

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

IN RE: : Case No. C-1-91-256  
BOWLING-PFIZER LITIGATION : Judge Herman J. Weber,  
: Senior Judge

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TWENTY-SIXTH REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING PERIOD FROM NOVEMBER 21, 2006 TO MAY 23, 2007

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SPECIAL MASTERS/TRUSTEES

Hon. Robert L. Black, Jr.  
Peter J. Strauss, Esq.

AGENDA

TWENTY-SIXTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

June 7, 2007  
11:00 A.M.

Hon. Herman J. Weber, Senior Judge

1. Introductory remarks by Judge Weber.
2. Report of the Special Masters/Trustees.
3. Comments from Counsel:
  - Class Counsel.
  - Counsel for Defendants.
4. Questions and comments from those in attendance.
5. Request for date of next report of Trustees.
6. Closing remarks of Judge Weber.

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- A. Twenty-Sixth Report of the Special Masters/Trustees
- B. Appendices to Court Report
  - 1. 2007 Guidelines
  - 2. Schedule of ongoing research projects.
  - 3. "Hit Report" regarding the Supervisory Panel's Website.
  - 4. Unaudited balance sheet as of April 30, 2007 and an unaudited statement of income and funds balance for the four months ended April 30, 2007.
  - 5. Unaudited balance sheet as of December 31, 2006 and an unaudited statement of income and funds balance for the year ended December 31, 2006.

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IN RE: : Case No. C-1-91-256  
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**TWENTY-SIXTH REPORT OF THE SPECIAL MASTERS/TRUSTEES**

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To the Honorable Herman J. Weber, Senior Judge, United States District Court:

Your Special Masters/Trustees respectfully present their twenty-sixth periodic report, covering activities from November 21, 2006 to May 23, 2007. This report is submitted fifteen days prior to the status hearing before the Court scheduled for June 7, 2007.

**I. PATIENT BENEFIT FUND**

A. Supervisory Panel. The Court held an evidentiary hearing on the Trustees' Motion to Approve the 2006 Amended Valve Replacement Guidelines (now called the 2007 Guidelines) on April 11, 2007. The following members of the Supervisory Panel testified at the hearing: David Miller, Dr. Tom Ivy, Dr. Ronald Brookmeyer, Dr. Arthur Weyman, Dr. Michel Ibrahim and Dr. Donald Harrison.

The initial patient studies with the ACES device at The Ohio State University have been concluded and the final report with the patient and earlier sheep study results is now being evaluated by

the Supervisory Panel. The Panel has not yet decided whether to request a proposal from ACES for additional work to further develop this potential diagnostic device.

With regard to BioQuantetics, Inc. an agreement regarding intellectual property was reached between the Trustees and BioQuantetics and certain equipment and other inventory was sold by the Trustees to BioQuantetics and to Polytec, Inc.

B. Guidelines. On April 18, 2007, the Court approved the 2007 Guidelines. Copy attached as Appendix 1. The Claims Administrator is in the process of having the 2007 Guidelines translated and distributed to Class Members and physicians.

C. Research. Our report on the status of the research program of the Supervisory Panel is set out in the attached Appendix 2.

D. Imaging. Since the imaging program at Penn State resumed again, effective April 26, 2005, 7 implantees who may qualify for replacement surgery have been imaged.

E. Repository. The Supervisory Panel maintains a publicly accessible repository of certain documents and information concerning the BSCC heart valve. The repository contains hard copy printouts of various items including, but not limited to, certain reports on the status and results of research sponsored by the Supervisory Panel, minutes of meetings of the Supervisory Panel, a bibliography of published literature regarding the BSCC heart valves, certain unpublished reports prepared by Dr. Brookmeyer of his statistical analysis, the Bowling Settlement Agreement, and

other information. The repository is currently located at the Trustees' office.

In addition, the Trustees have made many of the documents in the repository available electronically in a database which can be accessed through the internet at [www.bowling-pfizer.com/repository](http://www.bowling-pfizer.com/repository). Individuals are able to search for information using descriptive words. Some of the information, such as published articles, are not available for review online due to copyright and other intellectual property concerns. To access the online repository, an individual need only contact the Trustees' office for the website address and a password.

F. Website. The Supervisory Panel's website continues to be found at [www.bowling-pfizer.com](http://www.bowling-pfizer.com). It provides basic information on the parties involved (biographies, addresses, telephone numbers, email, etc.), certain orders of the Court including the 2007 Guidelines, a copy of the Settlement Agreement, Trustee Reports and a bibliography of relevant articles as well as other important information. A copy of the most recent "hit report" of the Supervisory Panel's website is attached to this Report as Appendix 3.

G. Valve Replacement Surgery Claims and Fracture Claims.

The Claims Administrator continues to receive and process claims for valve replacement surgery and outlet strut fracture. Some of the claimants have elected other courses of action rather than to receive the Settlement benefits.

The total number of qualified claims received from the beginning are: 95 (72 foreign) qualified outlet strut fracture

claims and 137 (55 foreign) qualified valve replacement surgery claims including 38 (16 foreign) qualified single leg fracture claims.

The office of the Claims Administrator has commenced to fulfill requests to calculate estimated annual fracture rates under the 2007 Guidelines. In addition, a review of the registered Class Member database was conducted and the 171 known Class Members who would potentially qualify for valve replacement surgery benefits under the 2007 Guidelines have been identified. The necessary information will be provided to Class Counsel so that after distribution of the 2007 Guidelines Class Counsel may notify those Class Members who would potentially qualify for benefits.

The office of the Claims Administrator continues to respond to other inquiries from and on behalf of Class Members.

## **II. FINANCIAL INFORMATION**

At April 30, 2007, the total balance of cash and cash equivalents was \$23,297,712. This amount takes into account net interest earned from January 28, 1992 through April 30, 2007 in the aggregate amount of \$25,822,033.

Attached as Appendix 4 are the following: an unaudited balance sheet as of April 30, 2007 and an unaudited statement of income and funds balance for the four months ended April 30, 2007 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 2007 through December 31, 2007).

Attached as Appendix 5 are the following: an unaudited balance sheet as of December 31, 2006 and an unaudited statement of

income and funds balance for the year ended December 31, 2006 (which includes the budgeted amounts for expenses for the administrative office for the year ended December 31, 2006.)

### III. COMMUNICATIONS

Communications remain open, whether with physicians, Class Members, other BSCC heart valve implantees, Class Counsel, Special Counsel, Defendant's Counsel, or Counsel for Public Citizen.

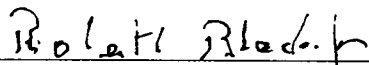
### IV. APPROVALS


Your honor, the Special Masters/Trustees request that the Court:

- Approve this Report, and
- Approve, or provide guidance with respect to, each of the Appendices to this Report, and
- Provide guidance with respect to any duty of the Special Masters/Trustees, and
- Fix the date for the next Report.

Respectfully submitted,

Dated: May 23, 2007

  
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Hon. Robert L. Black, Jr.

  
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Peter J. Strauss, Esq.

# APPENDIX

## 1

# **BOWLING-PFIZER HEART VALVE SETTLEMENT**

## **2007 AMENDED VALVE REPLACEMENT GUIDELINES**

*GUIDELINES TO DETERMINE IF CLASS MEMBERS WITH  
BJORK-SHILEY CONVEXO-CONCAVE (BSCC) HEART VALVES  
QUALIFY FOR PAYMENT OF MONETARY BENEFITS FOR  
ELECTIVE VALVE REPLACEMENT SURGERY*

**Proposed by the Bowling-Pfizer Supervisory Panel and Approved by the United States District Court for the Southern District of Ohio on April 18, 2007.**

## PART I. SUMMARY

### A. IMPORTANT INFORMATION.

- The terms of the Settlement Agreement in *Bowling, et. al. v. Pfizer Inc., et. al.* provide that benefits are available to certain qualifying *Bowling* Class Members who undergo BSCC heart valve replacement surgery *due to the risk of outlet strut fracture*.
- These 2007 Amended Valve Replacement Guidelines (2007 Guidelines) identify who is eligible to receive valve replacement surgery benefits from the *Bowling* Settlement funds.
- A summary of the valve replacement surgery benefits available for Class Members who undergo qualifying explant surgery is set forth in Appendix A: Glossary and Important Patient Information.
- The 2007 Guidelines are based on statistical estimates of the risks of fracture and the risks of reoperation.
- The 2007 Guidelines are based on a statistical analysis of group data and it should be noted that the risk for an individual patient may differ from those of the group.
- Class Members implanted with a BSCC heart valve manufactured after April 1, 1984 will *not* qualify for valve replacement surgery benefits because there have been no reported fractures of valves manufactured after that date.
- Class Members who have BSCC valve conduits will *not* qualify for valve replacement benefits because there have been no reported fractures of these valves.
- Replacement surgery benefits are age-related so qualification may be lost due to the passage of time. For example, if you potentially qualify for benefits now, you may not qualify in the future due to your change in age, because the passage of time is associated with a statistical reduction in the risk of BSCC outlet strut fracture, and an increase in operative mortality.
- If a Class Member's valve replacement surgery did not qualify for benefits in the past, it may now qualify under the 2007 Guidelines and if so, benefits will be paid.
- The 2007 Guidelines may be changed in the future.
- The 2007 Guidelines do not constitute medical advice.
- To learn whether you qualify for valve replacement surgery benefits or to make a claim for benefits, you must contact the *Bowling* Claims Administrator at:

**Wayne Smith**  
**Bowling Claims Administrator**  
**P. O. Box 3598**  
**Cincinnati, Ohio 45201-3598**  
**U. S. A.**  
**800-977-0779 (United States or Canada)**  
**00-1-513-421-3517 (International)**  
**513-421-7696 (Facsimile)**  
**bowlingpfizer@fuse.net (E-mail)**  
**www.bowling-pfizer.com (Website)**

**B. *WHAT IS NEW TO THE 2007 AMENDED VALVE REPLACEMENT GUIDELINES.***

1. There has been an overall decrease in surgical mortality and morbidity for elective explant surgery and this decrease in risk has been incorporated into the 2007 Guidelines.
2. The outlet strut fracture threshold rates found in Appendix D, Tables 3 and 4 are now provided in yearly age increments rather than in 5 year increments.
3. Additional time to make a claim has been provided to make sure that a Class Member who is eligible to receive valve replacement surgery benefits has sufficient time in which to make the decision regarding explant surgery.
  - A Class Member who is registered with the Claims Administrator as of April 18, 2007 and who potentially qualifies for valve replacement surgery benefits under the 2007 Guidelines has until July 18, 2009 OR the length of time of eligibility determined under the 2007 Guidelines, whichever is longer, in which to make the decision and have explant surgery and still receive valve replacement surgery benefits. A Class Member who registers with the Claims Administrator after April 18, 2007 and who potentially qualifies for valve replacement surgery benefits under the 2007 Guidelines will have two years from the date of registration OR the length of time of eligibility determined under the 2007 Guidelines, whichever is longer, in which to make the decision and have explant surgery and still receive valve replacement surgery benefits.
  - A Class Member who potentially qualified for valve replacement surgery benefits under the 2003 Guidelines as of April 18, 2007 (the effective date of the 2007 Guidelines), but does not qualify under the 2007 Guidelines, has until July 18, 2009 to undergo qualified valve replacement surgery.
4. A Glossary and Important Patient Information is included in Appendix A.
5. The Warning Signs of Outlet Strut Fracture (OSF) are contained in the Glossary and Important Patient Information in Appendix A.

**C. HOW QUALIFICATION FOR VALVE REPLACEMENT SURGERY BENEFITS IS DETERMINED.**

Provided below are the procedures for determining the qualification for monetary benefits when valve replacement surgery of a BSCC heart valve takes place due to the risk of strut fracture.

**1. Class Members with single or multiple BSCC heart valves with known serial number(s).**

Step One: The Class Member, his or her physician, or other authorized representative must contact the Bowling Claims Administrator and provide the Class Member's heart valve serial number, implant position, age and gender.

Step Two: The Class Member's estimated OSF rate (expressed as the percent chance that the valve will fracture in the next year) will be calculated by the Claims Administrator. For Class Members with multiple valves, the Class Member's OSF rate will be calculated by summing the OSF rates for each valve.

Step Three: If the estimated OSF rate is greater than the estimated risk of death or serious morbidity—that is, above the established threshold—then the Class Member would qualify for valve replacement surgery benefits.

**2. Class Members with BSCC mitral valves with unknown serial numbers.**

Step One: The Class Member, his or her physician, or other authorized representative must contact the Claims Administrator and provide the Class Member's age and gender and documentation showing that the Class Member has a 29, 31, or 33 mm BSCC mitral valve implanted prior to April 1984. Proof of the characteristics of the valve may be shown by x-ray, fluoroscopy, transesophageal echocardiography, or a review of medical records.

Step Two: If the Class Member is currently under age 35 and has a 29, 31, or 33 mm mitral BSCC valve implanted prior to April 1984, the Class Member would qualify for valve replacement surgery benefits.

**3. Class Members with documented single leg separation (SLS).**

Step One: The Class Member, his or her physician, or other authorized representative must provide to the Claims Administrator clear evidence of single leg separation of the Class Member's BSCC heart valve, documented by x-ray images or information definitively showing offset of one of the valve's two outlet strut legs.

Step Two: If SLS is documented, the Class Member would qualify for valve replacement surgery benefits.

**D. WHERE TO FIND MORE INFORMATION.**

Visit [www.bowling-pfizer.com](http://www.bowling-pfizer.com) for additional information about the *Bowling* Settlement and the Guidelines.

## **PART II. THE FULL TEXT OF THE 2007 AMENDED VALVE REPLACEMENT GUIDELINES**

### **A. INTRODUCTION.**

Under a class action Settlement Agreement in the *Bowling, et al. v. Pfizer Inc., et al.* heart valve litigation, monetary benefits are available to certain patients implanted with BSCC heart valves who undergo valve replacement surgery because of the risk of outlet strut fracture. Under the Settlement Agreement, an independent Supervisory Panel was appointed in May 1994 to develop and amend guidelines to be used to determine qualification for monetary benefits for qualifying valve replacement surgery. The 2007 Guidelines determine eligibility for valve replacement surgery benefits if the patient, after consulting with his or her treating physician, decides to undergo valve replacement surgery. A summary of the monetary benefits that are available for eligible patients who undergo valve replacement surgery are set forth in the Glossary and Important Patient Information contained in Appendix A to the 2007 Guidelines.

The Supervisory Panel recommended its first set of Guidelines in 1997, and they were approved by the Court. The Guidelines were revised and approved by the Court in 2000 and 2003 when updated data became available.

The Supervisory Panel has continued to monitor mortality (death) and morbidity (serious illness) data for elective valve replacement surgery, and, based on new data, the Supervisory Panel has developed, and the Court has approved, the 2007 Amended Valve Replacement Guidelines (2007 Guidelines). These 2007 Guidelines are based on all currently available data to derive the best statistical estimates of the risks of fracture and reoperation. Standard statistical criteria were used to identify valve and patient characteristics associated with these risks. The overall decrease in surgical mortality and morbidity for elective explant surgery has been incorporated into the risk calculations. Furthermore, a decision zone is provided to ensure that a Class Member who is potentially eligible to receive valve replacement surgery benefits has sufficient time in which to make the decision regarding elective explant surgery.

The 2007 Guidelines identify the subgroup of patients for whom, on average, BSCC heart valve replacement surgery will result in a gain in life expectancy. However, for some individual patients there can be an immediate loss of life expectancy (if death results from reoperation), while for other patients there can be a significant gain (if a strut fracture is avoided by a successful operation). For most patients who undergo replacement surgery, there may well be no change in life expectancy even if they survive the reoperation, because they may not have had an outlet strut fracture if the valve had been left in place. *Accordingly, it is important to emphasize that the 2007 Guidelines are based on a statistical analysis of group data and that the risk for an individual patient may differ from those of the group.*

The 2007 Guidelines will be reviewed by the Supervisory Panel as significant new data become available. They may be modified when appropriate, consistent with the best available epidemiologic, clinical, and other relevant information.

There are several words or terms used in or related to these 2007 Guidelines that may require explanation. A Glossary and Other Important Patient Information is included as Appendix A, which provides more information on the following:

- Advice to patients, including Outlet Strut Fracture (OSF) Warning Signs
- Elective surgery
- Group data
- Intact valve, Single Leg Separation (SLS) and OSF
- Monetary benefits
- New York Heart Association (NYHA) classification
- Optimal patient
- Rework status
- Shop order
- Significantly experienced facility
- Supervisory Panel
- Valve conduit
- Welder group

## ***B. HOW THE GUIDELINES ARE FORMULATED.***

### **1. RATIONALE AND ASSUMPTIONS**

The Supervisory Panel developed the 2007 Guidelines from detailed reviews of the relevant clinical and epidemiologic data concerning risks of OSF versus risks from reoperations to replace BSCC heart valves. These 2007 Guidelines incorporate two critical risk factors: (1) the risk that the valve will fracture, which results in death in approximately 65% of patients who suffer a fracture, and; (2) the risk of death or serious illness as a result of having surgery to replace the valve. In considering these two factors, the 2007 Guidelines attempt to identify those circumstances in which replacement of the valve would offer a meaningful extension of life expectancy.

The 2007 Guidelines weigh the benefit of eliminating the risk of OSF through surgery against the risk of mortality and morbidity associated with the surgery. The 2007 Guidelines assess reoperative risk based on two assumptions: (1) that the patient is in optimal health, and (2) that the surgery is performed at a significantly experienced facility. Qualification under these 2007 Guidelines does not mean that replacement surgery is appropriate for a particular patient because many patients are not in optimal health and some explantation surgeries take place at facilities that do not have significant experience in heart valve replacement surgery. Thus, when either of these assumptions is not met, the risk of surgery would increase and the likelihood of benefit to the patient would decrease.

