the acute treatment of schizophrenia in adolescents. The committee will be asked to vote on whether or not these products have been shown to be effective and acceptably safe for these pediatric indications.

Additional Facts: none

Basis for Granting the Waiver:

Dr. Pritchett owns stock in two competing firms. This stock is worth less than (b) (6) percent of his net worth, and is not so substantial as to be deemed likely to affect the integrity of his services.

Any positive or adverse recommendations by the committee regarding Seroquel, Geodon, and Zyprexa, or the subsequent actions by the Agency, would likely have a minimal affect on Dr. Pritchett's interests. These competing firms are large diverse firms that do not depend on one or two products for their economic survival. Both of these firms have products spanning many different therapeutic areas. Furthermore, there are many generic products from different companies available for the indications listed above, a fact that suggests that effects on any individual product of the committee's recommendations will be small. Finally, in addition, there are many companies that market products that are used for these indications.

The committee will be asked to vote on whether or not Seroquel, Geodon, and Zyprexa have been shown to be effective and acceptably safe for the pediatric indications indicated above. In particular, the committee will examine the long-term metabolic impact, including cardiac impact, of these atypical antipsychotic drugs to be used in pediatric patients who require them for control of often devastating psychiatric symptoms. The division will be able to reach an appropriate regulatory decision only with the help of experts qualified to balance the risks and benefits of these products in the pediatric population. Dr. Edward Pritchett is uniquely qualified to provide the Agency with just this expertise. He is a board certified Cardiologist and has several academic appointments, including Professor of Cardiology and Pharmacology. In addition, Dr. Pritchett has extensive experience serving on extra-mural scientific review boards (FDA, NIH, and American Heart Association). He served as a member of the Cardiovascular and Renal Drugs Advisory Committee from 1988 to 1992, and has served as an SGE consultant from 2003 until present. At past advisory committee meetings, Dr. Pritchett has distinguished himself as a major contributor in synthesizing available information and formulating a logical basis for regulatory decision-making. He has demonstrated efficiency in preparing thoroughly and guiding critical topics of discussion with challenging insights and perceptive inquiries. His ability to articulate important information facilitates an enhanced, well-balanced discussion amongst the Committee members. In addition, Dr. Pritchett's extensive expertise in complex clinical trials will contribute to the committee discussions

on the NDAs under consideration. His input will greatly enhance knowledge of the subject of long-term cardiac risk and allow us to fully consider the cardiac impact of these drugs.

Individuals with expertise in both the specialized field of Cardiology and in clinical trial evaluation that do not have disqualifying financial interests are rare. Of the ten Cardiologists invited to this meeting, only one other individual without a disqualifying financial interest was available, besides Dr. Pritchett. The division believes that more than one cardiologist on the panel is necessary to gain balanced opinions on the topics at hand.

Dr. Pritchett’s contribution to the Agency’s consideration of these applications will far outweigh any conflict of interest that might be perceived. The committee’s consideration of these applications in the absence of balanced cardiology expertise at the meeting would rightly be seen as inadequate, especially given that Dr. Pritchett, an expert in this area, would be otherwise available to assist the Agency in this most important matter. The Division feels strongly that Dr. Pritchett be permitted to attend and fully participate in this meeting.

Accordingly, we recommend that you grant a waiver for Edward Pritchett, M.D., a temporary member of the Psychopharmacologic Drugs Advisory Committee, from the conflict of interest prohibitions of 18 U.S.C. §208(a) as well as section 712(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act

Certification:

 X The individual may participate – The need for the Special Government Employee’s services outweighs the potential for a conflict of interest.

 X The individual may participate – The individual’s participation 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/
Randall W. Lutter, Ph.D.
Deputy Commissioner for Policy

5/21/09
Date