

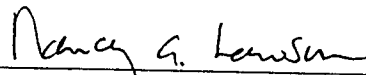
UNITED STATES DISTRICT COURT 2005 MAY 23 PM 4:52
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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

NOTICE OF FILING OF THE TWENTY-SECOND REPORT OF THE
SPECIAL MASTERS/TRUSTEES COVERING PERIOD
FROM NOVEMBER 24, 2004 TO MAY 23, 2005

NOTICE IS HEREBY GIVEN to all counsel of record that the TWENTY-SECOND REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING PERIOD FROM NOVEMBER 24, 2004, TO MAY 23, 2005, 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-Second Report of the Special Masters/Trustees Covering Period from November 24, 2004 to May 23, 2005, has been hand delivered to those in Cincinnati and Federal Expressed to those outside Cincinnati this 23rd day of May, 2005.

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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

TWENTY-SECOND REPORT OF THE SPECIAL MASTERS/TRUSTEES
COVERING PERIOD FROM NOVEMBER 24, 2004 TO MAY 23, 2005

SPECIAL MASTERS/TRUSTEES

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

AGENDA

TWENTY-SECOND REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

June 7, 2005
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-Second Report of the Special Masters/Trustees
- B. Appendices to Court Report
 - 1. Summary of Continuing Operation Plan.
 - 2. Schedule of ongoing research projects.
 - 3. "Hit Report" regarding the Supervisory Panel's Website.
 - 4. Unaudited balance sheet as of April 30, 2005 and an unaudited statement of income and funds balance for the four months ended April 30, 2005.
 - 5. Unaudited balance sheet as of December 31, 2004 and an unaudited statement of income and funds balance for the year ended December 31, 2004.

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

TWENTY-SECOND OF THE SPECIAL MASTERS/TRUSTEES

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

Your Special Masters/Trustees respectfully present their twenty-second periodic report, covering activities from November 24, 2004 to May 23, 2005. This report is submitted fifteen days prior to the status hearing before the Court scheduled for June 7, 2005.

I. PATIENT BENEFIT FUND

A. Supervisory Panel. On April 21, 2005, a Joint Motion to Approve Bowling-Pfizer Supervisory Panel Plan for Continuing Operation of the Supervisory Panel with Trustees Office twenty year estimated budget was filed with the Court. This Plan set forth the anticipated future work of the Panel relating to the Guidelines and diagnostic devices. The Plan also included the anticipated budget for the Panel through 2007 and for the operation of the Trustees

Office and other administrative expenses for 2005 through 2024. This Plan was approved by the Court on April 28, 2005. A summary of the Plan is attached to this report as Appendix 1.

B. Guidelines. The Panel will be considering revisions to the Guidelines in 2005.

C. Research. Our report on the status of the research program of the Supervisory Panel is set out in the attached appendix. Appendix 2 lists the projects that are ongoing at this time divided into two categories (epidemiological projects and imaging and acoustic projects).

D. Imaging. Since the imaging program at Penn State resumed again, effective April 26, 2005, no implantees who may qualify for replacement surgery have been imaged.

E. 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.

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.

F. Website. The Supervisory Panel's website continues to be found at 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 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.

Since the date of the last Trustees' report on November 24, 2004, two outlet strut fractures have been confirmed. One of the outlet strut fractures occurred prior to November 24, 2004.

During the period from the last Report to the date of this Report, Pfizer Inc. paid \$992,724 for qualifying strut fracture benefits and \$1,752 plus £1,370 for valve replacement surgery benefits for three claims processed by the Claims Administrator. These benefit payments relate to claims for an outlet strut fracture and two valve replacement surgeries that occurred prior to November 24, 2004.

The total number of qualified claims received from the beginning are now: 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 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 April 30, 2005, the total balance of cash and cash equivalents was \$23,627,998. This amount takes into account net interest earned from January 28, 1992 through April 30, 2005 in the aggregate amount of \$23,710,860. There remains one annual payment of \$6,250,000 to be received from Pfizer/Shiley under the

Settlement.

Attached as Appendix 4 are the following: an unaudited balance sheet as of April 30, 2005 and an unaudited statement of income and funds balance for the four months ended April 30, 2005 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 2005 through December 31, 2005).

Attached as Appendix 5 are the following: an unaudited balance sheet as of December 31, 2004 and an unaudited statement of income and funds balance for the year ended December 31, 2004 (which includes the budgeted amounts for expenses for the administrative office for the year ended December 31, 2004.)

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, 2005

Robert L. Black, Jr.
Hon. Robert L. Black, Jr.

Peter J. Strauss, Esq.
Peter J. Strauss, Esq.

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APPENDIX 1

**SUMMARY OF CONTINUING OPERATION PLAN
OF THE SUPERVISORY PANEL**

Background. The Supervisory Panel (Panel) was created by terms of the Settlement Agreement for the purpose of establishing and modifying Guidelines under which surgical benefits for Class Members will be provided. The Panel also was charged with the duties of conducting "research and development of diagnostic techniques to identify implantees who have a significant risk of strut fracture", and; conducting "research concerning the characterization and/or reduction of the risks of valve replacement surgery, including improvement of the techniques for such surgery." The Panel was appointed and began its work in 1994.

Part 5 of the Agreement creates the Patient Benefit Fund and sub-section 5.2 provides for Pfizer to provide a total of \$75 million for this fund. The following sub-sections stipulate the uses for the money including: research and development of diagnostic techniques to identify implantees who may have significant risk of strut fracture; research to reduce the risks of valve replacement surgery and improve surgical techniques; paying for the diagnostic techniques, and; paying for explant surgery as approved under the Guidelines. Sub-section 5.2.3.1 established that "the surgery must be in compliance with guidelines for C/C heart valve replacement as adopted from time to time by the Supervisory Panel, with the approval of the Court" (cross reference to 5.4.4.2)

Section 5.3.1 provides the Supervisory Panel may devote up to \$37.5 million of these funds to pay for the research, diagnostic tests, related expenses of the Panel, and the cost of the claims administrator. Further, this section states that if the \$37.5 million is exhausted and no diagnostic technique is approved, the Panel, with the approval of the Court may allocate additional incremental amounts to research and development.

The other half of the Patient Benefit Fund (\$37.5 million) provides for the operation of the Trustees office, fees and expenses of Class and Special Counsel, fees and expenses of Counsel for the Trustees, office administration and surgical expenses to class members. The Panel may have access to some of these funds, however, a large amount of these funds must be set aside to provide support to the Class members in the form of claims administration.

In the Status Conference of December 9, 2004 before Judge Weber, the issue of the continuing activities of the Panel was raised. The Court set a hearing for April 7, 2005 for the purpose of establishing a budget for the continued administration of the Settlement including the operation of the Bowling-Pfizer Trustees Office and a plan for the continuing operation of the Panel to include a time frame for when the Panel will cease its activities.

Overview of The Plan The Panel prepared a Plan for Continuing Operation which is based on three critical premises:

1. The need to preserve funds with which to operate a Claims Administration office to support the Class for the next 20 years.
2. The need to maintain the Guidelines for Class member eligibility for surgical benefits.
3. The need to determine if one or more diagnostic devices to detect single leg separation of the BSCC valves in Class members can be put to use.

The Court approved the Plan on April 28, 2005 and one aspect of the Plan is the creation of a Protocol for Funding Decisions, which follows:

The following are factors the Panel will consider as it makes decisions on research proposals. The underlying standard of this protocol for considering future projects is that of reasonable certainty. The

research project must demonstrate an ability to provide a direct benefit to the Class, and do so within a reasonable time frame.

1. The Panel will recommend funding of known technologies or study methodologies that have demonstrated reasonable certainty of resulting in a diagnostic device or technique, or improving the Guidelines. The Panel is at the point where it must focus on those research projects which have highly promising techniques with the potential to benefit the Class members in a reasonable period of time. It will not initiate new projects using different techniques or approaches unless some revolutionary method is introduced.
2. The Panel will focus on continuing to fund the projects which are now in place based upon a priority listing of projects it considers will most likely produce a diagnostic device or technique, or improve the Guidelines. The Panel will focus on a smaller number of highly promising projects which demonstrate the potential to produce results in a reasonable time frame. This Plan includes a listing of those projects.
3. As it relates to Imaging and Acoustics projects, the Panel will focus on those projects which have demonstrated "proof of concept" of their technology in either animal or human testing. This principle relates to in-vitro v. in-vivo test results. Favorable funding recommendations will be made based upon those projects which have demonstrated results in vivo, or which have a reasonable certainty of in-vivo success in the next funding cycle.
4. As it relates to Epidemiological or Guidelines related projects, the Panel will focus on those projects which have a reasonable certainty of providing meaningful data. The data obtained from these projects must be critical to assisting in the evaluation of the Guidelines.
5. The Panel will consider the issue of regulatory approval. The Panel must be mindful of the requirements of the FDA and other regulatory agencies abroad as it considers the viability of projects. These approval processes will be for use of any diagnostic techniques in the clinical trial setting as opposed to full FDA approval of any device as a diagnostic device.
6. The Panel will consider the issue of preservation of some funds for use with a diagnostic device or technique. The Panel must preserve money to implement any diagnostic device or technique, or in the absence of such a device or technique, consider how to use any remaining funds, such as establishing a medical monitoring program.

To further clarify the intent of the Panel regarding future diagnostic device research, the Panel determined any project it approves must have a clearly defined goal of meaningful application *in a patient within a 12-18 month time frame*. The Panel must now see if one or more diagnostic devices can be made available to patients soon or abandon these efforts.

The Plan set aside funds on which to operate a claims administration office for the next 20 years to support the Class members. In the Plan, the Panel outlined current epidemiological studies geared toward consideration of a revision of the Guidelines in 2005 and continuing work in this area. The Plan also identified several investigators, whose work has progressed to the point where the Panel is reasonably certain one or more diagnostic devices using acoustics methods will be developed for use in patients. The Court has allowed the Panel approximately 2 years to determine if such a device(s) can be developed for use in patients.

The Court has now given the Panel a specific plan for its continuing activities. Our focus remains on ensuring the Guidelines for providing surgical benefits are fair and appropriate and will give the most benefit to the Class. This follow up work is envisioned to continue for the next 10 years.

The Panel is also working to determine if a diagnostic device to detect the status of the BSCC valve in patients can be implemented. The studies to support these objectives will be fewer and must demonstrate, with reasonable certainty, a direct benefit to the Class in a relatively short time frame.

APPENDIX 2

ONGOING RESEARCH PROJECTS (as of April 30, 2005) - Cont'd.

	Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
6.	Michigan State University	10/23/01	11/12/06	EMAT Detection of SLS	3/07/05*	\$2,965,619	\$1,962,212
		11/01/04	6/30/05	Animal Testing of Catheter-Based Electromagnetic System for Detection of Outlet Strut Fracture In Bjork-Shiley Valves	3/8/05	\$202,687	\$00***
7.	Cleveland Clinic	1/22/04	3/22/05	Three Dimensional Motion of Prosthetic Heart Valves by Computed Tomography and Echocardiography	4/18/05*	\$199,988	\$124,904
			Final report pending				
8.	ACES	4/13/04	2/28/05	BSCC Heart Valve Performance Modeling Using Element Free Techniques	12/30/04*	\$99,400	\$99,400
			Final report pending.				
9.	ACES	4/13/04	6/30/05	Relationship Between Engineering Database and Epidemiological Studies	3/29/05*	\$144,500	\$76,650
10.	ACES	10/04/04	7/04/05	Evaluation of Hook-to-Well Separation on Tip Loading	3/29/05*	\$174,125	\$72,425
11.	Hershey Imaging	5/09/00	10/26/05	Radiographic Imaging to Detect SLS	7/29/04*	\$1,750/Session	\$240,631
		10/04/04	8/31/05	Passive Acoustic Detection Procedures On BSCC Heart Valves	3/29/05*	\$180,790	\$115,470
12.	ACES	10/04/04	8/31/05	Passive Acoustic Detection Procedures On BSCC Heart Valves	3/29/05*	\$180,790	\$115,470

*Date of latest Status Report which was given at the London Panel meeting or has been sent to Class Counsel

**No Status Report Available

*** Amount spent on this project is included in the project listed above

ONGOING RESEARCH PROJECTS (as of April 30, 2005)

A. Epidemiology Projects

	Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
1.	Utrecht Univ IEI Devtrack Pty. Ltd.	5/24/04 1/26/05	5/24/05 1/26/06	International Epidemiology Study	3/31/05* 5/5/05	\$63,500 (Utrecht) \$86,500 (IEI) \$37,500	\$00 \$28,385 \$00
2.	University Utrecht Van der Graaf	12/22/03	12/22/05	Continuation of Dutch Follow-Up Study	12/23/04*	77.019 Euro	77.019 Euro

B. Imaging & Acoustic Projects

	Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
3.	BioQuantetics	5/17/00	12/31/05	Ultrasound Detection of Single Leg Separation	3/21/05*	\$4,055,367.64	\$3,065,940
4.	Miromico, Inc.	7/25/03	4/07/05	Telemetry System for valve related Cardiac Emergencies	2/11/05*	\$397,178	\$344,894
5.	UMC Utrecht Konings	10/14/03	4/14/05	Development of High Frequency, Miniaturized, Electromagnetic Dip Meter (Phase I)	12/30/04*	\$183,295	\$145,348

Final report has been requested.

*Date of latest Status Report which has been sent to Class Counsel
 **No Status Report Available

