



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

DATE: June 10, 2011

TO: Jill Hartzler Warner, J.D.  
Associate Commissioner for Special Medical Programs (Acting), FDA

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, J.D. \_\_\_\_\_ /S/  
Director, Division of Advisory Committee and Consultant Management  
Center for Drug Evaluation and Research

Name of Advisory Committee Member: David J. Keljo, MD, PhD

Committee: Gastrointestinal Drugs Advisory Committee

Meeting date: July 21, 2011

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of the Financial Interest:

\_\_\_\_\_ (b) (6) The  
current market value of the stock is between \$ \_\_\_\_\_ (b) (6).

Description of the Particular Matter to Which the Waiver Applies:

On July 21, 2011, the committee will discuss the results from a clinical trial of supplement biologics license application 103772/5301, REMICADE (infliximab), by Janssen Biotech, Inc. (formerly known as Centocor Ortho Biotech Inc.), in the treatment of pediatric patients with moderately to severely active ulcerative colitis.

Additional Facts: None

Basis for Granting the Waiver:

David J. Keljo, MD, PhD, is a pediatric gastroenterologist at Children's Hospital of Pittsburgh and Director of the hospital's Inflammatory Bowel Disease Center.

He has notable expertise in inflammatory bowel disease (IBD) in children, including Crohn's disease and ulcerative colitis. His research interests include the natural history of pediatric inflammatory bowel disease, bone disease in pediatric inflammatory bowel disease, fecal inflammatory markers post small bowel transplant and patient education in IBD. He has authored approximately 34 peer reviewed research articles and contributed to the publication of dozens of papers, reviews, abstracts, or books.

Dr. Keljo has made numerous contributions to pediatric IBD, including advisory and leadership roles for the Pediatric IBD Collaborative Research Group and the Crohn's and Colitis Foundation of America. In 2006 he was awarded the Crohn's and Colitis Foundation of America Western Pa/WV Chapter Physician of the Year.

Dr. Keljo is the local PI on the "UPMC Center for Inflammatory Bowel Disease (IBD) Research Registry," a database that serves as a foundation for contacting patients for clinical trials, as well as on the "CCFA Risk Stratification Study." In addition, he is the site PI on the "Pediatric IBD Collaborative Research Group Registry."

The July 21, 2011 Gastrointestinal Drugs Advisory Committee (GIDAC) meeting has been convened to discuss a number of key issues that require expertise in the treatment of pediatric IBD. The committee currently has a paucity of physicians who have the substantial background and depth of knowledge that Dr. Keljo possesses in pediatric IBD. In an attempt to gain the appropriate representation, the Division contacted at least 31 other pediatric gastroenterology and adult and pediatric IBD experts, with at least nine being pediatric IBD experts. However, those individuals were either recused due to conflict of interests, self-recused at the beginning of the conflict of interest screening process, unable to attend due to schedule conflicts, or not screened because they had incomplete paperwork. We currently have one other pediatric IBD expert attending the committee meeting and another expert pediatric gastroenterologist with a research background in IBD that requires a waiver. It should be noted that the pediatric IBD community is relatively small. About 150,000 of the approximately 1.4 million patients with IBD in the United States are children under age 17. Many pediatric IBD experts are leaders at medical centers and institutions that actively engage in clinical research, most of which are commercially funded; therefore, it is difficult to find experts without conflicts.

It should be noted that REMICADE is already approved in children for other indications, including a subtype of inflammatory bowel disease called Crohn's disease. This advisory committee will discuss the results from a clinical trial in the treatment of pediatric patients with moderately to severely active ulcerative colitis. The use of Tumor Necrosis Factor (TNF) blockers, such as REMICADE, in a pediatric population presents a number of clinical challenges that require input from pediatric gastroenterologists who have experience with this drug class. The clinical study to be discussed will require a risk/benefit assessment unique to the IBD pediatric population, with which Dr. Keljo has considerable clinical experience. The application under review has given the division an

opportunity to review their past approach to guiding drug development for TNF blockers in children with IBD. Dr. Keljo's contributions to the advisory committee discussion could potentially result in the division changing their approach to the design and conduct of pediatric studies in ulcerative colitis.

In summary, the division believes that it is critical to have at least two experienced pediatric IBD experts participate in the advisory committee meeting and there has been a genuine effort to secure individual participation and representation without conflicts of interest. Dr. Keljo is highly skilled and knowledgeable in his field of pediatric IBD. His expertise will contribute to the diversity of opinions and expertise represented on the committee and will provide a foundation for developing advice that is fair and comprehensive. Therefore, we request this waiver for Dr. Keljo be approved due to the strong need for experienced pediatric IBD experts.

Accordingly, we recommend that you grant a waiver for Dr. David Keljo, a temporary member of Gastrointestinal 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/\_\_\_\_\_  
Jill Hartzler Warner, J.D.  
Associate Commissioner for Special  
Medical Programs (Acting)

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06/30/2011  
Date