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

DATE: June 30, 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

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

FROM: Kathleen L. Walker, RN, MEd. /S/
      Chief, Integrity, Committee and Conference Management Branch
      Division of Ethics and Management Operations, OMO
      Center for Devices and Radiological Health

Name of Advisory Committee Member: Jeffrey S. Borer, M.D

Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee

Meeting date: July 20, 2011

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of the Financial Interest(s):
Jeffrey S. Borer, M.D serves on the Circulatory System Devices Panel, which reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the circulatory system and makes appropriate recommendations to the Commissioner of Food and Drugs. Dr. Borer has an Adjunct Professor appointment at Cornell University. Cornell University has been identified as a clinical site for the Edwards SAPIEN Transcatheter Heart Valve study coming before the Panel for discussion. Dr. Borer is not involved with the Transcatheter Heart Valve study. His responsibilities are to give unpaid lectures at Cornell when...
asked. He has been asked once in three years (none this year). His privileges include the capacity
to admit and follow patients in the hospital. He has not admitted any patients under his name in the
2.5 years since he left Cornell; however, some of his patients have been admitted by others and,
when they are, he visits and bills them for the visits (money goes to his current employer, the State
University of New York Downstate, not to him and not to Cornell). There is no management
relationship between Dr. Borer, Dr. Krieger and Dr. Wong, the study’s principal investigators. His
employer was awarded between $100,001 and 300,000 in 2010, and between $50,001 – 100,000 in
2011 from Edwards Lifesciences LLC. In addition, fees between $0 and 5,000 a year will be paid
for follow up for each patient over a five year period (this amount is included in the total
outstanding amount due to the Institute). In the upcoming year, his institution will receive
payments over $300,000 for patient follow-up and as allocated for all visits completed and
potential travel reimbursement.

Description of the Particular Matter to Which the Waiver Applies:
Dr. Borer has been asked to participate in the meeting to discuss, make recommendations, and
vote on information related to the premarket approval application for the Edwards SAPIEN
Transcatheter Heart Valve sponsored by Edwards Lifesciences. The Edwards SAPIEN™
Transcatheter Heart Valve, model 9000TFX, sizes 23mm and 26mm and accessories implant
system consists of the following:
- The Edwards SAPIENTM Transcatheter Heart Valve consists of a heterologous (bovine)
  pericardium leaflet valve sutured within a stainless steel mesh frame, with a polyester skirt.
  It is offered in two sizes, a 23 mm and a 26 mm.
- The RetroFlex 3 Delivery System is used to advance the bioprosthesis through the
  RetroFlex sheath over a guide wire and to track the bioprosthesis over the aortic arch and
  for crossing and positioning in the native valve. The delivery system also comes with a
  sheath, introducer, loader, dilator, balloon (used to pre-dilate the native annulus) and a
  crimper.

The Edwards SAPIEN™ Transcatheter Heart Valve, model 9000TFX, sizes 23mm and 26mm and
accessories are indicated for use in patients with severe aortic stenosis who have excessively high
operative risk.

Additional Facts: None

Basis for Granting the Waiver
Dr. Borer’s vast experience in cardiovascular medicine, especially his recognition as a world
renowned heart valve disease expert, is considered a necessity for the July 20th Panel discussion.
Dr. Borer has distinguished himself as a key panel member in past meetings through his thought
provoking input and insight into clinical issues. He is a very well respected expert in heart valve
disease and has significant experience for both the Cardio-Renal Drugs Advisory Committee and
the Circulatory System Devices Panel.

The topic for discussion is the Edwards SAPIEN Transcatheter Heart Valve, specifically indicated
for transfemoral delivery in patients with severe aortic stenosis who have been determined by a
cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing co-
morbidities would not preclude the expected benefit from correction of the aortic stenosis. This is
the first percutaneously delivered aortic heart valve to undergo review by the FDA for premarket
approval, and represents a breakthrough technology. The target patient population included in the
proposed indication includes patients who are not candidates for surgical aortic valve replacement, leaving them with extremely limited options. As a result, this device has the potential to offer a major breakthrough as an alternative treatment option.

Dr. Borer is a recognized expert in heart valves, with a multitude of publications in this field. Dr. Borer currently serves as the President of the Heart Valve Society of America and the Heart Valve Trialists Society, Chairman of The Howard Gilman Institute for Heart Valve Disease, and is a member of the International Organization for Standardization (ISO) US Valve Experts Committee. As such, Dr. Borer has an expert understanding of the acute and chronic safety and effectiveness issues that may arise from the use of this device, and his knowledge of this field is without equal.

Dr. Borer is being sought for participation in this panel meeting because of his unique experience as a heart valve specialist, his expertise in clinical trial design and his understanding of the specific disease to be treated. In our panel preparation process, we approached multiple individuals who have experience in these areas, but were unsuccessful in finding the range of experience similar to Dr. Borer. The panelists we contacted who had expertise in this area were either ineligible or unavailable due to financial or scheduling conflicts, including physicians from the CDRH and CDER panels as well as the NIH database. The Agency believes that there must be a heart valve specialist perspective to balance the surgical expertise in order to have a thorough deliberation of the device under review. At this time there are no other heart valve specialists on the panel; therefore, the Center believes that a minimum of one heart valve specialist must be present for the panel discussions. Other heart valve experts that may have been able to fill this role are consultants to the device sponsor, Edwards Lifesciences. There is simply no other individual that could be found to replace this individual’s expertise for this particular meeting.

Accordingly, I recommend that you grant a waiver for Dr. Jeffrey S. Borer, a temporary voting member of the Circulatory System Devices Panel, from the conflict of interest prohibitions of 18 U.S.C. § 208(b)(3) and the policy standard that the individual’s service is necessary to afford the advisory committee essential expertise.

Certification:

X 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.

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)  

06/30/2011  Date