

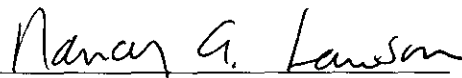
UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

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 TWENTIETH REPORT OF THE  
SPECIAL MASTERS/TRUSTEES COVERING PERIOD  
FROM NOVEMBER 26, 2003 TO JUNE 3, 2004

NOTICE IS HEREBY GIVEN to all counsel of record that the TWENTIETH REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING PERIOD FROM NOVEMBER 26, 2003, TO JUNE 3, 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 Twentieth Report of the Special Masters/Trustees Covering Period from November 26, 2003, to June 3, 2004, has been hand delivered to those in Cincinnati and Federal Expressed to those outside Cincinnati this **3rd** day of **June, 2004**.

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1513 PNC Tower  
5 West Fourth Street  
Cincinnati, OH 45201

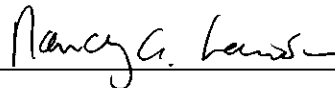
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\_\_\_\_\_

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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TWENTIETH REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING PERIOD FROM NOVEMBER 26, 2003 TO JUNE 3, 2004

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SPECIAL MASTERS/TRUSTEES

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

**AGENDA**

**TWENTIETH REPORT OF THE SPECIAL MASTERS/TRUSTEES**

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

June 18, 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.

## TABLE OF CONTENTS

- A. Twentieth Report of the Special Masters/Trustees
  
- B. Appendices to Court Report
  - 1. Quarterly Reports of ongoing research.
  - 2. Schedule of ongoing research projects.
  - 3. Schedule of approved research projects pending contract.
  - 4. Schedule of proposed but deferred research projects.
  - 5. April 2004 "Hit Report" regarding the Supervisory Panel's Website.
  - 6. Unaudited balance sheet as of April 30, 2004 and an unaudited statement of income and funds balance for the four months ended April 30, 2004.
  - 7. Unaudited balance sheet as of December 31, 2003 and an unaudited statement of income and funds balance for the year ended December 31, 2003.
  - 8. Deloitte & Touche LLP Proposal for auditing services for year ending 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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**TWENTIETH 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 twentieth periodic report, covering activities from November 26, 2003 to June 3, 2004. This report is submitted fifteen days prior to the status hearing before the Court scheduled for June 18, 2004.

**I. PATIENT BENEFIT FUND**

**A. Supervisory Panel.** The Supervisory Panel met on February 6, 2004 in Cincinnati, Ohio. The Supervisory Panel meeting was chaired by Kermit Smith. All Supervisory Panel members were present with the exception of Joseph J. Defauw, M.D., who was excused. The Supervisory Panel discussed potential replacements for Dr. Thomas, who resigned from the Supervisory Panel. After discussion, the Supervisory Panel unanimously agreed on the submission of three names to Judge Weber, with the first choice

being Lewis H. Kuller, M.D. The Supervisory Panel also approved a letter to be sent by Class Counsel to certain Class Members regarding the shop order fracture rate factor in the guidelines. The Supervisory Panel also discussed the necessity for FDA approval when a diagnostic device is developed for use by Class Members. The Supervisory Panel appointed Thomas Ivey, M.D. and Donald Harrison, M.D. as their representatives to meet with the Food and Drug Administration. The Panel also approved the establishment of a testing site in Europe and appointed Supervisory Panel member Dr. Joseph Defauw to take responsibility for finding a site. The Panel also considered nine research proposals and unanimously approved each of them.

The Supervisory Panel also met On April 6 and 7, 2004, in Cincinnati, Ohio. Since the former Chair, Kermit Smith, had resigned effective April 1, 2004, the meeting was opened by Trustee Judge Robert Black and chaired by Supervisory Panel member Donald Harrison, M.D. All other members of the Supervisory Panel were present. On April 6, 2004, the Supervisory Panel heard presentations from seven researchers. The presentations were as follows:

- Presentation by Andrea Rocco from the University Medical Center in Utrecht on the Development of High Frequency, Miniaturized, Electromagnetic Dip Meter (Phase I) Research Project;
- Presentation by Michael Oberle from Miromico, Inc., on

the Telemonitoring System for Valve Related Cardiac Emergencies (Phase I) Research Project;

- Presentation by Richard Miller from Information Systems Laboratories on the Noninvasive Assessment and Arterial Heart Valves Research Project;
- Presentation by Satish Udpa from Michigan State University on the Catheter Based and EMAT Detection of SLS Research Project;
- Presentation by Edmond Rambod from Bioquantetics on Ultrasound Detection of Single Leg Separation Research Project;
- Presentation by Mario Garcia from the Cleveland Clinic on the Three Dimensional Motion of Prosthetic Heart Valves by Computed Tomography and Echocardiography Research Project;
- Presentation by Jeffrey Crompton from ACES on Acoustic Detection of Outlet Strut Resonance in BSCC Heart Valves and Transmission of Acoustic Waves from a Vibrating Outlet Strut in BSCC Heart Valves Research Projects.

After hearing the presentations and having a discussion between the Supervisory Panel, the Researchers, and Counsel, the Supervisory Panel met without Counsel to take action on the proposals before it. The Supervisory Panel reaffirmed its approval



of the Pilot Phase of the Penn State Study and also approved the purchase of the Society of Thoracic Surgeons' database. The Supervisory Panel deferred a decision on obtaining copies of all of the BSCC Shiley Heart Valve manufacturing records until the Penn State Pilot Phase is concluded and the results have been evaluated.

The Supervisory Panel approved one research study proposal and disapproved two proposals. The Supervisory Panel deferred decision on one proposal pending further clarification of the proposal and resubmission by the researchers.

The Supervisory Panel also discussed the Imaging Site in Europe and appointed a subcommittee of Joseph Defauw, M.D., Michel A. Ibrahim, M.D. and Lewis H. Kuller, M.D. to submit a proposal to the Panel regarding the criteria and specifics of the center.

The Supervisory Panel discussed a new Chair of the Supervisory Panel in light of Kermit Smith's resignation. The Trustees and attorneys met with David E. Miller on April 22, 2004 in Judge Weber's Chambers.

During May 2004, the Trustees and four of the six members of the Supervisory Panel met with David E. Miller to discuss the duties and responsibilities of the Chair of the Supervisory Panel.

The other two panel members were consulted personally. After these meetings, the Trustees and the Supervisory Panel unanimously recommended to Judge Weber that David E. Miller be appointed Chair of the Supervisory Panel. On May 20, 2004, the Court appointed David E. Miller as Chair of the Supervisory Panel.

B. Guidelines. As the Court is aware, the 2003 Amended

Guidelines were approved by the Court. The Supervisory Panel has been developing a Patient Guide for the 2003 Amended Guidelines which will be distributed to all known class Members in the next several months.

C. Research. Our report on the status of the research program of the Supervisory Panel is set out in four appendices attached hereto. Appendix 1 is the first Quarterly Report (for the first quarter of 2004) regarding research programs, contract status and updates of progress for investigators with Bowling-Pfizer Supervisory Panel contracts. The Supervisory Panel will prepare and distribute Quarterly reports from this time forward. Appendix 2 lists the projects that are ongoing at this time divided into three categories (epidemiological projects, surgical 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.

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

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](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.

F. Website. The Supervisory Panel's website continues to be found at [www.bowling-pfizer.com](http://www.bowling-pfizer.com). It provides basic information on the parties involved (biographies, addresses, telephone numbers, email, etc.), certain orders of the Court including the 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.

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. The processing of some claims had been initiated by Shiley in the interim period from the date of the Settlement Agreement until the Claims Administrator was appointed. Also, some qualified claims were settled by Shiley with the Settlement benefits during this interim period. In addition, 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 25, 2003, four outlet strut fractures and two qualified valve replacement surgeries have been confirmed.

During the period from the last Report to the date of this Report, Pfizer Inc. paid \$220,000 for qualifying strut fracture benefits and \$38,000 for valve replacement surgery benefits for each of two claims processed by the Claims Administrator. These benefit payments relate to the claims for an outlet strut fracture and a valve replacement surgery that occurred prior to November 25, 2003. The total number of qualified claims received from the

beginning are now: 93 (71 foreign) qualified outlet strut fracture claims and 136 (54 foreign) qualified valve replacement surgery claims including; 38 (16 foreign) qualified single leg fracture claims.

Since the last Report the office of the Claims Administrator has completed updating the Class Members' database with current information obtained from the questionnaires that were returned to Class Counsel from their mailing to Class Members. This updating recorded many address changes and resulted in the mailing of approximately 1,400 additional "Dear Doctor" letters to physicians who were not on the guidelines notification listing.

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, 2004, the total balance of cash and cash equivalents was \$24,522,795. This amount takes into account net interest earned from January 28, 1992 through April 30, 2004 in the aggregate amount of \$23,267,985. There remain two annual payments of \$6,250,000 each to be received from Pfizer/Shiley under the Settlement.

Attached as Appendix 6 are the following: an unaudited balance sheet as of April 30, 2004 and an unaudited statement of income and funds balance for the four months ended April 30, 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 7 are the following: an unaudited balance sheet as of December 31, 2003 and an unaudited statement of income and funds balance for the year ended December 31, 2003 (which includes the budgeted amounts for expenses for the administrative office for the year ended December 31, 2003.)

Attached as Appendix 8 is a copy of the proposal of Deloitte & Touche LLP for auditing services for the year ending December 31, 2003. The Trustees recommend that the Court approve the proposal.

### **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: June 3, 2004

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

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

**APPENDIX 1**

**CONFIDENTIAL PROPRIETARY INFORMATION**



## APPENDIX 2

**ONGOING RESEARCH PROJECTS (as of May 25, 2004)**

**A. Epidemiological Projects**

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
1. UK Cohort	12/6/01	12/31/03	Patient Follow-up to Improve Estimation of Risk of Strut Fracture	5/28/03*	£36,938	£21,727
2. International Epidemiology Institute, Ltd.	11/13/03	11/13/04	Updating BSCC Patient Quality of Life Survey	**	\$116,900	\$00
3. University Utrecht Van der Graaf	12/22/03	12/22/05	Continuation of Dutch Follow-Up Study	**	77.019 Euro	\$00
4. IEI and Utrecht Univ Blot & Van der Graaf	5/24/04	5/24/05	International Epidemiology Study	**	\$63,500 (Utrecht) \$86,500 (IEI)	\$00 \$00

**B. Surgical Projects**

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
1. UAB	7/18/02	7/18/04	Evaluate Combined Therapy Approach to Improve Risk of Re-Operation	7/03/03*	\$146,073	\$17,390

**C. Imaging & Acoustic Projects**

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
1. University of Sheffield	12/21/01	6/21/03	Prediction of Closure Forces on BSCC Valves	4/8/04*	£177,544	£145,987
2. Information Systems Laboratories (ISL)	3/16/98	10/11/04	Noninvasive Assessment and Arterial Heart Valves	5/5/04*	\$4,006,430	\$3,213,663

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

\*\*No Status Report Available

**ONGOING RESEARCH PROJECTS** (as of May 25, 2004) - Cont'd.

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
3. Edison Welding Institute	5/24/99	2/06/03	Analysis and Assessment of Valve Failure	5/3/04*	\$888,200	\$844,297
4. Michigan State University	10/23/01	10/13/04	Catheter Based and EMAT Detection of SLS	4/6/04*	\$1,825,822	\$1,279,895
5. Eindhoven University - Tjhuis	4/18/03	4/18/04	Develop Catheter-Based Antenna for Detecting Flaws in BSCC Heart Valves	**	\$106,800	\$00
6. Erasmus University – De Jong Lancee	4/1/03	1/1/04	Ultrasound to Detect SLS (Initial Phase)	**	\$45,000	\$00
7. Hershey Imaging	10/6/03	10/6/04	Radiographic Imaging to Detect SLS	4/12/04	\$1,750/Session Plus overhead	\$80,114
8. BioQuantetics	5/17/00	10/28/04	Ultrasound Detection of Single Leg Separation	4/6/04*	\$3,252,390	\$2,035,698
9. Miromico, Inc.	7/25/03	3/25/04	Telemonitoring System for valve related Cardiac Emergencies (Phase I)	5/10/04*	\$197,778	\$128,328
10. Eindhoven University De Hart	11/13/03	11/13/04	Evaluate Effect of Modeling Assumptions and Boundary Conditions on BSCC Valve Loading	4/9/04*	\$194,000	\$83,493
11. ACES	11/12/03	5/12/04	Acoustic Detection of Outlet Strut Resonance in BSCC Heart Valves	4/6/04*	\$192,750	\$124,410
12. ACES	11/12/03	8/12/04	Transmission of Acoustic Waves from a Vibrating Outlet Strut in BSCC Heart Valves	4/6/04*	\$185,950	\$69,030
13. UMC Utrecht Konings	10/14/03	4/14/05	Development of High Frequency, Miniaturized, Electromagnetic Dip Meter (Phase I)	4/6/04*	\$183,295	\$00

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

\*\*No Status Report Available

**ONGOING RESEARCH PROJECTS** (as of May 25, 2004) - Cont'd.

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
14. Cleveland Clinic	1/22/04	1/22/05	Three Dimensional Motion of Prosthetic Heart Valves by Computed Tomography and Echocardiography	4/6/04	\$199,988	\$00
15. UMC Utrecht	1/5/04	7/5/04	Value of 3D Rotational Angiography in the Assessment of Fractured Bjork-Shiley Convexo-Concave Heart Valves (Feasibility )	**	\$100,000	\$60,000
16. ACES	3/29/04	6/29/04	Critical Evaluation of Role of Crack Initiation and Crack Growth	**	\$63,750	\$00
17. ACES	4/13/04	10/13/04	BSCC Heart Valve Performance Modeling Using Element Free Techniques	**	\$99,400	\$00
18. ACES	4/13/04	10/13/04	Modeling of BSCC Heart Valves – Effect of Compliant Support Conditions	**	\$77,800	\$00
19. ACES	4/13/04	10/13/04	Relationship Between Engineering Database and Epidemiological Studies	**	\$144,500	\$00

**D. Other Projects**

Name of Institution	Effective Date of Contract	Termination Date	Description of Project	Current Status	Contract Amount	Billed To Date
1. EAR Medical Comm.	1/5/04	3/5/04	User-Friendly Patient Brochure Regarding Guidelines	Draft	\$62,439	\$11,758
2. Penn State University	5/14/03	---	Create Database of Manufacturing Data (Feasibility Phase Approved)	**	\$346,858	\$00
31. WESTAT	8/20/03	9/14/04	Survey of Physicians and Class Members	**	\$199,517	\$1,447

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

\*\*No Status Report Available

## APPENDIX 3

**APPROVED RESEARCH PROJECTS PENDING CONTRACT (as of May 25, 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	Evaluation of Hook to Well Separation on Tip Loading	Awaiting signed contract	\$174,125

**C. Other**

Name of Institution	Description of Project	Status	Cost
	None		

## APPENDIX 4

**PROPOSED BUT DEFERRED RESEARCH PROJECTS (as of May 25, 2004)**

**A. Imaging & Acoustic Projects**

Name of Institution	Description of Project	Status	Proposed Cost
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None

**B. Other**

Name of Institution	Description of Project	Status	Proposed Cost
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1.	University of Amsterdam (Netherlands)	Ex-Vivo Analysis of Micro-Emboli Formation in Damaged and Intact Valves	*** 182,000 Euro
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\*\*\* Deferred by Supervisory Panel for stated reasons, or made subject to clarification or a demonstration of feasibility.



## APPENDIX 5

January 2004 February 2004 March 2004 April 2004

Total Visits	1051	786	828	855
Average Daily Visits	33	27	26	28
Average Visit Length	14:22	8:52	6:48	9:12
Median Visit Length	4:49	3:21	1:41	2:22
International Visits	8%	14%	18%	24%
US Visits	14%	17%	81%	75%
Unknown Origin Visits	78%	68%	1%	1%

Unique Visitors	524	472	571	505
One-Time Visitors	401	367	476	424
Multiple-Time Visitors	123	105	95	81

Top Downloads	Nineteenth Report - 173 times	amended 2003 - 107 times	Nineteenth Report - 255 times	Nineteenth Report - 117 times
	Amended 2003 - 94 times	nineteenth report - 102 times	Amended 2003 - 49 times	Amended 2003 - 58 times
	Class Letter 2003 - 47 times	doctor letter 2003 - 59 times	Settlement - 43 times	Settlement - 31 times
	Pamphlet - 37 times	settlement - 51 times	Doctor Letter 2003 - 18 times	Class Letter 2003 - 15 times
	Settlement - 35 times	pamphlet - 49 times	Precautions - 16 times	Pamphlet - 15 times
	Precautions - 31 times	class letter 2003 - 39 times	Class Letter 2003 - 16 times	Precautions - 13 times
	Doctor Letter 2003 - 31 times	precautions - 23 times	Pamphlet - 12 times	Haynes - 12 times
Total Downloads	605	557	605	440

Top Visitors Locations	Reston, VA	Reston, VA	San Mateo, CA	Mountain View, CA
	San Francisco, CA	San Francisco, CA	Mountain View, CA	San Mateo, CA
	Pasadena, CA	Irving, TX	San Francisco, CA	San Francisco, CA
	Irving, TX	Stamford, CT	San Diego, CA	Lisbon, Portugal
	Stamford, CT	Nashville, TN	San Jose, CA	San Diego, CA

Countries viewing the site	United States	United States	United States	United States
	Hong Kong	Belize	France	France
	Canada	Netherlands	Canada	Germany
	France	Canada	Germany	Portugal
	Netherlands	France	Netherlands	Japan
	Seychelles	Saudi Arabia	China	Netherlands
	Germany	Japan	Taiwan	United Kingdom
	Israel	United Kingdom	United Kingdom	China

	January 2004	February 2004	March 2004	April 2004
States/Provinces viewing site	California Virginia Texas Connecticut Pennsylvania Colorado Tennessee Ohio Ontario	Virginia California Texas Connecticut Tennessee North Dakota Ontario Illinois Maryland	California Virginia Texas Florida Ohio Ontario New York Illinois Colorado	California Massachusetts Minnesota Wisconsin Pennsylvania Virginia New Jersey Ohio Washington

Search Engine & Reference -
AOL inktomi.com looksmart.com Google tw telecom.net alexa.com comcast.net
Inktomi Corporation Google AOL Looksmart Yahoo Alexa
Google AOL Inktomi Ask Jeeves Alexa Yahoo

Top Domain Types
Commercial (.com) - 650 Network (.net) - 183 Education (.edu) - 9 Organization (.org) - 3 Government (.gov) - 2
Commercial (.com) - 409 Network (.net) - 134 Education (.edu) - 17 Organization (.org) - 9
Commercial (.com) - 449 Network (.net) - 138 Education (.edu) - 18 Organization (.org) - 2
Commercial (.com) - 541 Network (.net) - 92 Education (.edu) - 16 Informational (.info) - 12 Government (.gov) - 3

## APPENDIX 6

TRUSTEES FOR THE BOWLING-PFIZER  
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF APRIL 30, 2004

UNAUDITED

ASSETS

CASH	\$ 145,339
U.S. TREASURY BILLS	24,377,456
OTHER ASSETS	<u>13,370</u>
	<u>\$ 24,536,165</u>

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 797,940 (1)
FUNDS BALANCE	<u>23,738,225</u>
	<u>\$ 24,536,165</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 FOUR MONTHS ENDED APRIL 30, 2004

UNAUDITED

INVESTMENT INTEREST INCOME	<u>\$ 80,245</u>
RESEARCH PROGRAMS - COSTS	<u>1,065,111</u>
LITIGATION ATTORNEYS - FEES & EXPENSES	<u>797,646</u>
EXPENSES:	
Supervisory Panel	377,268 (1)
Trustees' fees and expenses	46,905
Professional fees	116,365
Administrative office	<u>188,628 (1)</u>
Total	<u>729,166</u>
NET CHANGE IN FUNDS BALANCE	(2,511,678) (2)
FUNDS BALANCE, DECEMBER 31, 2003	<u>26,249,903</u>
FUNDS BALANCE, APRIL 30, 2004	<u>\$ 23,738,225</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- 4/30/04</u>
<b>SUPERVISORY PANEL:</b>		
Panel members' compensation		\$ 216,400
Consultants' compensation		63,257
Travel and incidental expenses		58,702
Miscellaneous		9,906
Notification expenses		29,003
Total		\$ 377,268
 <b>ADMINISTRATIVE OFFICE:</b>		
Rents	\$ 72,000	\$ 23,539
Office payroll	407,000	131,368
Payroll taxes	25,000	10,795
Employee benefits	55,000	15,333
Outside services	12,000	1,912
Printing and postage	6,000	943
General insurance	3,000	2,448
Telephone	9,000	2,099
Office supplies and expense	6,000	1,163
Depreciation	3,000	808
Miscellaneous	6,000	157
Administrative services income	(6,000)	(1,937)
Total	\$ 598,000	\$ 188,628

## APPENDIX 7



TRUSTEES FOR THE BOWLING-PFIZER  
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF DECEMBER 31, 2003

UNAUDITED

ASSETS

CASH	\$ 732,776
U.S. TREASURY BILLS	26,557,160
OTHER ASSETS	<u>14,995</u>
	<u>\$ 27,304,931</u>

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 1,055,028(1)
FUNDS BALANCE	<u>26,249,903</u>
	<u>\$ 27,304,931</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 2002.

TRUSTEES FOR THE BOWLING-PFIZER  
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME AND FUNDS BALANCE

FOR THE YEAR ENDED DECEMBER 31, 2003

UNAUDITED

INVESTMENT INTEREST INCOME	<u>\$ 277,247</u>
VALVE REPLACEMENT SURGERY BENEFITS	<u>193,570</u>
RESEARCH PROGRAMS - COSTS	<u>3,089,384</u>
LITIGATION ATTORNEYS - FEES & EXPENSES	<u>748,849</u>
EXPENSES:	
Supervisory Panel	1,425,040 (1)
Trustees' fees and expenses	85,855
Professional fees	214,277
Administrative office	<u>516,521 (1)</u>
Total	<u>2,241,693</u>
CONTRIBUTION BY SHILEY INCORPORATED	<u>6,250,000</u>
NET CHANGE IN FUNDS BALANCE	253,751 (2)
FUNDS BALANCE, DECEMBER 31, 2002	<u>25,996,152</u>
FUNDS BALANCE, DECEMBER 31, 2003	<u>\$ 26,249,903</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>1/1/03-12/31/03</u>	<u>1/1/03-12/31/03</u>
<b>SUPERVISORY PANEL:</b>		
Panel members' compensation		\$ 819,499
Consultants' compensation		103,455
Travel and incidental expenses		283,126
Miscellaneous		19,151
Notification expenses		<u>199,809</u>
Total		<u>\$ 1,425,040</u>
 <b>ADMINISTRATIVE OFFICE:</b>		
Rents	\$ 72,000	\$ 73,233
Office payroll	383,000	373,870
Payroll taxes	23,000	21,543
Employee benefits	30,000	36,429
Outside services	18,000	4,160
Printing and postage	9,000	2,947
General insurance	3,000	2,326
Telephone	9,000	6,372
Office supplies and expense	9,000	3,334
Travel	6,000	
Depreciation	6,000	2,426
Miscellaneous	6,000	499
Administrative services income	<u>(12,000)</u>	<u>(10,618)</u>
Total	<u>\$ 562,000</u>	<u>\$ 516,521</u>

## APPENDIX 8



December 2, 2003

Trustees of the Bowling-Pfizer Heart Valve Litigation Settlement Fund  
525 Vine Street, Suite 2300  
Cincinnati, Ohio 45202

Dear Sirs:

We are pleased to serve as independent accountants and auditors for The Bowling-Pfizer Heart Valve Litigation Settlement Fund (the "Fund"). Mr. Russ Ferneding, Director, will be responsible for the services that we perform for the Fund. Mr. Ferneding will, as he considers necessary, call on other individuals with specialized knowledge, either in this office or elsewhere in our firm, to assist in the performance of our services.

While auditing and reporting on the Fund's annual financial statements for the year ending December 31, 2003, is the service that we are to provide under this engagement letter, we would also be pleased to assist the Fund on issues as they arise throughout the year. Hence, we hope that the Fund will call Mr. Ferneding whenever the Fund and management believe he can be of assistance.

We will perform this engagement subject to the terms and conditions set forth herein.

#### **AUDIT OF FINANCIAL STATEMENTS**

Our audit of the Fund's financial statements for the year ending December 31, 2003, will be conducted in accordance with auditing standards generally accepted in the United States of America (hereinafter referred to as "generally accepted auditing standards").

We will plan and perform our audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether caused by error or fraud. However, because of the characteristics of fraud, a properly planned and performed audit may not detect a material misstatement. Therefore, an audit conducted in accordance with generally accepted auditing standards is designed to obtain reasonable, rather than absolute, assurance that the financial statements are free of material misstatement. An audit is not designed to detect error or fraud that is immaterial to the financial statements.

An audit includes obtaining an understanding of internal control sufficient to plan the audit and to determine the nature, timing, and extent of audit procedures to be performed. An audit is not designed to provide assurance on internal control or to identify reportable conditions.

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.

The objective of our audit is the expression of an opinion on the fairness of the presentation of the Fund's financial statements in conformity with accounting principles generally accepted in the United States of America (hereinafter referred to as "generally accepted accounting principles"), in all material respects. Our ability to express an opinion and the wording of our opinion will, of course, be dependent on the facts and circumstances at the date of our report. If, for any reason, we are unable to complete the audit or are unable to form or have not formed an opinion, we may decline to express an opinion or decline to issue a report as a result of this engagement. If we are unable to complete our audit or if our auditors' report requires modification, the reasons therefore will be discussed with the Fund's management.

## **MANAGEMENT'S RESPONSIBILITY**

The financial statements are the responsibility of the Fund's management. In this regard, management has the responsibility for, among other things: (1) establishing and maintaining effective internal control over financial reporting, (2) identifying and ensuring that the Fund complies with the laws and regulations applicable to its activities and informing us of any known material violations of such laws or regulations, (3) properly recording transactions in the accounting records, (4) adjusting the financial statements to correct material misstatements, (5) making appropriate accounting estimates, (6) safeguarding assets, (7) the overall accuracy of the financial statements and their conformity with generally accepted accounting principles, and (8) making all financial records and related information available to us.

Additionally, management is responsible for the design and implementation of programs and controls to prevent and detect fraud and for informing us about all known or suspected fraud affecting the Fund involving, (1) management, (2) employees who have significant roles in internal control, and (3) others where the fraud could have a material effect on the financial statements. Management is also responsible for informing us of its knowledge of any allegations of fraud or suspected fraud affecting the Fund received in communications from employees, former employees, analysts, regulators, short sellers, or others.

We will make specific inquiries of the Fund's management about the representations embodied in the financial statements. As part of our audit procedures, we will request that management provide us with a representation letter acknowledging management's responsibility for the preparation of the financial statements and affirming management's belief that the effects of any uncorrected financial statement misstatements aggregated by us during the current audit engagement and pertaining to the latest period presented are immaterial, both individually and in the aggregate, to the financial statements taken as a whole. We will also request that management confirm certain representations made to us during our audit. The responses to those inquiries and related written representations of management required by generally accepted auditing standards are part of the evidential matter that we will rely on as auditors in forming our opinion on the Fund's financial statements. Because of the importance of management's representations, the Fund agrees to release and indemnify D&T and its personnel from all claims, liabilities, and expenses relating to our services under this engagement letter attributable to any misrepresentation by management.

If the Fund intends to publish, or otherwise reproduce in any document, our report on the Fund's financial statements, or otherwise make reference to D&T in a document that contains other information in addition to the audited financial statements (e.g., in a periodic filing with a

regulator, in a debt or equity offering circular, or in a private placement memorandum). thereby associating D&T with such document, the Fund agrees that its management will provide us with a draft of the document to read and obtain our approval for the inclusion or incorporation by reference of our report, or the reference to D&T, in such document before the document is printed and distributed. The inclusion or incorporation by reference of our report in any such document would constitute the reissuance of our report. The Fund also agrees that its management will notify us and obtain our approval prior to including our report on an electronic site.

Our engagement to perform the services described above does not constitute our agreement to be associated with any such documents published or reproduced by or on behalf of the Fund. Any request by the Fund to reissue our report, to consent to its inclusion or incorporation by reference in an offering or other document, or to agree to its inclusion on an electronic site will be considered based on the facts and circumstances existing at the time of such request. The estimated fees outlined herein do not include any services that would need to be performed in connection with any such request; fees for such services (and their scope) would be subject to our mutual agreement at such time as we are engaged to perform the services and would be described in a separate engagement letter.

It is also management's responsibility to ensure that the Fund has not caused D&T's independence to be impaired by hiring a former or current D&T partner, principal, or professional employee in a key position, as defined in the *Code of Professional Conduct* of the American Institute of Certified Public Accountants (AICPA), that would cause a violation of the AICPA *Code of Professional Conduct* or other applicable independence rules. Any employment opportunities with the Fund for a former or current D&T partner, principal, or professional employee should be discussed with Mr. Ferneding before entering into substantive employment conversations with the former or current D&T partner, principal, or professional employee. For the purpose of this paragraph, "D&T" shall mean Deloitte & Touche LLP and Deloitte Touche Tohmatsu, its member firms and the affiliates of Deloitte & Touche LLP, Deloitte Touche Tohmatsu, and its member firms.

#### OTHER COMMUNICATIONS ARISING FROM THE AUDIT

In connection with the planning and the performance of our audit, generally accepted auditing standards require that certain matters be communicated to the Board of Trustees. We will report directly to the Board of Trustees any fraud of which we become aware that involves senior management, and any fraud (whether caused by senior management or other employees) of which we become aware that causes a material misstatement of the financial statements. We will report to senior management any fraud perpetrated by lower level employees of which we become aware that does not cause a material misstatement of the financial statements; however, we will not report such matters directly to the Board of Trustees, unless otherwise directed by the Board of Trustees.

We will inform the appropriate level of management of the Fund and determine that the Board of Trustees is adequately informed with respect to illegal acts that have been detected or have otherwise come to our attention in the course of our audit, unless the illegal act is clearly inconsequential.

We will also report directly to The Bowling-Pfizer Heart Valve Litigation Settlement Fund's management and the Board of Trustees matters coming to our attention during the course of our audit that we believe are reportable conditions. Reportable conditions are significant deficiencies in the design or operation of internal control that could adversely affect the Fund's ability to initiate, record, process, and report financial data consistent with the assertions of management in the financial statements.

We may also have other comments for the Board of Trustees and management on matters we have observed and possible ways to improve the efficiency of the Fund's operations or other recommendations concerning internal control.

**FEES**

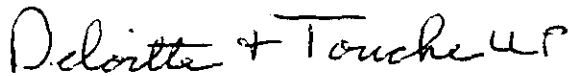
We estimate that our total fees for this audit will be \$12,500, plus expenses. Payments are due 30 days from the date of the invoice. Expenses will be billed in addition to fees. Expenses will be stated separately on the invoices.

The estimate of our fees is based on certain assumptions. To the extent that certain circumstances, as listed in Appendix A, arise during the engagement, our fee estimate and targeted completion dates may be significantly affected and additional fees may be necessary. We will notify you promptly of any circumstances we encounter that could significantly affect our estimate and discuss with you any additional fees, as necessary. Additional services provided beyond the described scope of services will be billed separately.

\* \* \* \* \*

If the above terms are acceptable to the Fund, and the services outlined are in accordance with your understanding, please sign the copy of this engagement letter in the space provided and return it to us.

Yours truly,



Accepted and agreed to by the Bowling-Pfizer Heart Valve Litigation Settlement Fund:

By: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_



APPENDIX A  
CIRCUMSTANCES AFFECTING TIMING AND FEE ESTIMATE  
YEAR ENDING DECEMBER 31, 2003

The fees quoted for auditing and reporting on the Fund's annual financial statements for the year ending December 31, 2003, are based on certain assumptions. Circumstances may arise during the engagement that may significantly affect the targeted completion dates and our fee estimate. As a result, additional fees may be necessary. Such circumstances include but are not limited to the following:

1. Changes to the timing of the engagement at the Fund's request. Changes to the timing of the engagement usually requires reassignment of personnel used by Deloitte & Touche LLP ("D&T") in the performance of services hereunder. However, because it is often difficult to reassign individuals to other engagements, D&T may incur significant unanticipated costs.
2. All audit schedules are not (a) provided by the Fund on the date requested, (b) completed in a format acceptable to D&T, (c) mathematically correct, or (d) in agreement with the appropriate Fund records (e.g., general ledger accounts). D&T will provide the Fund with a separate listing of required schedules and deadlines.
3. Electronic files in an appropriate format and containing the information requested are not provided by the Fund on the date requested for our use in performing file interrogation. D&T will provide the Fund with a separate listing of the required files and the dates the files are needed.
4. Weaknesses in the internal control structure.
5. Significant new issues or changes as follows:
  - a. Significant new accounting issues that require an unusual amount of time to resolve.
  - b. Significant changes in accounting policies or practices from those used in prior years.
  - c. Significant changes or transactions that occur prior to the issuance of our reports.
  - d. Significant changes in the Fund's accounting personnel, their responsibilities, or their availability.
  - e. Significant changes in auditing requirements set by regulators.
6. Significant delays in the Fund's assistance in the engagement or delays by the Fund in reconciling variances as requested by D&T. All invoices, contracts, and other documents, which we will identify for the Fund, are not located by the Fund's personnel or made ready for our easy access.

7. The engagement team, while performing work on the Fund's premises, is not provided with access to the Internet (via the Fund's existing network or through a T1, DSL, or cable connection) for purposes of conducting the engagement.
8. Deterioration in the quality of the Fund's accounting records during the current-year engagement in comparison with the prior-year engagement.
9. A trial balance in financial-statement format, which references to supporting detailed working papers (by general ledger account number), is not provided by the Fund. All entries are not posted to this trial balance prior to our receiving it. Draft financial statements that agree with the trial balance and are internally referenced to supporting documentation (for footnotes and cash flow statements) are not prepared by the Fund's personnel.
10. Significant levels of proposed audit adjustments are identified during our audit.
11. Changes in audit scope caused by events that are beyond our control.
12. Untimely payment of our invoices as they are rendered.