### UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

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

# NOTICE OF FILING OF THE THIRTIETH REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING THE PERIOD FROM OCTOBER 9, 2008 TO APRIL 15, 2009

NOTICE IS HEREBY GIVEN to all counsel of record that the THIRTIETH REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING THE PERIOD FROM OCTOBER 9, 2008 to APRIL 15, 2009 is hereby filed with the Court.

Respectfully submitted,

/s/ Nancy A. Lawson
Nancy A. Lawson (0012699)
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Attorney for
Special Masters/Trustees

### 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

## THIRTIETH REPORT OF THE SPECIAL MASTERS/TRUSTEES COVERING THE PERIOD FROM OCTOBER 9, 2008 TO APRIL 15, 2009

### **SPECIAL MASTERS/TRUSTEES**

James A. Higgins, Esq. Peter J. Strauss, Esq.

### **AGENDA**

### THIRTIETH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

April 30, 2009 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. Thirtieth Report of the Special Masters/Trustees
- B. Appendices to Court Report
  - 1. Summary of Research
  - 2. "Hit Report" regarding the Supervisory Panel's Website.
  - 3. Summary of the Status of Funding for the Settlement at December 31, 2008.
  - 4. Unaudited balance sheet as of December 31, 2008 and an unaudited statement of income and funds balance for the year ended December 31, 2008.
  - 5. Independent Auditors' Report for the year ended December 31, 2007.

### 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

### THIRTIETH 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 thirtieth periodic report, covering activities from October 9, 2008 to April 15, 2009. This report is submitted fifteen days prior to the status hearing before the Court scheduled for April 30, 2009.

### I. PATIENT BENEFIT FUND

A. <u>Supervisory Panel.</u> The research project for ACES to study the BSCC heart valve sound recordings made on patients who participated in the imaging studies at Stanford and Beaumont has been completed. Unfortunately, the quality of the imaging study recordings was not at a level which permitted ACES to successfully analyze the acoustic signals of the heart valves therein. The panel is waiting on the outcome of the study by Dr. J. de Hart of HemoLab Cardiovascular Engineering in The Netherlands entitled "Outlet strut vibratory response study of BSCC valves at disc-strut closure impact" prior to considering possible next steps with ACES. The purpose of that study is to conduct in vitro research on seven BSCC heart valves, including the valve which had been implanted in a sheep at BioSurg, but was misclassified. The results of Phase I (static study of valves in air) of the study are expected in April, 2009.

The Supervisory Panel received a proposal from MedicAlert to provide emergency alert services to class members in Europe. After discussions with representatives from MedicAlert and with counsel, the Panel decided not pursue the proposal at this time because the Panel is still hopeful of developing a device or method that will give class members important information about the status of their valves and funds need to be preserved for this research.

A renewal agreement for the Penn State University, Hershey Imaging Program was approved by the Court on October 27, 2008 for a period of an additional six months or until the \$160,000 funding authorized by the Court is expended. As of February 28, 2009, the balance of funds remaining for this program was \$65,338. The Panel has recommended another six-month extension of this program.

In December 2008, Drs. Harrison and Weyman and the Chair of the Supervisory Panel along with John Johnson made an on-site visit to Hershey Medical Center. As a result of that visit, the Panel is in preliminary discussions with Hershey regarding Hershey's review of cine fluoroscopy films of BSCC heart valve patients.

In October 2008, Class Counsel requested that the panel consider posting a list of high-risk valves on the Bowling Pfizer website. After review of the materials submitted, the Panel decided not to post such a list as it is the Panel's position that such a list would undermine the guidelines and create confusion for the vast majority of class members who do not qualify for payment of surgical benefits under the guidelines.

At the April 30, 2008 hearing with the Court, the Court requested that the Trustees investigate the ramifications of indemnification by the Trust of the parties who are not otherwise protected by insurance in the event that the trust funds dwindle to the extent that indemnification is meaningless. The Trustees analyzed this issue and determined that commercial insurance should be investigated. The Trustees have investigated commercial insurance and have submitted several

applications for insurance. In each instance, the carriers either declined to provide coverage for the members of the Supervisory Panel or imposed such exclusions from their proposed coverage as to make the coverage pointless in relation to eliminating the risk of indemnification of the members of the Panel by the Trust. At this time the Trustees are not optimistic that satisfactory insurance can be obtained for the members of the Supervisory Panel. The Trustees will pursue this matter if circumstances change and a carrier is located that will provide coverage for the members of the Supervisory Panel. The Trustees will continue to report to the Court on the status of this matter.

- B. <u>Guidelines.</u> Drs. Harrison, Ibrahim and Ivey regularly monitor the pertinent world-wide literature and review reported events occurring to class members to ensure that any issues which may impact the guidelines are detected and considered by the full panel. They have found no information indicating the need to change the Guidelines at this time.
- C. <u>Research.</u> Our report on the status of the research program of the Supervisory Panel is set out in the attached Appendix 1.
- D. <u>Imaging.</u> Since the imaging program at Penn State resumed again, effective April 26, 2005, there have been eleven imaging sessions for seven implantees who may qualify for valve replacement surgery. One implantee was imaged three times and two implantees were imaged two times during this period.
- E. <u>Repository</u>. The Supervisory Panel maintains a repository of certain documents and information concerning the BSCC heart valve. The repository contains reports on the 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. Ron Brookmeyer of his statistical analysis, the <u>Bowling</u> Settlement Agreement, and other information. The repository is available electronically in a database. Some of the information, such as published articles are not available for review due to copyright and other intellectual

property concerns. To access the on-line repository, an individual need only contact the Trustees' office for the website address and a password.

F. Website. The Supervisory Panel's website continues to be found at www.bowling-pfizer.com. It provides basic information on the parties involved (biographies, addresses, telephone numbers, email, etc.), certain orders of the Court including the Guidelines, the Settlement Agreement, Trustee Reports and a bibliography of relevant articles as well as other important information. The panel prepared a summary of key studies which is intended to provide a more user-friendly bibliography. This user-friendly bibliography is available on the website. A copy of the most recent "hit report" of the Supervisory Panel's website is attached to this Report as Appendix 2.

### 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.

From the beginning there have been 98 (74 foreign) qualified outlet strut fracture claims and 99 (39 foreign) qualified valve replacement surgery claims other than single leg fracture claims. In addition, there have been 39 (16 foreign) single leg fracture claims.

The office of the Claims Administrator continues to fulfill requests to calculate estimated annual fracture rates under the 2007 Guidelines and to respond to other inquiries from and on behalf of Class Members.

### II. FINANCIAL INFORMATION

At December 31, 2008, the total balance of cash and cash equivalents was \$21,880,946.

Attached as Appendix 3 are a summary of the status of funding for the Settlement and five related schedules.

Attached as Appendix 4 are the following: an unaudited balance sheet as of December 31, 2008 and an unaudited statement of income and funds balance for the year ended December 31, 2008 (which includes the budgeted amounts for expenses for the administrative office for the year ended December 31, 2008).

Attached as Appendix 5 is a copy of the Independent Auditors' Report for the year ended December 31, 2007.

### 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,

Peter J. Strauss, Esq.

### **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of this Thirtieth Report of the Special Master/Trustee Covering Period from October 9, 2008 to April 15, 2009, has been electronically sent to the following this 15th day of April, 2009.

Stanley M. Chesley, Esq.
Fay E. Stilz, Esq.
Paul DeMarco, Esq.
Waite, Schneider, Bayless & Chesley Co., LPA
1513 PNC Tower
5 West Fourth Street
Cincinnati, OH 45201

Brian Wolfman, Esq. Public Citizen 1600 20th Street, NW Washington, D.C. 20009-1001

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James T. Capretz, Esq. 5000 Birch Street Suite 2500 Newport Beach, CA 92660

John T. Johnson, Esq. 55 Waugh Drive, Suite 505 Houston, TX 77007

Gregory Wallance, Esq. Kaye Scholer LLP 425 Park Avenue New York, NY 10022

/s/ Nanc	y A. Lawson	
Nancy A	. Lawson	

# SUPERVISORY PANEL SUMMARY OF RESEARCH PROJECTS (as of April 6, 2009)

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ACES	Projects Completed During Quarter	HemoLab Cardiovascular (Jurgen de Hart)		Hershey Imaging	Name of Institution	Current Imaging & Acoustic Projects	None	Name of Institution	Current Epidemiology Projects
7/14/08	ıg Quarter	12/10/08		10/27/08	of Contract	ic Projects		of Contract	ects Fffective Date
12/22/08		8/9/09		4/28/09	<u>Date</u>	Termination		<u>Date</u>	Termination
Analysis of acoustic recordings of human volunteers		Study of second harmonic in BSCC valves.		Radiographic Imaging to Detect SLS	Project	Description of		Project	Description of
ers					Status	Current		Status	Current
\$37,900		€75,000		\$160,000	Amount	Contract		Amount	Contract
\$37,900		0		\$94,662	To Date	Rilled		To Date	Billed

# Approved Research Projects Pending Contract None

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**Proposed Research Projects** 

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