

November 2003

**IMPORTANT UPDATED INFORMATION FOR PHYSICIANS ABOUT PATIENTS WITH  
BJORK-SHILEY CONVEXO-CONCAVE HEART VALVES**

Dear Doctor:

This letter provides new information about the risk of outlet strut fracture for Bjork-Shiley Convexo-Concave (BSCC) heart valves and new recommendations from an independent expert panel regarding prophylactic valve replacement. The recommendations are described in detail in the enclosed attachment.

Under the Settlement Agreement that was entered into by a worldwide class of BSCC heart valve patients and Shiley Incorporated and approved by the U.S. District Court in Cincinnati, Ohio in Bowling v. Pfizer, an independent expert medical and scientific panel consisting of cardiothoracic surgeons, cardiologists, epidemiologists and a cardiovascular radiologist was created called the Supervisory Panel (Panel). Under the terms of the Settlement Agreement, the Panel is charged with the responsibilities of conducting studies and research, and of making recommendations regarding which BSCC heart valve patients should be considered for prophylactic valve replacement. The Panel's recommendations also serve to determine which class members qualify for explantation benefits under the Settlement Agreement. The Panel's work has enabled it to develop these 2003 Amended Guidelines for valve replacement surgery.

**Recommendations Regarding Prophylactic Valve Replacement**

In order for a Bowling class member to receive monetary benefits from the Bowling Patient Benefit Fund for prophylactic valve replacement, the valve replacement must meet the objective standards set forth in the 2003 Amended Guidelines. Qualification under these objective standards does **not** mean that replacement surgery is appropriate for a particular patient, but only that monetary benefits under the Bowling settlement are available should the surgery take place due to the risk of strut fracture.

The recommendations regarding prophylactic valve replacement require the calculation of patient-specific estimated annual fracture rates. The 2003 Amended Guidelines set forth a formula based upon current information that can be used to identify BSCC heart valve patients who may have a significantly greater risk of outlet strut fracture. The Panel has identified eight risk factors in addition to the constant factor to be used in calculating estimated annual fracture rates for 60 degree BSCC heart valve patients: valve size, valve implant position (mitral vs. aortic), weld date, welder identity, valve shop order, current patient age, gender and rework status. The Panel has identified seven risk factors in addition to the constant factor to be used in

calculating estimated annual fracture rates for 70 degree BSCC heart valve patients: valve size, valve implant position (mitral vs. aortic), welder identity, valve shop order, current patient age, gender and rework status. Because current age must be included in the calculation, estimated annual fracture rates for each patient must be calculated on a case-by-case basis.

Replacement surgery benefits are also available for surgery to explant a BSCC heart valve due to the risk of strut fracture, if the surgery complies with the 2000 Amended Guidelines.

**In order to obtain the estimated annual fracture rate for a specific patient, or to determine if the patient qualifies for benefits for reoperation under the Settlement Agreement, you will need to communicate the valve serial number, valve implant position, and the patient's gender and current age to the Bowling Claims Administrator. A telephone number, fax number, and mailing address for the Claims Administrator are provided at the end of this letter. A prompt response will be provided, including a copy of the calculation of the estimated annual fracture rate and whether the patient qualifies for the payment of the costs of reoperation.**

#### **Attachment A.**

Attachment A contains the Panel's recommendations and 2003 Amended Guidelines. That document is intended to provide valve implantees and their treating physicians with additional information that is relevant and important to the explantation decision. For example, it sets forth factors which should be seriously considered by the patient and physician when deciding whether or not explantation of a BSCC heart valve identified to be at a greater risk of outlet strut fracture may be beneficial for a particular implantee. The 2003 Amended Guidelines contain additional information that the Panel believes is helpful in the clinical management of BSCC heart valve patients, so please read them carefully.

The 2003 Amended Guidelines include manufacturing rework status as a new risk factor for calculation of estimated annual fracture rates for BSCC heart valve patients. The rework factor describes any special manufacturing operations that were carried out on the valve concerning polishing a crack or rewelding a valve. The data were provided in the BSCC worldwide database and was based on a review of baggie cards. Based upon statistical analyses, the rework factor in the proposed new guidelines classifies valve into two categories. The first category refers to those valves for which there was no indication on the baggie card of either a crack or rewelding operation. The second classification refers to all valves that had either an indication of a crack-polishing or rewelding operation. There were some valves for which the data provided in the research database was incomplete and the classification could not be determined. These valves with incomplete documentation of the manufacturing process were first considered separately in the analysis, but because it was found that the fracture rates of these valves were similar to valves in the second classification (evidence of crack or rewelding), ultimately all of these valves were grouped together.

Since guidelines development is a dynamic process, the 2003 Amended Guidelines will be continuously reviewed by the Panel as new data become available. They will be modified when appropriate in accord with the best scientific, epidemiological and clinical information made available to the Panel.

The Panel's recommendations are based upon the best data available at the present time and are not meant to be absolute recommendations for individual patients. The final decision regarding explantation in an

individual patient must be made by the patient in consultation with the treating cardiologist or cardiovascular surgeon, after careful examination and explanation of the available data.

**The Panel encourages you to obtain estimated annual fracture rates for your BSCC heart valve patients and to speak with them about this new information.** Also note that in the event that you or any of your patients disagree with the decision rendered regarding qualification for valve replacement surgery, please contact the Claims Administrator for information regarding an appropriate appeal process.

The Panel and the Trustees of the Bowling-Pfizer Heart Valve Settlement Funds have created a website to provide information to the Class Members and other interested individuals. The Website can be found on the internet at [www.bowling-pfizer.com](http://www.bowling-pfizer.com) and is available for anyone to review at no cost. The Website provides basic information such as: the parties involved (addresses, telephone numbers, email, biographies, etc.), certain orders of the Court, the Panel's recommendations and Amended Guidelines, a copy of the Settlement Agreement, Trustee Reports and a bibliography of relevant articles as well as other important information. The Website continues to be updated as additional relevant information becomes available.

If you have any questions about this letter or want to obtain an estimated annual fracture rate for a specific patient, please contact the Claims Administrator in the English language at 513-421-3517. Someone will be available to answer questions between 9:00 a.m. and 5:00 p.m. Eastern Time, Monday through Friday. You can also contact the Claims Administrator in your native language by fax at 513-421-7696, or by mail at Claims Administrator, P.O. Box 3598, Cincinnati, Ohio 45201-3598.

Sincerely,

J. Kermit Smith  
Chairman  
Supervisory Panel  
Bowling-Pfizer Settlement