

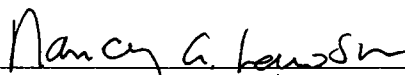
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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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DINSMORE & SHOHL LLP
1900 Chemed Center
255 East Fifth St.
Cincinnati, OH 45202
(513) 977-8200
Attorney for
SpecialMasters/Trustees

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 27th day of November, 2004.

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

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

TWENTY-FIRST REPORT 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-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. 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. 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.

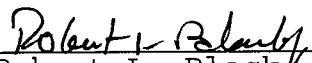
IV. APPROVALS


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,

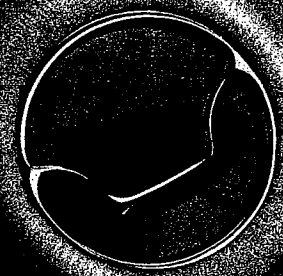
Dated: November 24, 2004


Hon. Robert L. Black Jr.


Peter J. Strauss, Esq

APPENDIX 1

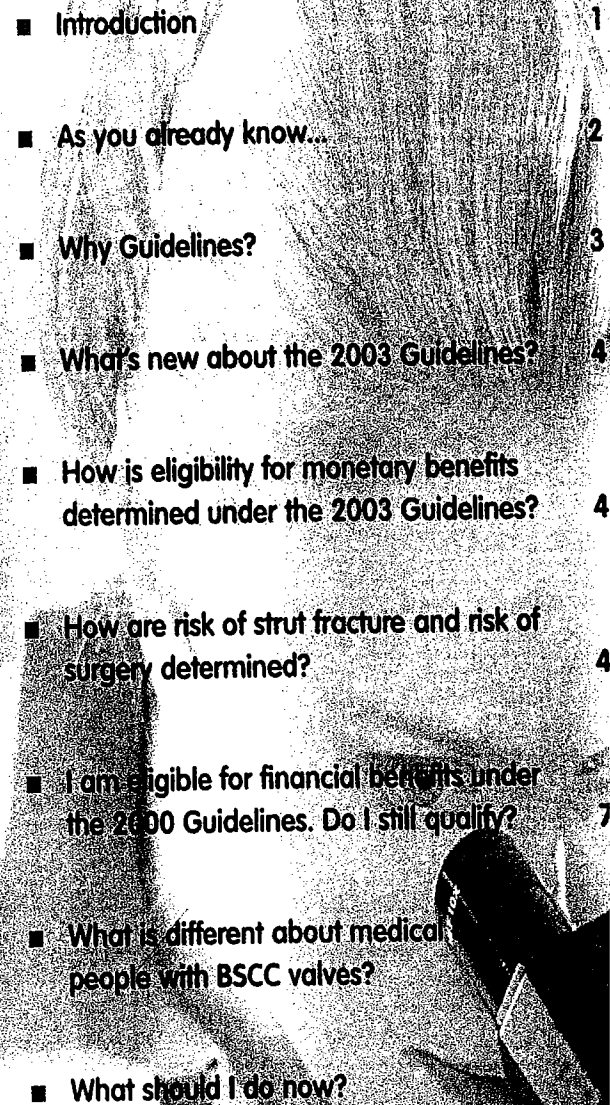
Patient Guide



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
■ As you already know...	2
■ Why Guidelines?	3
■ 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
■ I am eligible for financial benefits under the 2000 Guidelines. Do I still qualify?	7
■ What is different about medical people with BSCC valves?	
■ 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.





To determine
your estimated
risk of OSF,
you or your
physician
should provide
the Claims
Administrator
with the valve
serial number,
your age, your
gender, and
valve implant
position.

Please note: The risk of surgery refers to the risk of death or serious complications from an operation to replace the BSCC heart valve. The calculation of risk is based on heart valve explant data and is affected by a patient's age and the number of valves being replaced. For example, there have been reports of valve strain to the 60° BSCC heart valve implant (after April, 1984).

The risk of surgery refers to the risk of death or serious complications from an operation to replace the BSCC heart valve. The calculation of risk is based on heart valve explant data and is affected by a patient's age and the number of valves being replaced.

If a person's life expectancy is likely to be extended by explantation surgery, then he or she would qualify for monetary benefits if the surgery is due to the risk of strut fracture.

Even if a patient qualifies for benefits, it does not mean that surgery is appropriate. The 2003 Guidelines identify the small group of patients for whom, on average, by replacing their BSCC heart valve, life expectancy would be extended. The decision to have surgery must be made by the patient along with a physician who understands the estimated risk of fracture of the particular BSCC valve implanted in the patient, the overall health of the patient, and the risk of serious injury or death from undergoing explant surgery.

A patient who does not qualify under the Guidelines formula but who chooses to have explantation surgery anyway will not be eligible for financial benefits.

There are two possible exceptions: the explanted valve has a single leg fracture or the guidelines are modified to qualify the patient.



I am eligible for financial benefits
under the 2000 Guidelines.
Do I still qualify?

Yes. Financial benefits are available for
patients who still qualify under the 2000
Guidelines.

What is different about medical
care for people with BSCC valves?

Patients should be aware of the importance
of doctor visits on a regular basis. Patients
and their families and friends should also be
aware of symptoms of outlet strut fracture,
including the following:

- valve no longer makes a clicking sound
- sudden, sharp, and lasting pain, or tight
pressure in the chest
- sudden, severe shortness of breath
- sudden loss of consciousness
- sudden irregular or rapid heart beat



- ◆ Additional recommendations include carrying at all times the name, address, and telephone number of an open heart surgery center and your cardiologist.
- ◆ In case of emergency, it is extremely important that you go to a hospital where emergency heart surgery to replace the valve can be performed. Know in advance where this hospital is located and inform family members and close friends.
- ◆ If you plan to travel, know in advance the name, address, and phone number of a hospital close by where emergency BSCC heart valve replacement surgery can be performed.
- ◆ Always carry written instructions telling emergency rescue or ambulance workers of the importance of being transported to your selected hospital and of alerting doctors that you are on your way.
- ◆ Always carry written instructions telling emergency room staff that a chest x-ray should be done right away that may determine whether your BSCC heart valve is intact. If the valve is fractured, surgery should be performed without delay.

What should I do now?

Doctors have been told about the 2003 Guidelines. Doctors who want more information, or who are helping you assess your eligibility for monetary benefits for elective explantation, are urged to contact the Claims Administrator.

By letter Wayne Smith
Claims Administrator
Bowling-Pfizer Heart Valve Settlement Funds
P.O. Box 3598
Cincinnati, Ohio 45201-3598 USA

Or by phone 1-800-977-0779, from the U.S. or Canada
00-1-513-421-4415, from elsewhere. These callers may reverse the phone charges.
Non-English speakers must correspond by letter, fax, or email.

Or by fax 1-513-421-7696

Or by email BowlingPfizer@fuse.net

More information is available on the Internet, at
www.bowling-pfizer.com.



Trustees for the
Bowling-Pfizer Heart Valve
Settlement Funds

APPENDIX 2

ONGOING RESEARCH PROJECTS (as of November 1, 2004)

A. Epidemiology Projects

	Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
1.	IEI and Utrecht Univ Blot & Van der Graaf	5/24/04	5/24/05	International Epidemiology Study	9/28/04*	\$63,500 (Utrecht) \$86,500 (IEI)	\$00 \$11,635
2.	Penn State University	5/14/03	2/28/05	Create Database of Manufacturing Data (Feasibility Phase Approved)	9/27/04*	\$346,858	\$89,524
3.	International Epidemiology Institute, Ltd.	11/13/03	11/13/04	Updating BSCC Patient Quality of Life Survey	9/30/04*	\$116,900	\$74,112
4.	University Utrecht Van der Graaf	12/22/03	12/22/05	Continuation of Dutch Follow-Up Study	8/17/04*	77,019 Euro	\$00

B. Imaging & Acoustic Projects

	Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
5.	Information Systems Laboratories (ISL)	3/16/98	12/31/04	Noninvasive Assessment and Arterial Heart Valves	10/12/04*	\$4,403,010	\$3,883,622
6.	BioQuantetics	5/17/00	120/31/04	Ultrasound Detection of Single Leg Separation	10/12/04*	\$3,439,905	\$2,439,459
7.	Miromico, Inc.	7/25/03	4/07/05	Telemonitoring System for valve related Cardiac Emergencies	10/12/04*	\$397,178	\$215,453
8.	UMC Utrecht Konings	10/14/03	4/14/05	Development of High Frequency, Miniaturized, Electromagnetic Dip Meter (Phase I)	10/12/04*	\$183,295	14,497 Euro

*Date of latest Status Report which has been sent to Class Counsel

**No Status Report Available

ONGOING RESEARCH PROJECTS (as of November 1, 2004) - Cont'd.

	Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
9.	Michigan State University	10/23/01	12/31/04	Catheter Based and EMAT Detection of SLS	10/12/04*	\$1,825,822	\$1,603,525
		11/01/04	3/01/05	Animal Testing of Catheter-Based Electromagnetic System for Detection of Outlet Strut Fracture In Bjork-Shiley Valves	**	\$167,562	\$00
10.	Erasmus University – De Jong Lancee	4/1/03	1/1/04	Ultrasound to Detect SLS (Initial Phase)	10/12/04*	\$45,000	\$00
11.	Eindhoven University De Hart	11/13/03	11/13/04	Evaluate Effect of Modeling Assumptions and Boundary Conditions on BSCC Valve Loading	10/12/04*	\$194,000	\$117,899
12.	Eindhoven University - Tijnhuis	4/18/03	4/18/04	Develop Catheter-Based Antenna for Detecting Flaws in BSCC Heart Valves	10/12/04*	\$106,800	\$00
13.	Cleveland Clinic	1/22/04	1/22/05	Three Dimensional Motion of Prosthetic Heart Valves by Computed Tomography and Echocardiography	10/12/04*	\$199,988	\$86,076
14.	ACES	11/12/03	10/31/04	Transmission of Acoustic Waves from a Vibrating Outlet Strut in BSCC Heart Valves	10/12/04*	\$185,950	\$185,950
15.	ACES	3/29/04	11/30/04	Critical Evaluation of Role of Crack Initiation and Crack Growth	10/12/04*	\$63,750	\$22,950
16.	ACES	4/13/04	2/28/05	BSCC Heart Valve Performance Modeling Using Element Free Techniques	10/12/04*	\$99,400	\$32,520
17.	ACES	4/13/04	2/28/05	Modeling of BSCC Heart Valves – Effect of Compliant Support Conditions	10/12/04*	\$77,800	\$14,050
18.	ACES	4/13/04	12/31/04	Relationship Between Engineering Database and Epidemiological Studies	10/12/04*	\$144,500	\$6,750
19.	ACES	10/04/04	7/04/05	Evaluation of Hook-to-Well Separation on Tip Loading	**	\$174,125	\$00

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

****No Status Report Available**

ONGOING RESEARCH PROJECTS (as of November 1, 2004) - Cont'd.

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
20. Hershey Imaging	10/6/03	4/05/05	Radiographic Imaging to Detect SLS	7/29/04* Plus overhead	\$1,750/Session	\$85,614

C. Projects Completed During Quarter

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
21. WESTAT	8/20/03	9/14/04	Survey of Physicians and Class Members	***	\$199,517	\$11,838
22. UK Cohort	12/6/01	12/31/03	Patient Follow-up to Improve Estimation of Risk of Strut Fracture	9/30/04*	£36,938	£21,727
23. ACES	11/12/03	8/31/04	Acoustic Detection of Outlet Strut Resonance in BSCC Heart Valves	10/12/04*	\$192,750	\$192,750
24. UMC Utrecht (Mali)	1/5/04	7/5/04	Value of 3D Rotational Angiography in the Assessment of Fractured Bjork-Shiley Convexo-Concave Heart Valves (Feasibility)	9/27/04*	\$100,000	\$100,000

*Date of latest Status Report which has been sent to Class Counsel

**No Status Report Available

*** Project terminated prior to completion.

APPENDIX 3

APPROVED RESEARCH PROJECTS PENDING CONTRACT (as of November 1, 2004)

A. Epidemiological Projects

Name of Institution	Description of Project	Status	Cost
1. Devtrack Pty. Ltd. (Australia)	International Study of Patients with Explanted BSCC Valves	Awaiting signed contract	\$37,500

B. Imaging & Acoustic Projects

Name of Institution	Description of Project	Status	Cost
1. ACES	Application of Passive Acoustic Detection Procedures to BSCC Heart Valves Implanted in Sheep—Revised August, 2004	Awaiting Ct. Approval	\$180,790
2. Hemolab B.V./ Eindhoven Univ. of Technology	A Working Heart Phantom Based on Slaughterhouse Pig Hearts to Assist and Validate Research on BSCC Valves	Awaiting Signature	151,000 Euro

C. Other

Name of Institution	Description of Project	Status	Cost
	None		

APPENDIX 4

PROPOSED BUT DEFERRED RESEARCH PROJECTS (as of November 1, 2004)

A. Imaging & Acoustic Projects

	Name of Institution	Description of Project	Status	Proposed Cost
1.	Michigan State University	Design and Construction of a Clinical Scale EMAT Prototype Unit	***	\$1,136,467

B. Other

Name of Institution	Description of Project	Status	Proposed Cost
	None		

*** Deferred by Supervisory Panel for stated reasons, or made subject to clarification or a demonstration of feasibility.

APPENDIX 5

Hit Report for Bowling-Pfizer.com

	August 2004	September 2004	October 2004
Total Visits	779	790	1,185
Average Daily Visits	25	26	38
Average Visit Length	12:01	12:38	13:17
Median Visit Length	4:59	5:41	6:48
International Visits	8.47%	7.97%	3.88%
US Visits	64.95%	67.34%	79.57%
Unknown Origin Visits	26.57%	24.68%	16.54%
Unique Visitors	361	409	404
One-Time Visitors	268	300	283
Multiple-Time Visitors	93	109	121
Top Downloads	Nineteenth Report - 36 times Amended 2003 - 40 times Settlement - 32 times Doctor Letter 2003 - 25 times Update - 25 times Haynes - 23 times Guidelines - 21 times	Nineteenth Report - 36 times Settlement - 33 times Amended 2003 - 30 times Haynes - 30 times Pamphlet - 27 times French guidelines - 24 times Precaution - 18 times	Twentieth Report - 243 times Nineteenth Report - 103 times Settlement - 47 times Pamphlet - 35 times Haynes - 31 times Amended 2003 - 26 times Report 1 - 24 times
Total Downloads	458	406	692
Top Visitors Locations	San Francisco, CA Reston, VA Stanford, CT University Park, PA Nashville, TN	Reston, VA San Francisco, CA Stanford, CT Cincinnati, OH Nashville, TN	Reston, VA San Francisco, CA Stanford, CT IRVING, TX Coudersport, PA
Countries viewing the site	United States France Switzerland Netherlands Seychelles Canada Germany Poland	United States France Netherlands Canada Saudi Arabia Finland Germany Seychelles	United States Canada United Kingdom Netherlands Seychelles Belgium Finland Switzerland

Hit Report for Bowling-Pfizer.com

August 2004

September 2004

States/Provinces viewing site

California	Virginia
Virginia	California
Connecticut	Connecticut
Pennsylvania	New York
Maryland	Ohio
Ohio	Tennessee
Illinois	Pennsylvania
Ontario	Massachusetts
Tennessee	Colorado
	Michigan
	Mississippi
	New York

Search Engine & Reference -

Google	Google	Google
Looksmart	Teoma	Teoma
Teoma	Inktomi	Inktomi
Inktomi		

Top Domain Types

Commercial (.com) - 417	Commercial (.com) - 428	Commercial (.com) - 474
Network (.net) - 94	Network (.net) - 99	Network (.net) - 459
Education (.edu) - 8	Education (.edu) - 12	Education (.edu) - 13
Government (.gov) - 3	Government (.gov) - 2	Organization (.org) - 3
Organization (.org) - 1	Organization (.org) - 2	Government (.gov) - 1

** - NOTE - Site went active on

APPENDIX 6

APPENDIX 7

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF OCTOBER 31, 2004

UNAUDITED

ASSETS

CASH	\$ 82,898
U.S. TREASURY BILLS	27,472,644
OTHER ASSETS	<u>10,932</u>
	<u>\$ 27,566,474</u>

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 586,650 (1)
FUNDS BALANCE	<u>26,979,824</u>
	<u>\$ 27,566,474</u>

- (1) - Does not include any provision for fees and expenses for Class Counsel and Special Counsel and Public Citizen, Inc. for the period since October 2003.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME AND FUNDS BALANCE

FOR THE TEN MONTHS ENDED OCTOBER 31, 2004

UNAUDITED

INVESTMENT INTEREST INCOME	\$ 240,427
RESEARCH PROGRAMS - COSTS	<u>2,953,440</u>
LITIGATION ATTORNEYS - FEES & EXPENSES	<u>797,646</u>
EXPENSES:	
Supervisory Panel	1,054,159 (1)
Trustees' fees and expenses	87,360
Professional fees	243,533
Administrative office	<u>624,368 (1)</u>
Total	<u>2,009,420</u>
RECEIVED FROM PFIZER INC.	<u>6,250,000</u>
NET CHANGE IN FUNDS BALANCE	729,921 (2)
FUNDS BALANCE, DECEMBER 31, 2003	<u>26,249,903</u>
FUNDS BALANCE, OCTOBER 31, 2004	<u>\$ 26,979,824</u>

(1) - See Schedule 1 herewith.

(2) - See note (1) on Balance Sheet herewith.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

SCHEDULE OF EXPENSES
UNAUDITED

	<u>BUDGET</u>	<u>ACTUAL</u>
	<u>1/1/04-12/31/04</u>	<u>1/1/04-10/31/04</u>
SUPERVISORY PANEL:		
Panel members' compensation		\$ 600,940
Consultants' compensation		134,279
Travel and incidental expenses		256,599
Miscellaneous		16,909
Notification expenses		<u>45,432</u>
Total		<u>\$ 1,054,159</u>
 ADMINISTRATIVE OFFICE:		
Rents	\$ 72,000	\$ 57,454
Office payroll	407,000	317,459
Payroll taxes	25,000	19,115
Employee benefits	221,000	213,954
Outside services	12,000	3,714
Printing and postage	6,000	2,715
General insurance	3,000	2,448
Telephone	9,000	5,591
Office supplies and expense	6,000	3,688
Depreciation	3,000	2,021
Miscellaneous	6,000	467
Administrative services income	<u>(6,000)</u>	<u>(4,258)</u>
Total	<u>\$ 764,000</u>	<u>\$ 624,368</u>

APPENDIX 8

Bowling-Pfizer Heart Valve Litigation Settlement Fund

*Statements of Assets, Liabilities and Fund
Balance—Modified Cash Basis as of December 31,
2003 and 2002 and Statements of Income,
Expenses and Benefit Payments and Change in
Fund Balance—Modified Cash Basis for the Years
Ended December 31, 2003 and 2002 and
Independent Auditors' Report*

INDEPENDENT AUDITORS' REPORT

Bowling-Pfizer Heart Valve Litigation Settlement Fund

We have audited the accompanying statements of assets, liabilities and fund balance—modified cash basis of the Bowling-Pfizer Heart Valve Litigation Settlement Fund (the "Fund") as of December 31, 2003 and 2002, and the related statements of income, expenses and benefit payments and change in fund balance—modified cash basis for the years then ended. These financial statements are the responsibility of the Fund's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As described in Note 2 to the financial statements, these financial statements were prepared on the modified cash basis of accounting, which is a comprehensive basis of accounting other than accounting principles generally accepted in the United States of America.

In our opinion, such financial statements present fairly, in all material respects, the assets, liabilities and fund balance of the Fund at December 31, 2003 and 2002, and its income, expenses and benefit payments and change in fund balance for the years then ended, on the basis of accounting described in Note 2.



October 28, 2004

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

STATEMENTS OF ASSETS, LIABILITIES AND FUND BALANCE—MODIFIED CASH BASIS DECEMBER 31, 2003 AND 2002

ASSETS	2003	2002
CASH	\$ 732,776	\$ 50,072
INVESTMENTS	26,557,160	26,605,098
OTHER ASSETS	<u>14,995</u>	<u>19,604</u>
TOTAL ASSETS	<u>\$27,304,931</u>	<u>\$26,674,774</u>
LIABILITIES AND FUND BALANCE		
ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 1,055,028	\$ 678,622
FUND BALANCE	<u>26,249,903</u>	<u>25,996,152</u>
TOTAL LIABILITIES AND FUND BALANCE	<u>\$27,304,931</u>	<u>\$26,674,774</u>

See notes to modified cash basis financial statements.

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

STATEMENTS OF INCOME, EXPENSES AND BENEFIT PAYMENTS AND CHANGE IN FUND BALANCE—MODIFIED CASH BASIS YEARS ENDED DECEMBER 31, 2003 AND 2002

	2003	2002
INCOME:		
Settlement payments by Pfizer/Shiley	\$ 6,250,000	\$ 6,250,000
Net investment income	<u>277,247</u>	<u>466,347</u>
Total income	<u>6,527,247</u>	<u>6,716,347</u>
EXPENSES AND BENEFIT PAYMENTS:		
Benefit payments—valve replacement surgery	193,570	6,397
Research programs	3,089,384	3,127,174
Litigation attorneys—fees and expenses	748,849	630,531
Supervisory panel expenses	1,225,231	1,067,518
Trustees' fees and expenses	85,855	120,187
Notification expense	199,809	
Professional fees	214,277	207,179
Other administrative expenses	<u>516,521</u>	<u>478,180</u>
Total expenses and benefit payments	<u>6,273,496</u>	<u>5,637,166</u>
INCREASE IN FUND BALANCE	253,751	1,079,181
FUND BALANCE—Beginning of year	<u>25,996,152</u>	<u>24,916,971</u>
FUND BALANCE—End of year	<u>\$ 26,249,903</u>	<u>\$ 25,996,152</u>

See notes to modified cash basis financial statements.

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

NOTES TO MODIFIED CASH BASIS FINANCIAL STATEMENTS YEARS ENDED DECEMBER 31, 2003 AND 2002

1. ORGANIZATION AND GENERAL INFORMATION

The Bowling-Pfizer Heart Valve Litigation Settlement Fund ("Fund") is the result of a settlement between Pfizer Inc. ("Pfizer") and its wholly-owned subsidiary Shiley Incorporated ("Shiley") and a class of plaintiffs ("Plaintiffs") consisting of all persons who were alive on January 23, 1992 with a Bjork-Shiley Convexo-Concave ("BSCC") heart valve still implanted, and their spouses on that date, except those persons who filed valid and timely requests for exclusion from the class.

The Settlement requires that Pfizer/Shiley pay a minimum of \$165 million to the Fund to settle the claims of the Plaintiffs. Certain provisions exist whereby Pfizer may be required to pay additional amounts to the Fund based on certain criteria as defined in the Settlement. The minimum Settlement is allocated between the "Patient Benefit Fund" (\$75 million) and the "Consultation Fund" (\$90 million).

The Patient Benefit Fund is to be used for: research and development of diagnostic techniques to identify implantees who may have a significant risk of strut fracture and to make such diagnostic techniques available to Plaintiff implantees; research concerning the characterization and/or reduction of the risks of valve replacement surgery; and payment of covered medical expenses for qualifying surgery to explant, due to the risk of strut fracture, a Plaintiff implantee's BSCC heart valve and replace it with another prosthetic heart valve.

The research activities of the Patient Benefit Fund are supervised by a Supervisory Panel ("Panel"). The Panel, subject to Court approval, shall adopt and amend guidelines for valve replacement surgery. Also, the Panel will create a publicly accessible repository of information concerning the status of the research and the risks of valve fracture and of valve replacement. The Panel is made up of six members who are recognized scientific or medical experts and one member who is not a scientist or physician.

The Consultation Fund, initially \$80,000,000 for Plaintiff implantees, was intended to provide Plaintiff implantees with funds to obtain medical and psychological consultation as they deem best. It was to be divided equally among qualified Plaintiff implantees after paying or providing for fees and expenses to be paid out of the implantee portion of the Fund. In addition, \$10,000,000 was paid into the Fund which was paid, after fees and expenses, equally to all qualified Plaintiff spouses.

The terms of the Settlement required Pfizer/Shiley to initially deposit \$12,500,000 into the Patient Benefit Fund. Additionally, beginning on the second anniversary of the final approval of the Settlement, Pfizer/Shiley is required to make annual deposits into the Patient Benefit Fund of not less than \$6,250,000 until a total of \$75,000,000 has been paid.

Pfizer/Shiley paid \$80,000,000 to the Consultation Fund in 1992. In 1994 Pfizer/Shiley paid \$10,000,000 to the Consultation Fund and \$12,500,000 to the Patient Benefit Fund. Pfizer/Shiley also paid \$6,250,000 annually in 1996 through 2003 to the Patient Benefit Fund.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting—The Fund prepares its financial statements on the modified cash basis of accounting. Therefore, it records interest receivable for interest earned not yet received, taxes receivable

(payable) (see Note 5) and accounts payable for expenses when incurred rather than when paid (modified cash basis). Under this basis all Settlement payments by Pfizer/Shiley are recognized when received and all benefit payments and Plaintiffs' counsel fees and expenses are recognized when paid rather than when incurred.

Settlement Payments—All Consultation Fund claims submitted by each claimant were reviewed for qualification by the Fund and payments of qualified claims were approved by the Court.

Litigation Attorneys, Fees and Expenses—Represents Court approved payments to Plaintiffs' counsel and to Public Citizen, Inc.

Other Assets—Other assets represents prepaid expenses, office furniture and computer equipment used by the Fund.

3. INVESTMENTS

Investments at December 31, 2003 and 2002 consist of U.S. Treasury Bills and are carried at cost plus accrued interest. The market value of such investments was approximately \$26,557,000 and \$26,616,000, at December 31, 2003 and 2002, respectively.

4. OPERATING LEASES

The Fund leases its office facilities under an agreement classified as an operating lease from an unrelated party. Total future minimum lease payments due are as follows:

2004	\$ 64,870
2005	64,074
2006	64,074
2007	<u>16,019</u>
Total	<u>\$ 209,037</u>

5. TAX STATUS

For Federal income tax purposes, the Fund is treated as a taxable designated settlement fund under Section 468(B) of the Internal Revenue Code. The Fund is required to pay taxes on the excess of interest income earned over expenses incurred for the administration of the Fund. The Settlement payments by Pfizer/Shiley, benefit payments and payment of Plaintiffs' counsel fees and expenses are not taxable transactions.

In March 1996, the Fund requested a ruling from the Internal Revenue Service regarding the taxability of the Fund and the deductibility of certain disbursements from the Fund. In January 1997, the Fund received a favorable ruling regarding these issues and, consequently, recorded no tax provision for 2003 or 2002.

6. SUBSEQUENT EVENT

In October 2004, a defined benefit plan ("Plan") was adopted and is effective January 1, 2004. Employees of the Fund are eligible to participate in the Plan.

* * * * *