

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

<b>ARTHUR RAY BOWLING, ET AL.,</b>	:	
	:	<b>No. C-1-91-256</b>
<b>PLAINTIFF,</b>	:	
	:	
v.	:	<b>JUDGE HERMAN J. WEBER,</b>
	:	<b>SENIOR JUDGE</b>
<b>PFIZER, INC. ET AL.,</b>	:	
	:	
<b>DEFENDANT.</b>	:	

**NOTICE OF FILING OF THE TWENTY-SEVENTH REPORT OF THE  
SPECIAL MASTERS/TRUSTEES COVERING PERIOD  
FROM MAY 23, 2007 TO NOVEMBER 15, 2007**

NOTICE IS HEREBY GIVEN to all counsel of record that the TWENTY-SEVENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING PERIOD FROM MAY 23, 2007 TO NOVEMBER 15, 2007 is hereby filed with the Court.

Respectfully submitted,

/s/ Nancy A. Lawson  
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Special Masters/Trustees*

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

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

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TWENTY-SEVENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING PERIOD FROM MAY 23, 2007 TO NOVEMBER 15, 2007

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SPECIAL MASTERS/TRUSTEES

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

**AGENDA**

**TWENTY-SEVENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES**

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

December 6, 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-Seventh Report of the Special Masters/Trustees
- B. Appendices to Court Report
  - 1. Summary of 2007 Guidelines.
  - 2. Supervisory Panel Protocol to Monitor Issues Relating to the Guidelines.
  - 3. Update on the Status of the Supervisory Panel's Continuing Operation Plan.
  - 4. Summary of Research Expenditures Under the Supervisory Panel's Continuing Operation Plan and Schedules of the Research Projects.
  - 5. "Hit Report" regarding the Supervisory Panel's Website.
  - 6. Summary of the Status of Funding for the Settlement.
  - 7. Unaudited balance sheet as of October 31, 2007 and an unaudited statement of income and funds balance for the ten months ended October 31, 2007.
  - 8. Independent Auditors' Report for the year ended December 31, 2006.

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-SEVENTH 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-seventh periodic report, covering activities from May 23, 2007 to November 15, 2007. This report is submitted seventeen days prior to the status hearing before the Court scheduled for December 6, 2007.

**I. PATIENT BENEFIT FUND**

A. Supervisory Panel. The 2007 Guidelines along with a summary have been distributed to class members and physicians. A copy of the summary is attached as Appendix 1.

The Supervisory Panel has developed a protocol to insure that it remains aware of new developments which may impact the Guidelines. The protocol involves regular review of world-wide literature pertinent to heart valve research and diligent monitoring of reported events that occur to known class members. A copy of the protocol is attached hereto as Appendix 2.

The patient studies with the ACES device at the Ohio State University have been concluded and a final report was received in May, 2007. The imaging and acoustics committee was favorably impressed with the ACES work and has made a recommendation to the full panel for continued studies. The panel has considered the results of the ACES work and agrees that

there is sufficient promise in the technology to pursue additional work. The panel is currently working with ACES and others in an effort to resolve several issues prior to asking them to submit a formal proposal for additional follow-up work.

With regard to BioQuantetics, Dr. Edmond Rambod reported that the clinical trials at Cedars Sinai Medical Center were completed without the sponsorship or funding of the Trustees. Dr. Rambod is in the process of completing his report and will send a summary to the Panel when completed.

B. Guidelines. The 2007 Guidelines along with a summary have been 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 Appendices 3 and 4.

D. Imaging. Since the imaging program at Penn State resumed again, effective April 26, 2005, there have been nine imaging sessions for six implantees who may qualify for valve replacement surgery. Three implantees were imaged two times during this period.

E. Update on the Status of the Continuing Operation Plan. Attached as Appendices 3 and 4 is an update on the status of the Supervisory Panel's Continuing Operation Plan.

F. 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. Ron 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. Some of the information, such as published articles, however are not available for review on line due to copyright and other intellectual property concerns. The repository is currently being updated. To access the on-line repository, once it is updated, an individual need only contact the Trustees' office for the website address and a password.

G. 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, 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 5.

H. 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.

Since the date of the last Trustees' report on May 23, 2007, Pfizer Inc. paid \$260,000 US plus 273,074 Polish PLN for qualifying strut fracture benefits for a claim processed by the Claims Administrator. These benefit payments relate to a claim for an outlet strut fracture that occurred prior to May 23, 2007.

The total number of qualified claims received from the beginning are: 96 (73 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 continues to fulfill requests to calculate estimated annual fracture rates under the 2007 Guidelines and to respond to other inquiries from and on behalf of Class Members.

## **II. FINANCIAL INFORMATION**

At October 31, 2007, the total balance of cash and cash equivalents was \$22,799,710. This amount takes into account net interest earned from January 28, 1992, through October 31, 2007 in the aggregate amount of \$26,390,092.

Attached as Appendix 6 are a summary of the status of funding for the Settlement and four related schedules.

Attached as Appendix 7 are the following: an unaudited balance sheet as of October 31, 2007 and an unaudited statement of income and funds balance for the ten months ended October 31, 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 8 is a copy of the Independent Auditors' Report for the year ending 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.

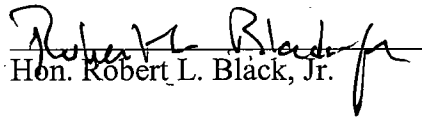
IV. APPROVALS


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: November 15<sup>th</sup>, 2007

  
Hon. Robert L. Black, Jr.

  
Peter J. Strauss, Esq.

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of this Twenty-Seventh Report of the Special Masters/Trustees Covering Period from May 23, 2007 to November 15, 2007, has been electronically sent to the following this 19<sup>th</sup> of November, 2007:

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/s/ Nancy A. Lawson  
Nancy A. Lawson



# APPENDIX

1

 **NOTICE TO BJORK- SHILEY CONVEXO-CONCAVE (BSCC) HEART VALVE  
CLASS MEMBERS AND THEIR PHYSICIANS** 

**Changes in the Guidelines for Determining Whether BSCC Class Members are Eligible for  
Monetary Benefits for Qualifying Valve Replacement Surgery**

The Court appointed Supervisory Panel for the Bowling-Pfizer Settlement has continued to monitor mortality (death) and morbidity (serious illness) data for elective valve replacement surgery. Because of changes in surgical mortality and morbidity for elective valve replacement surgery the Panel has amended the guidelines for determining eligibility for monetary benefits for qualifying valve replacement surgery. The Court approved the 2007 Amended Valve Replacement Guidelines (2007 Guidelines) on April 18, 2007.

Since age is a factor in determining both the surgical risk and the fracture rate, for most Class Members the length of time they are eligible to receive monetary benefits in connection with qualifying valve replacement surgery is limited. To provide more flexibility for individuals to make their decision regarding valve replacement surgery, the 2007 Guidelines provide a decision zone to ensure that a Class Member who is potentially eligible to receive valve replacement surgery benefits has at least until July 18, 2009 in which to make the decision and have valve replacement surgery.

On the back of this page is “Benefits Provided Under the Bowling-Pfizer Settlement Agreement for a Qualifying BSCC Heart Valve Replacement Surgery.” This explains the valve replacement surgery benefits to which the Class Member may be entitled.

To determine qualification for valve replacement surgery benefits, the Class Member, his or her doctor or other authorized representative must provide the valve serial number, along with the current age, gender and valve implant position of the patient, to the Claims Administrator. This may be accomplished by telephone to 800-977-0779 in the United States or Canada or to 00-1-513-421-3517 internationally (English only), by fax to 513-421-7696, by email to [bowlingpfizer@fuse.net](mailto:bowlingpfizer@fuse.net), via the internet at [www.bowling-pfizer.com](http://www.bowling-pfizer.com) , or by regular mail to Claims Administrator, P.O. Box 3598, Cincinnati, Ohio 45201-3598, U.S.A.

A copy of the 2007 Guidelines is attached. While you are encouraged to read the entire document, be advised that Part I is a summary which may provide sufficient information to understand how to find out if the patient is qualified to receive valve replacement surgery benefits.

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**Benefits Provided Under the Bowling-Pfizer Settlement Agreement for a Qualifying Bjork-Shiley Convexo-Concave (BSCC) Heart Valve Replacement Surgery**

1. **Medical Expenses:** Payment of the usual and customary costs actually incurred by the patient for hospital care from admission for the valve replacement surgery through discharge, medical supplies during that period, and usual and customary fees of physicians and allied health professionals during that period and for a reasonable period thereafter following discharge, for any complications directly resulting therefrom, to the extent that the costs and fees for these services are not covered by a private health insurance carrier or health maintenance organization, governmental benefit or other third party payer. To receive this benefit, a patient must make all reasonable efforts to utilize or claim every other applicable kind of coverage, including available public or private health insurance. Proof of expenses is required to receive this benefit.
2. **Out-of-pocket Expenses:** A lump sum of \$38,000 for all miscellaneous costs and expenses relating to and following hospitalization (including travel and lodging expenses; care of family during hospitalization and recuperation; post-operative home care; miscellaneous other economic loss; etc.) No proof of expenses is required to receive this payment.
3. **Lost Income:** Reimbursement of actual lost income due to time lost from work during hospitalization and recuperation from the valve replacement surgery to the extent not covered by worker's compensation, sick pay, disability insurance or any other kind of coverage; up to a maximum of \$1,500 per week, for up to one year following the surgery.\* To receive this benefit, proof of loss is required.
4. **Disability or Death:** Alternative specified benefits are available if the valve recipient dies or becomes permanently and totally disabled as a result of the valve replacement surgery.

To receive the benefits set forth in paragraphs 2 through 4 above, a patient and his or her spouse and all other persons who may make a claim must agree to release all claims they might have relating to the removed BSCC heart valve. A patient may elect to reject these benefits and instead bring an individual legal action against Pfizer. However, if a patient chooses to bring a lawsuit against Pfizer, the patient will permanently lose any rights to these benefits. Also, any payment received on the patient's behalf under paragraph number 1 would be deducted from any award resulting from such legal action.

In addition, in the event that a patient has his or her BSCC heart valve replaced due to the risk of strut fracture and it is determined that one leg of the outlet strut of the valve was separated from the flange prior to the surgery, the patient would qualify for benefits under the Settlement Agreement. For this condition that some refer to as a "single leg fracture", the patient is referred to Class Counsel for further information about available benefits and options.

*\*Compensation may be provided beyond one year in the event that a patient is partially disabled as a direct result of complications of the surgery and as a direct result of such partial disability continues to suffer economic loss in the form of diminished earning capacity.*

**TO QUALIFY FOR VALVE REPLACEMENT SURGERY BENEFITS UNDER THE SETTLEMENT AGREEMENT, THE SURGERY MUST BE DUE TO THE RISK OF STRUT FRACTURE AND MUST COMPLY WITH GUIDELINES FOR BSCC HEART VALVE REPLACEMENT AS ADOPTED FROM TIME TO TIME BY THE SUPERVISORY PANEL, WITH THE APPROVAL OF THE COURT.**

APPENDIX

2

## PROTOCOL FOR MONITORING ISSUES RELATING TO THE GUIDELINES

The 2007 Amended Guidelines Valve Replacement Guidelines were approved by the Court on April 18, 2007. The Supervisory Panel is establishing the following protocol to ensure it is aware of any issues which may impact the Guidelines. The Chair has appointed a sub-committee for monitoring guideline issues consisting of Tom Ivey, Michel Ibrahim and Donald Harrison.

### 1. Monitoring the Literature.

Regular review of pertinent journals will be performed by various panel members as outlined below. Tom Ivey, Donald Harrison and Michel Ibrahim will meet with David Miller via conference call on a quarterly basis to report on the results of the monitoring. Any significant issues will be shared with all members of the Panel.

Tom Ivey will review:

The Society of Thoracic Surgeons Annuals of Cardiac Surgery  
The Journal of Cardio-Thoracic Surgery  
The European Journal of Cardio-Vascular Surgery

Donald Harrison will review:

The American Journal of Cardiology  
The Journal of the American College of Cardiology  
The New England Journal of Medicine  
The Journal of the American Medical Association  
The European Journal of Cardiology  
Circulation

Michel Ibrahim will review:

The New England Journal of Medicine  
The Journal of the American Medical Association  
The Lancet  
Circulation  
The Journal of Heart Valve Disease  
The American Journal of Public Health  
The American Journal of Epidemiology

Dr. Ibrahim will also conduct a periodic search of PubMed for any articles specifically mentioning BSCC heart valves.

### 2. Review of the BSCC Research Database

An annual review of the updated BSCC Research Database, which is maintained by Pfizer, will be conducted by a consultant of the Panel. This will serve to validate the continued use of the risk factors and the values assigned to them as part of the guidelines formula. A report of this work will be made to the

Panel on an annual basis. The results of his report will be discussed at the quarterly conference call of the sub-committee. Any significant issues will be shared with all members of the Panel.

### 3. Review of Reports of Fractures

The Panel will review the semi-annual reports of outlet strut fracture statistics submitted to the FDA by Pfizer. The Panel will review the quarterly report of the Australian and New Zealand patient registry. The data from these reports will be discussed by the sub-committee on a quarterly basis via conference call with any significant issues shared with the all Panel members.

### 4. Passive Surveillance of the Major Cohorts

In addition to the Australian/New Zealand cohort, the other major cohorts which have been followed are the United States, the United Kingdom and the Dutch. Passive surveillance will ensure that no unexpected events pass unnoticed among the cohorts regarding fracture rates or important events which may have an impact on the guidelines.

- a. The U. S. cohort of patients registered with the Claims Administrator will be monitored through an annual review of the National Death Index to determine if any registered class members died. The staff of the Trustees office will conduct this review and report the results to the Panel for analysis.
- b. The UK cohort was last reviewed in 2004 and at that time there were 1,043 living BSCC patients. Of course, it is likely that number has decreased further. Contact has been made with Professor Kenneth Taylor who has monitored the UK cohort. He will soon retire and reports that UK Registry is being disbanded thus any follow up on this cohort will be limited to the updated data contained in the BSCC research database.
- c. The Dutch cohort was monitoring by contractual agreement with Utrecht University and Dr. Yolanda van der Graaf. The last cohort follow up study was completed in 2006 with the follow up period ending 12-31-2004. At that time, the living cohort with implanted valves numbered 467 and Dr. van der Graaf concluded and the Panel agreed that further follow up on the cohort will reveal no additional information as the cohort is too small to draw robust conclusions.

Any significant data from these follow ups will be discussed by the sub-committee when they meet on a quarterly basis via conference call with any significant issues shared with the all Panel members.

August, 2007



# APPENDIX

3

