

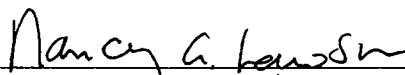
UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

ARTHUR RAY BOWLING, ET AL.,	:	
	:	No. C-1-91-256
PLAINTIFF,	:	
	:	
V.	:	JUDGE HERMAN J. WEBER,
	:	SENIOR JUDGE
PFIZER, INC. ET AL.,	:	
	:	
DEFENDANT.	:	
	:	

NOTICE OF FILING OF THE TWENTY-FIRST REPORT OF THE  
SPECIAL MASTERS/TRUSTEES COVERING PERIOD  
FROM JUNE 4, 2004 TO NOVEMBER 24, 2004

NOTICE IS HEREBY GIVEN to all counsel of record that the TWENTY-FIRST REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING PERIOD FROM JUNE 4, 2004, TO NOVEMBER 24, 2004, is hereby filed with the Court.

Respectfully submitted,

  
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of this Notice of Filing of the Twenty-First Report of the Special Masters/Trustees Covering Period from June 4, 2004, to November 24, 2004, has been hand delivered to those in Cincinnati and Federal Expressed to those outside Cincinnati this 27<sup>th</sup> day of November, 2004.

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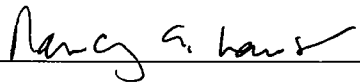
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UNITED STATES DISTRICT COURT

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-FIRST REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING PERIOD FROM JUNE 4, 2004 TO NOVEMBER 24, 2004

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SPECIAL MASTERS/TRUSTEES

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

**AGENDA**

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

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

December 9, 2004

10:00 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-First Report of the Special Masters/Trustees
  
- B. Appendices to Court Report
  - 1. Patient Guide to the 2003 Amended Guidelines.
  - 2. Schedule of ongoing research projects.
  - 3. Schedule of approved research projects pending contract.
  - 4. Schedule of proposed but deferred research projects.
  - 5. "October Hit Report" regarding the Supervisory Panel's Website.
  - 6. Trustees' Inventory of Intellectual and Physical Property and Anticipated Budget for Years 2005-2024.
  - 7. Unaudited balance sheet as of October 31, 2004 and an unaudited statement of income and funds balance for the ten months ended October 31, 2004.
  - 8. Independent Auditor's Report for the year ended December 31, 2003.

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-FIRST 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-first periodic report, covering activities from June 4, 2004 to November 24, 2004. This report is submitted fifteen days prior to the status hearing before the Court scheduled for December 9, 2004.

**I. PATIENT BENEFIT FUND**

A. Supervisory Panel. The Supervisory Panel met on October 12 and 13, 2004, in London, England. The Supervisory Panel meeting was chaired by David Miller. All Supervisory Panel members were present. On October 12, 2004, The Supervisory Panel heard presentations on the status of the following current research projects:

- Detecting Broken Struts Using Standard Ultrasound

Instruments by Nico de Jong of Erasmus Medical Center.

- Development of High Frequency Miniaturized Electromagnetic Dip Meter (Phase I) by Andrea Rocco of the University Medical Center at Utrecht.
- Develop Catheter Based Antenna for Detecting Flaws in BSCC Heart Valves by Anton Tijhuis of Eindhoven University.
- Non-invasive Assessment of the BSCC Heart Valve by Richard Miller of Information Systems Laboratories.
- Telemonitoring System for Valve Related Cardiac Related Emergencies by Michael Oberle of Miromico, Inc.
- Three Dimensional Motion of Prosthetic Heart Valves by Computed Tomography and Echocardiography by Neil Greenberg of the Cleveland Clinic.
- Transmission of Acoustic Waves from a Vibrating Outlet Strut in BSCC Heart Valves by Jeff Crompton of Advanced Computational and Engineering Services (ACES).
- Acoustic Detection of Outlet Strut Resonance in BSCC Heart Valves by Jeff Crompton.
- Ultrasound Detection of Single Leg Separation by Edmond Rambod of Bioquantetics, Inc.
- International Explant Studies by Michel Ibrahim and Bill Blot.
- Catheter Based and EMAT Detection of Single Leg Separation (including a new study proposal) by Satish

Udpa of Michigan State University.

- Evaluate the Effect of Modeling Assumptions and Boundary Conditions on BSCC Valve Loading (including new study proposal) by Jurgen de Hart of Eindhoven University.

After hearing the presentations from the Researchers, the Supervisory Panel met with Counsel. Counsel and the Supervisory Panel had a discussion regarding various issues of interest.

On October 13, 2004, the Supervisory Panel heard presentations from the following Researchers on the current status of the research projects:

- BSCC Heart Valve Performance Modeling Using Element Free Techniques by James Dydo of ACES.
- Modeling of BSCC Heart Valves-Effect of Complaint Support Conditions by James Dydo of ACES.
- Critical Evaluation of the Role of Crack Initiation and Crack Growth by Jeff Crompton of ACES.
- Relationship Between Engineering Database and Epidemiological Studies by Jeff Crompton of ACES.

At the conclusion of the morning session on October 13, 2004, there were two breakout sessions. One session involved those involved with or interested in Imaging and Acoustics, which was moderated by Ned Weyman and Nicholas Bom. The other session was moderated by Michel Ibrahim regarding the Guidelines and Epidemiology issues. Following the breakout sessions, all participants met for a brief summary of the results of each



breakout session. The meeting was then adjourned for the Investigators and Counsel.

In the afternoon session on October 13, 2004, the Supervisory Panel met with its consultants Ron Brookmeyer and Bill Blot and its Counsel, Nancy Lawson and David Malone. The Supervisory Panel heard the following presentations:

- A report regarding potential Intellectual Property issues arising out of the Panel's research;
- A report regarding the status of FDA issues and considerations with respect to current research projects; and
- A report regarding the updated statistics of the World Wide Database.

The Supervisory Panel then took the following actions:

- Held a discussion on the status of the funding for continued Panel research and supporting activities. Established a sub-committee of Don Harrison, Michel Ibrahim, Ned Weyman and David Miller to provide a protocol for requesting additional incremental funds from the Court.
- Decided to recommend to the Trustees not to extend the time for Westat, Inc. to complete the "Survey of Class Members and Physicians" study which ended September 14, 2004.
- Agreed on a recommendation from Tom Ivey to begin

consideration of possible revision to the Guidelines and a method for doing so. Agreed with his recommendation not to purchase the STS database, rather to determine if we can purchase the specific data required on an as-needed basis.

- Agreed to formulate a working group in early 2005 to make a recommendation to the full Panel as to whether all Class members or a selected group will be eligible to be screened or tested if a diagnostic device or test is developed.
- Approved the new study proposal of Jurgen de Hart of Eindhoven University entitled, "A working heart phantom based on slaughterhouse pig hearts to assist and validate research on BSCC valves".
- Approved an extension of 2 months (not the 6 month extension requested) of the work of Edmond Rambod of Bioquantetics on "Ultrasound Detection of Single Leg Separation", pending satisfactory resolution of the budget details by Chairman Miller.
- Deferred action on the study proposal from Satish Udpa of Michigan State University, "Design and Construction of a Clinical Scale EMAT Prototype Unit" until additional analysis on his current research results is finalized.
- Heard a report from Joseph Defauw regarding the so-called European testing center. Agreed with his recommendation

that any testing done in Europe will need to be done via mobile testing that can move from country to country; that a central coordinating facility from a neutral institute would be needed, and; that the Julius center in the Netherlands has the capability to serve this purpose.

Agreed that Jo should proceed to contact the Julius Center to see if they are willing to write a proposal to serve as the coordination center for such an endeavor.

- Declined to request medical and manufacturing records pertaining to the 6 most recent fracture cases.

B. Guidelines. The Supervisory Panel finalized and distributed a Patient Guide for the 2003 Amended Guidelines. The Patient Guide was mailed to all known Class Members and is posted on the Bowling-Pfizer website. A copy is attached as Appendix 1. The Panel decided that revisions to the Guidelines will be considered in 2005.

C. Research. Our report on the status of the research program of the Supervisory Panel is set out in the attached appendices. Appendix 2 lists the projects that are ongoing at this time divided into two categories (epidemiological projects and imaging and acoustic projects). Appendix 3 shows those projects that have been approved and are pending the finalization of contracts. Appendix 4 sets forth those projects that remain under further consideration at this time.

For a description of the Panel's division of its research program into three categories, reference is made to Section II. C of the Seventeenth Report.

A Settlement Agreement originally set forth a total of \$37.5 million for the use of the Supervisory Panel to fulfill its duties as outlined in the Agreement. The Panel has spent or is currently obligated to spend more than \$37.5 million and will be approaching the Court seeking approval to allocate additional money to conduct its research and development. Before the end of the year 2004, the Trustees will request approval of the Court to expend the funds necessary to continue any research now approved by the Court, pending projects if approved by the Court and the normal expenses of the Panel members in carrying out their duties for 2004. The Panel also intends within the next several months to present the Court with a proposed budget for research for 2005.

D. Inventory of Intellectual and Physical Property and Anticipated Budget for Years 2005-2024. On October 15, 2004, the Trustees submitted its report concerning the Intellectual and Physical Property, as well as a Budget for 2005 to 2025. A copy of that Inventory with minor revisions is attached hereto as Appendix ~~to~~

E. Imaging. Since the imaging program at Penn State resumed, effective September 18, 2002, 19 implantees who may qualify for replacement surgery have been imaged, and all their valves were interpreted to be intact.

F. Repository. The Supervisory Panel continues to maintain 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, 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 location and a password. The Trustees have placed an announcement on its website providing class members and other interested individuals with information about the electronic database.

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 2003 Amended Guidelines, a copy of the Settlement Agreement, Trustee

Reports and a bibliography of relevant articles as well as other important information.

As noted above, an announcement has been placed on the website explaining that many of the documents contained in the document repository are now available on-line. Further, 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 June 3, 2004, one outlet strut fracture and one qualified valve replacement surgery have been confirmed. The outlet strut fracture occurred prior to June 4, 2004.

During the period from the last Report to the date of this Report, Pfizer Inc. paid a total amount of \$118,997 for valve replacement surgery benefits for three claims processed by the Claims Administrator. Of these benefit payments, \$80,997 relate to claims for two valve replacement surgeries that occurred prior to June 4, 2004.

The total number of qualified claims received from the beginning are now: 93 (71 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 2003 Amended Guidelines. In addition, the office of the Claims Administrator continues to respond to other inquiries from and on behalf of Class Members.

## **II. FINANCIAL INFORMATION**

At October 31, 2004, the total balance of cash and cash equivalents was \$27,555,542. This amount takes into account net interest earned from January 28, 1992 through October 31, 2004 in the aggregate amount of \$23,428,167. There remains one annual payment of \$6,250,000 to be received from Pfizer/Shiley under the Settlement.

Attached as Appendix 7 are the following: an unaudited balance sheet as of October 31, 2004 and an unaudited statement of income and funds balance for the ten months ended October 31, 2004 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 2004 through December 31, 2004).

Attached as Appendix 8 is a copy of the Independent Auditors' Report for the year ended December 31, 2003.

## **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.

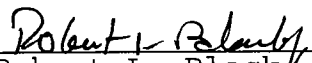
IV. APPROVALS


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 24, 2004

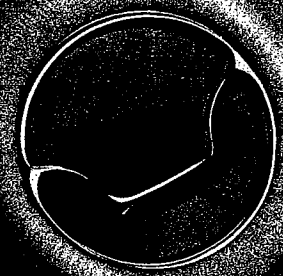
  
\_\_\_\_\_  
Hon. Robert L. Black Jr.

  
\_\_\_\_\_  
Peter J. Strauss, Esq



## APPENDIX 1

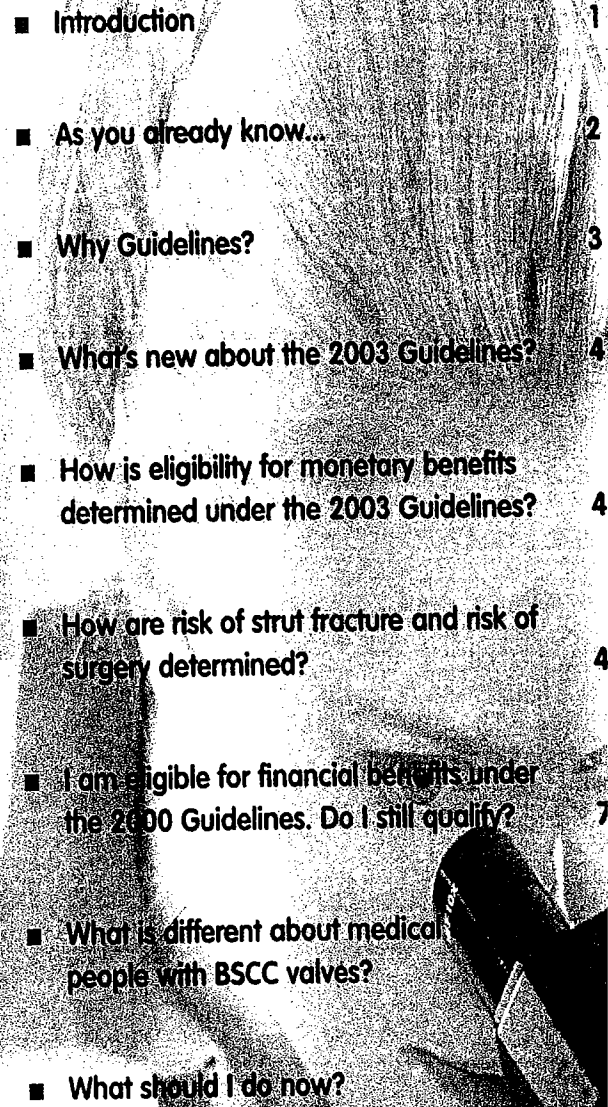
*Patient Guide*



For Class Members  
in the  
Bowling-Pfizer Litigation

2003 Amended Guidelines  
for Determining Eligibility  
for Monetary Benefits  
for Elective Explantation

Bjork-Shiley  
Convexo-Concave  
Heart Valve Recipients



■ Introduction	1
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■ What's new about the 2003 Guidelines?	4
■ How is eligibility for monetary benefits determined under the 2003 Guidelines?	4
■ How are risk of strut fracture and risk of surgery determined?	4
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■ What should I do now?	

# Introduction

The 2003 Guidelines determine the eligibility of people with Bjork-Shiley Convexo-Concave (BSCC) heart valves for monetary benefits **for elective explantation due to the risk of strut fracture**. The Guidelines were prepared by the Bowling-Pfizer Supervisory Panel and adopted by the U.S. District Court. The Panel consists of cardiothoracic surgeons, cardiologists, and epidemiologists.

Earlier versions of the Guidelines were issued in 1997 and 2000. The 2003 Guidelines are based on updated information about the risk of outlet strut fracture (OSF).

This booklet is to help patients and their physicians understand the 2003 Guidelines.

The full title of the 2003 Guidelines is "Amended Guidelines to Assess Patients with Bjork-Shiley Convexo-Concave Heart Valves for Elective Explantation Proposed by the Bowling-Pfizer Supervisory Panel." They were officially adopted on July 9, 2003, by the U.S. District Court in Cincinnati, Ohio.



## As you already know...

Between 1979 and 1986, thousands of people worldwide had one or more of their natural heart valves replaced with a BSCC heart valve.

The BSCC heart valve has a tilting disk, which is held in place by an inlet strut and an outlet strut. The outlet strut can fracture and the disk can break free. This event is known as OSF. For most patients, the risk of OSF is extremely low. Although rare, OSF could cause death or serious permanent injury.

In some cases, a patient can undergo an operation (called explantation) to replace the valve.

Some patients who undergo elective explantation due to the risk of strut fracture are eligible for monetary benefits. If a patient, with the advice of a doctor, decides to undergo explantation, he or she may be entitled to monetary benefits under the Guidelines.



# Why Guidelines?

The 2003 Guidelines, like earlier versions, were developed under the Bowling-Pfizer settlement to determine who is eligible for **monetary benefits** for elective surgery to replace a BSCC heart valve. These guidelines are not intended to constitute medical advice to patients with BSCC heart valves. Medical decisions are to be made by patients and their physicians.

Monetary benefits—which are available to people who fit certain criteria—are specific:

- payment of covered medical expenses not paid for by insurance or by government benefits
- lump sum payment of \$38,000 to pay for non-medical expenses related to the surgery
- reimbursement for actual lost income not paid by other disability benefits (with limitations)
- extended disability or death compensation

Eligibility for monetary benefits for elective BSCC valve replacement surgery is based on the Supervisory Panel's improved formula to calculate estimated annual rates of OSF.



## What's new about the 2003 Guidelines?

The 2003 Guidelines include a **new risk factor for calculating estimated annual strut fracture rates**. This new risk factor is **manufacturing rework status**. "Rework" refers to any special step taken during the manufacturing process, such as re-welding the outlet strut or polishing the strut to remove cracks that appeared after welding. Rework is associated with an increased risk of fracture.

For the vast majority of patients, these Guidelines will not affect their medical care.

## How is eligibility for monetary benefits determined under the 2003 Guidelines?

**Two values are compared:**

1. risk of valve fracture
2. risk of surgery to replace the valve

## How are risk of strut fracture and risk of surgery determined?

The **risk of outlet strut fracture** is based on several risk factors:

- patient's age
- patient's gender
- valve size
- position of the implant (mitral and/or aortic)
- several manufacturing characteristics, including rework status, the welder group, and the date of manufacture

A statistical analysis is used to calculate the probability that the valve will fracture.



