

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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THIRTY-FIRST REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING THE PERIOD FROM APRIL 16, 2009 TO OCTOBER 14, 2009

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SPECIAL MASTERS/TRUSTEES

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

**AGENDA**

**THIRTY-FIRST REPORT OF THE SPECIAL MASTERS/TRUSTEES**

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

October 29, 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. Thirty-First Report of the Special Masters/Trustees
- B. Appendices to Court Report
  - 1. Schedule of Funding for the Settlement and Proposed Ongoing Budgets.
  - 2. Summary of Research.
  - 3. "Hit Report" regarding the Supervisory Panel's Website.
  - 4. Unaudited balance sheet as of August 31, 2009 and an unaudited statement of income and funds balance for the eight months ended August 31, 2009.
  - 5. Independent Auditors' Report for the year ended December 31, 2008.

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SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

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: **BOWLING-PFIZER LITIGATION** : **Judge Herman J. Weber,**  
: **Senior Judge**

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**THIRTY-FIRST 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 thirty-first periodic report, covering activities from April 16, 2009 to October 14, 2009. This report is submitted fifteen days prior to the status hearing before the Court scheduled for October 29, 2009.

**I. PATIENT BENEFIT FUND**

A. Supervisory Panel. The project entitled "Outlet strut vibratory response study of BSCC valves at disc-strut closure impact" being done by Dr. Jurgen de Hart of HemoLab Cardiovascular Engineering in The Netherlands has been completed and the panel is waiting on the submission of a final report.

The Court approved a six-month extension of the Hershey Imaging program on April 23, 2009. As of August 31, 2009 the balance of the funds remaining for this program was \$56,192.

On July 28, 2009, a meeting of the Trustees, all counsel, Wayne Smith and David Miller was conducted in Cincinnati. The purpose of the meeting was to consider the future of the Settlement. A review of pertinent data about the class was distributed to all participants in advance of the meeting.

The following is a summary of that data:

1. *Age and gender distribution of registered class members:* As of October 2, 2009 there are 7,045 registered class members believed to be living with BSCC heart valves still implanted (based upon records maintained by the Claims Administrator). These class members were divided into 3,736 males, 3,220 females, and 36 of unknown gender with another 53 class members whose date of birth is unknown. The aging of class members is evident as 84% of them are 60 years old and older, 63% are 70 years old and older, and 34% are 80 years old and older.
2. *Estimated number of living class members:* Applying the mortality experience of the US, UK, and the Dutch cohorts to all of the worldwide data, it is estimated that as of January 1, 2010, there will be between 9,600 and 12,300 patients living with 60° and somewhat less than 500 patients with 70° valves (based upon work of Dr. Bill Blot, panel consultant).
3. *The number of Outlet Strut Fracture (OSF) over time:* As of July, 2009 there were reported 662 OSF's; the first occurrence was in 1978 and the last was in November, 2006. The occurrence of OSF increased over time since 1978 to reach a peak in 1983 and has declined ever since (based upon data from the BSCC research database).
4. *The number of qualified SLS and valve replacement surgery claims over time:* From 1992 until the present, there were a total of 139 claims, divided into 39 qualified SLS claims and 100 qualified surgery claims processed through the Claims Administrator's office. The majority of the claims (60%) occurred by

or before 1995, and only 2 claims were received after 2003.

5. *The frequency of SLS:* Using data maintained by the manufacturer and the results of examinations for SLS in explanted valves, it was estimated that SLS is prevalent in 6.8% (4.1-9.4% confidence intervals) of the class members. Using the estimated range of class members reported in #2 above, this means we might expect somewhere between 393 and 1,156 patients worldwide to have the SLS condition in their valve. The mid-point in this range is 775 (based upon a published study conducted by Dr. Blot and others).
6. *Class members who qualify under the guidelines:* As of October 14, 2009, there are 108 class members believed to be living who qualify for surgical benefits under the guidelines, 82 males and 26 females. The majority of these class members (86%) are 40 to 70 years of age (based upon records maintained by the Claims Administrator).

During the meeting of July 28<sup>th</sup>, Class counsel, Special counsel and Public Citizen stated their position that it is unlikely that further research will result in a diagnostic test or other meaningful benefit to the class. They asserted that it was time for the Supervisory panel to consider Section 5.5 of the Settlement Agreement, which provides: *“If the Supervisory Panel at any time determines that any money remaining in the Patient Benefit Fund cannot productively be spent for the specific purposes set forth herein, including payment of benefits for valve replacement surgery, it may recommend to the Court that such remainder should therefore be devoted to some other purpose for the benefit of the Settlement Class (other than direct distribution to class members). Subject to the approval of the Court, the Panel shall then direct the disposition of the remainder of the Fund. At*

*such time, all of Shiley's and Pfizer's obligations under this section 5 shall cease, except to make any remaining unpaid required installments (up to a maximum of \$75 million) into the Patient Benefit Fund."*

The panel considered Section 5.5 and its future mission and has determined that it is time for active research to develop a diagnostic tool to stop, but that other activities of the panel should continue. One of the main issues the panel considered was the continuation of the work of ACES to develop a reliable diagnostic tool by conducting another series of clinical trials on patients using their testing technology. This was a close question for the panel to consider, but ultimately the panel decided that it is highly unlikely that enough class members would participate in the trials to make the results valid. More importantly, the panel did not think a sufficient number of those who did participate in the clinical trial would undergo explantation of their valve. This means the ACES testing method would not be validated with sufficient data.

The conclusion of research activities will not conclude all Panel activities. The Panel will continue to have a number of continuing responsibilities and will need funds to support those activities as well as other purposes set forth in Section 5 of the Settlement Agreement. Specifically, the Supervisory Panel recommends that the following functions continue to be funded from the Patient Benefit Fund:

- to set aside sufficient funds to pay for uninsured surgical claims as outlined in the Settlement Agreement;
- to provide for claims administration for the class;
- to continue its protocol of quarterly monitoring and surveillance of issues relating to the guidelines and its review of scientific literature relevant to the BSCC heart valve;
- to obtain an annual review of the BSCC research data base by its consultant;

- to obtain updated surgical mortality and morbidity statistics;
- to implement an amended version of the guidelines should the data support the need to do so;
- to provide notice to class members in the event that a diagnostic test is developed in the scientific community , and;
- to continue to maintain the website and document repository.

A budget and supporting documentation are attached as Appendix 1. Therefore, pursuant to Section 5.5 of the Settlement Agreement, the Supervisory Panel recommends that \$8,440,000 be devoted to some other purpose for the benefit of the Settlement Class. Pfizer had advised the Trustees that notwithstanding the language of Section 5.5, it will continue to be responsible for its obligations under Section 5 of the Settlement Agreement.

B. Guidelines. 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. Research. Our report on the status of the research program of the Supervisory Panel is set out in the attached Appendix 2.

D. Imaging. Since the imaging program at Penn State resumed again, effective April 26, 2005, there have been thirteen imaging sessions for seven implantees who may qualify for valve replacement surgery. Two implantees were imaged three times and two implantees were imaged two times during this period.

E. Repository. 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 Bowling 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.

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 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 3.

G. Valve Replacement Surgery Claims and Fracture Claims.

The Claims Administrator continues to receive and process claims for valve replacement surgery and outlet strut fracture. Some of the claimants have elected other courses of action rather than to receive the Settlement benefits.

Since the last Trustees' report there has been confirmation of one qualified valve replacement surgery that occurred on April 17, 2008. The amount of Hong Kong \$8,260 (\$1,145 US) was paid from the Patient Benefit Fund for the medical expense component of the benefits for this qualifying replacement surgery. The processing of this claim is still in process regarding the additional benefit(s) that may be available for the claimant and payable by Pfizer Inc.

From the beginning there have been 98 (74 foreign) qualified outlet strut fracture claims and 100 (40 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 August 31, 2009, the total balance of cash and cash equivalents was \$21,152,645.

Attached as Appendix 4 are the following: an unaudited balance sheet as of August 31, 2009 and an unaudited statement of income and funds balance for the eight months ended August 31, 2009 (which includes the budgeted amounts for expenses for the administrative office for the year ended December 31, 2009).

Attached as Appendix 5 is a copy of the Independent Auditors' Report for the year ended December 31, 2008.

## **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.

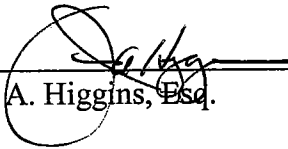
## **IV. APPROVALS**


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,

  
\_\_\_\_\_  
James A. Higgins, Esq.

  
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Peter J. Strauss, Esq.

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of this Thirty-First Report of the Special Master/Trustee Covering Period from April 16, 2009 to October 14, 2009, has been electronically sent to the following this 14th day of October, 2009.

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Nancy A. Lawson

**APPENDIX**

**1**

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

Funding for the Settlement

Estimated net balance of funds - December 31, 2009	<u>\$20,300,000</u>
Proposed budgets:	
Supervisory Panel	920,000
Medical expenses-valve replacement surgery claims	1,000,000
Administration expenses	9,940,000
	<hr/>
Total	<u>11,860,000</u>
Estimated balance available for other purposes	<u>\$ 8,440,000</u>

SCOPE OF AND ESTIMATED COSTS OF ACTIVITIES  
OF THE SUPERVISORY PANEL

The following table outlines the activities of the supervisory panel, the frequency of those activities and the estimated costs of each. In most cases, the costs are based on estimates of the amount of time panel members or consultants will need to complete the activity.

**The total amount requested is \$920,000.**

	2010	2011	2012	2013	2014	2015	Cost
Monitoring & Surveillance Protocol	4 times; \$30,000 per year	4 times; \$30,000 per year	4 times; \$30,000 per year	4 times; \$30,000 per year	4 times; \$30,000 per year	4 times; \$30,000 per year	\$180,000
Review of guideline Risk factors & BSCC Research database	1 time; \$4,000 per year	1 time; \$4,000 per year	1 time; \$4,000 per year	1 time; \$4,000 per year	1 time; \$4,000 per year	1 time; \$4,000 per year	\$24,000
Obtain Updated surgical Mortality & morbidity Data	1 time; \$8,000			1 time; \$10,000			\$18,000
Informal review of Guidelines by panel	1 time; \$20,000			1 time; \$20,000			\$40,000
Revise guidelines (if data supports need)				1 time; \$100,000			\$100,000
Distribute guidelines (if revision is made)				1 time; \$200,000			200,000
Provide notice of Diagnostic test to class (if developed)			1 time; \$25,000		1 time; \$25,000		\$50,000
Maintain website/ repository for 25 years							\$225,000
Cost per year	\$62,000	\$34,000	\$59,000	\$464,000	\$59,000	\$34,000	\$837,000

*Monitoring and surveillance protocol* is the quarterly monitoring of events occurring in the cohort and a comprehensive review of the scientific literature by Drs. Harrison, Ibrahim and Ivey, facilitated by David Miller. This ensures the panel is aware of any factors that may impact on the guidelines; any new research which may be important to the BSCC heart valve issue, and; any new scientific development that could be a diagnostic tool.

*Review of guideline risk factors & BSCC research database* is completed annually by our consultant, Bill Blot. This activity involves obtaining an updated version of the BSCC research database from Pfizer and having Blot review it and each of the risk factors contained in the guidelines to determine if the values assigned to any risk factor should be changed.

*Obtain updated surgical mortality & morbidity data* is contracting with the Society for Thoracic Surgeons to obtain the most current data on surgical risk to heart valve patients who undergo valve replacement surgery.

*Informal review of guidelines by panel* is the review of pertinent data by the panel to determine if the guidelines should be revised. These data include: surgical mortality and morbidity rates; Blot's review of the risk factors using the BSCC research database; the occurrence of outlet strut fractures and single leg fractures over time, and; the number of registered class members believed to be living by age grouping.

*Revise guidelines (if data supports need)* is self-explanatory. If the data supports the need for a guidelines revision this activity ensures there is funding for the panel to do so.

*Distribute guidelines (if revision is made)* provides funding for the actual distribution of revised guidelines should a revision occur.

*Provide notice of diagnostic test to class (if developed)* provides funding to provide notice to class members in the event the panel becomes aware of a diagnostic test or other important information the class members should know about.

*Maintain website for 25 years* provides funds to reimburse Dinsmore & Shohl for their costs to maintain the Bowling-Pfizer website and document repository. The current cost per year is \$7,000 and an increase of 2% per year for twenty-five years is included.

Contingency provision. Because the above scope of work and related budget figures are estimates it is necessary to add a contingency amount to allow for miscalculations or unforeseen circumstances. Also, because most of the work ends after 2015, this amount will cover possible additions to the website or the document repository. A contingency amount of 10% is recommended. Adding this contingency would increase the total to \$920,700. It is suggested this be rounded to \$920,000.

DEM

9/30/09 (rev. 10/7/09)

**Uninsured qualifying surgery claims cost estimate.**

The estimate for an amount to set aside to cover those portions of qualifying surgery claims which are uninsured is \$1,000,000.

Since January, 2001 there have been twelve qualifying surgical claims for which benefits have been paid. The range of payments is from \$1,000 to \$90,452. The wide difference in the range is due to the fact that the Settlement is only required to pay uninsured medical expenses. The last claim was settled in April, 2004, however there is one claim pending payment at this time. It appears that it will result in a claim of approximately \$1,000. The average claim over the nine year time span is \$32,861 and there is an average of 1.3 claims per year.

I looked at medical cost trends on the U. S. Department of Health and Human Services website to estimate recent hospital cost increases. The average annual increase in cost for the top six cardiovascular conditions for the most recent years reported (2003-2006) was 0.5% per year.

If one adds a 3% inflation factor (0.5% per year since 2001) to the average surgical claim figure, it yields an amount of \$33,846 as an adjusted average claim. If we then assume the same number of surgery claims per year over the next 20 years which is 1.3 per year we could expect 26 claims. Multiplying 26 claims times \$33,846 yields a total of \$879,996. However, we must add an inflation factor and since the surgery claims will occur over the 20 time period. Because these expected surgeries will likely occur over the entire time period, I chose to take 0.5% per year for 10 years, or a 5% increase. Doing so results in an amount of \$923,995

Because there are several assumptions used to build this figure, it seems reasonable to add an amount of at least 10% to serve as a cushion. Doing so results in an amount of \$1,016,395 which might be rounded to \$1,000,000.

DEM  
9-21-09

