

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

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

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TWENTY-FIFTH REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING PERIOD FROM MAY 24, 2006 TO NOVEMBER 21, 2006

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SPECIAL MASTERS/TRUSTEES

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

AGENDA

TWENTY-FIFTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

December 7, 2006

11:00 A.M.

Hon. Herman J. Weber, Senior Judge

1. Introductory remarks by Judge Weber.
2. Report of the Special Masters/Trustees.
3. Comments from Counsel:
  - Class Counsel.
  - Counsel for Defendants.
4. Questions and comments from those in attendance.
5. Request for date of next report of Trustees.
6. Closing remarks of Judge Weber.

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- A. Twenty-Fifth Report of the Special Masters/Trustees
- B. Appendices to Court Report
  - 1. Schedule of ongoing research projects.
  - 2. "Hit Report" regarding the Supervisory Panel's Website.
  - 3. Unaudited balance sheet as of October 31, 2006 and an unaudited statement of income and funds balance for the ten months ended October 31, 2006.
  - 4. Independent Auditors' Report for the year ended December 31, 2005.

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

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

Your Special Masters/Trustees respectfully present their twenty-fifth periodic report, covering activities from May 24, 2006 to November 21, 2006. This report is submitted sixteen days prior to the status hearing before the Court scheduled for December 7, 2006.

**I. PATIENT BENEFIT FUND**

A. Supervisory Panel. The Supervisory Panel has not met as a whole panel since October 31, 2005, but has had numerous committee meetings. Specifically, the Guidelines Committee has been very active on the revision to the 2003 Amended Guidelines. The work has been done largely through conference calls with the Guidelines Committee, the Supervisory Panel and Dr. William Blot and Dr. Ron

Brookmeyer. A Motion to Approve 2006 Amended Valve Replacement Guidelines was filed with the Court on November 2, 2006.

The Supervisory Panel decided in September 2006 to terminate the research being conducted at BioQuantetics.

The patient studies with the ACES device are currently being conducted at the Ohio State University.

B. Guidelines. The Panel has completed a revision to the 2003 Guidelines as discussed above.

C. Research. Our report on the status of the research program of the Supervisory Panel is set out in the attached Appendix 1.

D. Imaging. Since the imaging program at Penn State resumed again, effective April 26, 2005, six implantees (one was imaged twice) 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, certain reports on the status and results of research sponsored by the Supervisory Panel, minutes of meetings of the Supervisory Panel, a bibliography of published literature regarding the BSCC heart valves, certain unpublished reports prepared by Dr. 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 2.

The website was amended to allow for Class Registration on the website in thirteen (13) different languages, including English.

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 May 24, 2006, there has been one reported outlet strut fracture. This event has not yet been confirmed.

The total number of qualified claims received from the beginning are: 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.

In an effort to locate unregistered class members, a notice was published in 7 foreign and 13 U.S. newspapers. In addition, the notice was placed on the domestic and foreign newswires once a month for four consecutive months. To date there have been 91 responses, resulting in the registration of 7 class members. Most of the responses are from class members who have already registered or from persons who are not class members. In addition, the Canadian Shiley Patient Notification and Registration System mailed

a notice to approximately 360 implantees.

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, 2006, the total balance of cash and cash equivalents was \$24,494,219. This amount takes into account net interest earned from January 28, 1992 through October 31, 2006 in the aggregate amount of \$25,226,232.

Attached as Appendix 3 are the following: an unaudited balance sheet as of October 31, 2006 and an unaudited statement of income and funds balance for the ten months ended October 31, 2006 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 2006 through December 31, 2006).

Attached as Appendix 4 is a copy of the Independent Auditors' Report for the year ending December 31, 2005.

## 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.



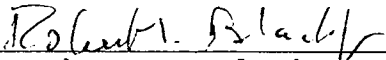
IV. APPROVALS

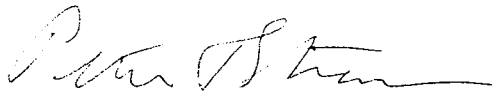
Your honor, the Special Masters/Trustees request that the Court:

- 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<sup>21</sup>\_\_, 2006

  
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Hon. Robert L. Black, Jr.

  
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Peter J. Strauss, Esq.

## APPENDIX 1

**Trustees for the Bowling-Pfizer Heart Valve Settlement Funds**  
**Supervisory Panel Research Projects Initiated After January 31, 2005**

Continuing Operation Plan Future Projects	Termination Date	Contract Amounts			Billed Through 9/30/2006	Remainder 9/30/2006	
		Projected	Actual	Savings		Committed Unbilled	Completed Cost Savings
<b>Committed</b>							
Michigan State University							
EMAT System	11/12/2006	\$1,000,000	\$982,686	\$17,314	\$376,047		\$606,639
Sheep Study	6/30/2005	40,000	35,125	4,875	34,547		578
EMAT System Testing		30,000	30,000				30,000
BioQuantetics							
Ultrasound Burst-Spect.	12/31/2005	600,000	589,928	10,072	579,365		10,563
April 2005 Interim Funding	4/30/2005		25,535	(25,535)	24,918		617
January 2006 Interim Fund.	1/31/2006		50,827	(50,827)	50,818		9
March 2006 Addendum	4/30/2006		181,950	(181,950)	168,890		13,060
ACES							
Passive Accoustics	8/31/2005		5,259	(5,259)	5,259		
UCSD							
Maintain Research Sheep			21,809	(21,809)	21,809		
Cleveland Clinic & STS							
Guidelines Data		20,000	68,044	(48,044)	68,044		
BioSurg		100,000	230,120	(130,120)	176,065	54,055	
International Epidem. Inst.			35,000	(35,000)	24,162	10,838	
Hershey Imaging		43,219	43,219		43,219		
ACES							
Passive Accoustics	11/8/2006	500,000	499,675	325	348,989	150,686	
<b>Total</b>		<b>\$2,333,219</b>	<b>\$2,799,178</b>	<b>(\$465,959)</b>	<b>\$1,922,133</b>	<b>\$215,579</b>	<b>\$661,466</b>
<b>Not Yet Committed</b>							
Hershey Imaging		116,781					
Pilot Test		262,250					
Testing Center		1,597,500					
Guidelines Notification		400,000					
<b>Total</b>		<b>\$2,376,531</b>					
<b>Total</b>		<b>\$4,709,750</b>					

**Trustees for the Bowling-Pfizer Heart Valve Settlement Funds  
Supervisory Panel Research Projects Ongoing At January 31, 2005**

Continuing Operation Plan Ongoing Projects	Termination Date	Balance 1/31/2005	Billed 2/1/2005 9/30/2006	Remainder 9/30/2006	
				Committed Unbilled	Completed Cost Savings
International Epidemiology Inst. Utrecht University	8/31/2005	\$65,340	\$65,340		
Devtrack Pty. Ltd. International Epidemiology Study	8/31/2005	63,500	63,500		
	8/31/2005	37,500	37,500		
Penn State University Database of Mfg. Records	9/30/2005	103,159	95,889		\$7,270
International Epidemiology Inst. Patient Quality of Life Survey	(1) 3/31/2005	26,362	26,362		
Utrecht University Dutch Follow Up Study	12/22/2005	106,006	106,006		
Information Systems Laboratories, Noninvasive Assessment of Heart Valves	2/25/2005	77,997	77,997		
BioQuantetics Ultrasound Burst-Spectrography	2/28/2005	139,104	139,104		
Miromico, Inc. Telemonitoring System	4/7/2005	199,400	199,400		
UMC Utrecht Electromagnetic Dip Meter	4/14/2005	37,947	37,947		
Michigan State University Catheter Based and EMAT Detection of SLS	6/30/2005	238,722	227,016		11,706
Michigan State University EMAT Continuation Project	5/12/2005	157,111	107,188		49,923
Eindhoven University Catheter Based Antenna	4/18/2004	106,800	106,800		
Cleveland Clinic 3-D Motion of Heart Valves	3/22/2005	73,134	69,234		3,900
ACES Evaluation of the Role of Crack Growth and Initiation	11/30/2004	2,100	2,100		

ACES BSCC Valve Performance Modeling Using Element Free Techniques	(2)	2/28/2005	17,290	17,290	
ACES Modeling of BSCC Heart Valves, Effect of Compliant Support Conditions	(3)	2/28/2005	45,200	45,200	
ACES Relationship of Engineering and Epidemiology	(4)	9/30/2005	132,050	132,050	
ACES Hook to Well Separation	(5)	9/30/2005	127,675	127,675	
ACES Passive Accoustic Detection	(6)	8/31/2005	137,470	137,470	
UAB Evaluate Approach to Improve Risk of Re-Operation		7/18/2004	128,683	112,181	16,502
<b>TOTAL</b>			<b>\$2,022,550</b>	<b>\$1,933,249</b>	<b>\$0</b> <b>\$89,301</b>

Note - The 1/31/2005 balances are the amounts included in Schedule II of the Supervisory Panel's continuing operation plan.

- (1) The total charges of the researcher exceeded the amount that the court approved agreement allowed the Trustees to pay. The researcher absorbed this cost overrun as a "professional discount". In this case the professional discount was \$5,200.
- (2) Professional discount of \$3,050.
- (3) Professional discount of \$3,555.
- (4) Professional discount of \$7,450.
- (5) Professional discount of \$20,690.
- (6) Professional discount of \$53,151.

**APPENDIX 2**

Hit Report for Bowling-Pfizer.com

	June 2006	July 2006	August 2006
Total Visits	1136	1027	1405
Average Daily Visits	37	33	45
Average Visit Length	7:40	9:55	5:38
Median Visit Length	1:18	2:52	0:46
International Visits	6.37%	4.08%	6.40%
US Visits	79.38%	78.18%	79.07%
Unknown Origin Visits	15.24%	17.72%	14.51%
Unique Visitors	464	346	526
One-Time Visitors	332	258	399
Multiple-Time Visitors	132	88	127
Top Downloads	Amended 2003 - 78 times Class Letter 2003 - 39 times Notice of filing 23 report - 35 times Settlement - 33 times Doctor Letter 2003 - 28 times Precautions - 18 times Legal Notices to Class - 17 times	Update - 27 times Settlement - 26 times Pamphlet - 25 times Haynes - 19 times Doctor Letter 2003 - 16 times Guidelines - 15 times Notice of Filing 23 Report - 13 times	Amended 2003 - 48 times 17th Report - 30 times Pamphlet - 23 times Settlement - 22 times Notice of Filing 23 Report - 22 times German Translation - 20 times Haynes - 20 times
Total Downloads	402	258	307
Top Visitors Locations	Reston, VA Altadena, CA Redmond, WA Cincinnati, OH Menlo Park, CA	Redmond, WA Cincinnati, OH Menlo Park, CA Altadena, CA Reston, VA	Mountain View, CA Cincinnati, OH Reston, VA Menlo Park, CA Altadena, CA
Countries viewing the site	United States United Kingdom Poland Belgium Italy Australia Seychelles Canada	United States Italy United Kingdom Seychelles Netherlands Belgium Taiwan Switzerland	United States United Kingdom Canada Switzerland Poland Germany United Arab Emirates Australia

Hit Report for Bowling-Pfizer.com

June 2006

July 2006

August 2006

States/Provinces	Viewing site	June 2006	July 2006	August 2006
California	Washington	California	Ohio	California
Virginia	Ohio	Ohio	California	Ohio
Washington	California	California	Virginia	Virginia
Ohio	Virginia	Virginia	Connecticut	Connecticut
Tennessee	New York	New York	Tennessee	Tennessee
New York	D.C.	D.C.	Massachusetts	Massachusetts
Maryland	Texas	Texas	Illinois	Texas
Massachusetts	Illinois	Illinois	Connecticut	New York
Connecticut	Connecticut	Connecticut	Ontario	Ontario
<hr/>				
Search Engine & Reference -				
MSN	MSN	MSN	Google	Google
Ask	Google	Google	Microsoft Live	Microsoft Live
Inktoni	Inktoni	Inktoni	Healthline	Healthline
Healthline	Healthline	Healthline	Yahoo	Yahoo
Google	Google	Google		
<hr/>				
Top Domain Types				
Commercial (.com) 744	Commercial (.com) 646	Commercial (.com) 858		
Network (.net) 166	Network (.net) 161	Network (.net) 257		
Organization (.org) 5	Education (.edu) 11	Government (.gov) 9		
Education (.edu) 2	Organization (.org) 4	Education (.edu) 9		
	Government (.gov) 2	Organization (.org) 5		
	Military (.mil) 2			



