

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
WESTERN DIVISION

IN RE: : Case No. C-1-91-256  
BOWLING-PFIZER LITIGATION : (Judge Spiegel)

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TWELFTH REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING PERIOD FROM DECEMBER 22, 1999 TO JUNE 27, 2000

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SPECIAL MASTERS/TRUSTEES

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

**AGENDA**

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

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

June 27, 2000  
11:00 A.M.

Hon. S. Arthur Spiegel

1. Introductory remarks by Judge Spiegel.
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 Spiegel.

TABLE OF CONTENTS

- A. Twelfth Report of the Special Masters/Trustees
  
- B. Appendices to Court Report
  - 1. Unaudited balance sheet as of April 30, 2000 and an unaudited statement of income and funds balance for the four months ended April 30, 2000.
  
  - 2. Unaudited balance sheet as of December 31, 1999 and an unaudited statement of income, benefit payments and funds balance for the year ended December 31, 1999.

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TWELFTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

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To the Honorable S. Arthur Spiegel, Judge, United States District Court:

Your Special Masters/Trustees respectfully present their twelfth periodic report, covering activities from December 22, 1999 to June 27, 2000.

**I. CONSULTATION FUND**

Although checks totaling in excess of \$470,000 have been reissued, there remain checks on the Consultation Fund issued to qualified claimants aggregating approximately \$900,000 that have not been negotiated and are outstanding. The total approved distributions were \$6,147 each for implantees and \$1,009 each for spouses of implantees resulting in a total amount of \$91,718,314 sent to claimants.

The Trustees continue to attempt to locate those claimants who have checks outstanding and unnegotiated, and to pay them. As previously reported the Trustees have obtained the assistance of heart valve registries (both U.S. and foreign), other foreign

governmental agencies, doctors and hospitals known to have assisted claimants in filing claims, researchers with claimant data and foreign legal counsel who have previously assisted Class Counsel in the Settlement proceedings. In addition, assistance has been provided by other legal representatives, relatives of claimants and a CD Rom directory. A major problem is that many of the claimants are deceased and their next of kin do not have the same mailing address. The Trustees will continue to utilize all reasonable means to locate these claimants or their beneficiaries.

## **II. PATIENT BENEFIT FUND**

A. Amended Guidelines. The *Amended Guidelines To Assess Patients With Bjork-Shiley Convexo-Concave Heart Valves For Elective Explantation* (herein 2000 Amended Guidelines) were adopted by the Court on March 8, 2000 (Document 1440). Procedures are in process to disseminate the Guidelines to the broadest extent possible, given the information available to the administrative team and the desires of foreign ministries. This has involved the preparation of appropriate letters to doctors and Class Members, the translation of the letters and the guidelines into twelve languages, and making arrangements with ministries and registries worldwide to inform their implantees. Drafts of the letters were sent to Class Counsel and Counsel for Defendants, for their comments.

In the March Order (Document 1440), the Court ordered the Trustees to provide to Class Counsel and Special Counsel materials

used in designing the 2000 Amended Guidelines. The Court further stated that Counsel may move the Court to reconsider its adoption of the 2000 Amended Guidelines. The Trustees and the Chairman of the Supervisory Panel have delivered, under a confidentiality agreement, the materials controlled by the Panel that were used in guideline design. The only item not delivered is the Shiley research database. It is owned by Defendant Pfizer and was used by the Panel under a confidentiality agreement. The delivery of that database depends on the existence of a protective order. Counsel for the two parties have not been able to agree on one, and the matter is now before the Court on Plaintiff's motion.

B. Research. The Supervisory Panel met in Cincinnati on June 1 and 2, 2000, to hear reports about current and proposed research programs. Class and Special Counsel and Counsel for Defendants were present during these presentations and had full opportunity to participate in the discussions about the reports.

There is an emphasis at this time on the use of acoustic techniques to detect high risk valves. Acoustic research is proceeding along two lines: passive acoustics, by which is meant the recording and analyzing of the sounds of a working valve without intervention of any nature; and active acoustics, by which is meant the creating of vibrations in a valve by one means or another and the recording and analyzing of the responses of the valve or its constituent parts.

Passive acoustic programs include the existing project at Lawrence Livermore National Laboratories, in which the attempt is

to find a method to record and analyze sounds in an anechoic chamber. This has been difficult and it is an unattained objective. Another passive acoustic research program has been proposed by Structural Acoustics, Inc., of which Dr. Allen C. Eberhardt is president, but Dr. Eberhardt's impartiality has been seriously questioned by Class and Special Counsel because he testified as an expert witness for Pfizer in BSCC heart valve litigation. Without going into the details of the unresolved controversy about Dr. Eberhardt's impartiality, the Trustees will not enter into a contract with Structural Acoustics, Inc. at this time, if ever.

Active acoustic research projects are using new methods of exciting the valve and its parts by external means. One method is electromagnetometry. Two researchers are at work in this field. Information Systems Laboratories (ISL) is one. ISL uses a coil to induce an electronic beam that can be directed at different parts of a working valve, including the outlet strut (the part that breaks). The other researcher is Vanderbilt University, working in conjunction with Iowa State University; this project uses an electromagnetic acoustic transponder that will be positioned by catheter. Neither researcher has brought its proposal to the place where it can be tested in vivo (in a human body).

Another active acoustic technique is the use of ultrasound specifically focused on the valve or any part of it. This is proposed by BioQuantetics, Inc., an organization taking over this line of research from California Institute of Technology. The

proposal includes cooperation with the Mayo Clinic. This method appears to hold promise, and BioQuantetics, Inc. will proceed with the first two phases of a six-phase research program. The practicality of using this technique in a human body will have to be validated.

The metallurgical research project at Edison Welding Institute has been completed. Valuable and interesting information about the welding process used in the manufacture of BSCC heart valves and its consequences has been obtained. The Panel has a clearer idea of the welds (which are, technically, fusions of metal parts) and the effect on adjoining metal. However, the project did not produce or suggest any method of identifying a high risk valve.

Epidemiology continues to be of highest value. The Epidemiology Subcommittee is calling an international workshop early this fall to consider what lessons from the past might give direction to future epidemiological research. In the meantime, the so-called merger of the three country cohort studies produced a consideration that needs immediate attention. The British and the Dutch studies of Shiley manufacturing records identified a test used in the manufacturing process that clearly appears to be directly related to outlet strut fractures (OSFs). The outlet strut has a bend in its apex that is called "the hook." The test in question placed a weight on the hook to determine how much, if at all, the strut was deflected. Even though for a limited period of time, manufacturing procedures called for one such test per valve, some valves were subjected to two or more hook deflection tests

(HDTs). The Dutch and UK researchers found this connection between multiple HDTs and OSFs appeared to increase the risk of OSF six to eight times. Only a total of 8 OSFs in both cohorts were related to multiple HDTs, a figure too small for any final conclusion. The Panel has approved a pilot study of Shiley's manufacturing records in order to establish the validity of the hypothesis and of the need for a study of all manufacturing records during that period during which HDTs were performed (May 1980 to February 1982).

Three Dutch research studies continue.

C. Independent Reviews of Research. At the June meeting, the Supervisory Panel received reports from the two organizations that have reviewed the Panel's research. Battelle Institute presented its final report, which is based on the research actually performed by Shiley/Pfizer or the Panel. The report from the Health Policy Institute of the University of Cincinnati was not final. This organization is examining the reports of all pertinent research whether conducted by Shiley/Pfizer or the Panel or others. The scope of their investigation includes more than 1,100 papers beyond those created by Shiley/Pfizer or Panel research. Their final report will be ready in November, in time for consideration before the presumed date of the Trustees' next report to the Court.

D. Imaging Test. After an extraordinary amount of time pursuing administrative procedures, the program to offer an imaging test of Class Members' valves at the Hershey Institute of Penn State has been placed in operation. That program is now available to all Class Members as an option. For those implantees who

qualify for replacement surgery benefits under the 2000 Amended Guidelines, the costs of taking the test (including transportation, housing, imaging and reports) will be paid from the Patient Benefit Fund. Those who do not qualify must pay those costs, including \$2,250 for the imaging test and the reports.

E. Repository. The Repository is being established. The Chairman has assembled most of the documents that will go into the Repository. A search is being conducted to find an employee to catalogue and index this material, to place it in electronic form with adequate backup, and to manage the whole operation. Further report will be made about the Repository.

F. Valve Replacement Surgery Claims and Fracture Claims. The Claims Administrator has received 458 claims for valve replacement surgery and outlet strut fracture claims. The processing of many of these claims had been initiated by Shiley in the interim period from the date of the Settlement Agreement until the Claims Administrator was appointed. In addition, other qualified claims were settled by Shiley with the Settlement benefits during this interim period.

Of the above 458 claims, there are 73 (58 foreign) qualified outlet strut fracture claims, 36 (15 foreign) qualified single leg fracture claims and 58 (22 foreign) qualified valve replacement surgery claims. Some of the claimants have elected other courses of action rather than to receive the Settlement benefits. The remaining claims have been reviewed and they either do not qualify or additional information is needed and has been requested from the

claimants.

The office of the Claims Administrator has commenced to fulfill requests to calculate estimated annual fracture rates under the 2000 Amended Guidelines. In addition, a review of the valve replacement surgery claims and the Consultation Fund claims is being conducted in order to identify those implantees who may qualify for valve replacement surgery benefits under the 2000 Amended Guidelines.

### III. FINANCIAL INFORMATION

At April 30, 2000, the total balance of cash and cash equivalents was \$17,836,833. This amount takes into account net interest earned from January 28, 1992 through April 30, 2000, in the aggregate amount of \$21,045,058.

Attached as Appendix 1 are the following: an unaudited balance sheet as of April 30, 2000 and an unaudited statement of income and funds balance for the four months ended April 30, 2000 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 2000 through December 31, 2000).

Attached as Appendix 2 are the following: an unaudited balance sheet as of December 31, 1999 and an unaudited statement of income, benefit payments and funds balance for the year ended December 31, 1999 (which includes the budgeted amounts for expenses for the administrative office for the year ended December 31, 1999).

**IV. COMMUNICATIONS**

There is daily contact with Class Members about a variety of their concerns. The Claims Administrator, the Chairman of the Supervisory Panel and the Trustees have met with Class Counsel throughout the period.

**V. APPROVALS**

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

- (a) approve this report, and
- (b) approve or provide direction with respect to each of the Appendices to this Report, and
- (c) fix the date of the next Report.

Respectfully submitted,

Dated: June 27, 2000

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Hon. Robert L. Black, Jr.

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Peter J. Strauss, Esq.

**TRUSTEES FOR THE BOWLING-PFIZER**  
**HEART VALVE SETTLEMENT FUNDS**

**BALANCE SHEET**

**AS OF APRIL 30, 2000**

**UNAUDITED**

**ASSETS**

CASH	\$ 313,801
U.S. TREASURY BILLS (Par Value \$17,803,000)	17,523,032
OTHER ASSETS	<u>19,854</u>
	<u>\$ 17,856,687</u>

**LIABILITIES AND FUNDS BALANCE**

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 825,962(1)
FUNDS BALANCE	<u>17,030,725</u>
	<u>\$ 17,856,687</u>

- (1) - Does not include any provision for fees and expenses relating to applications filed with the Court in November 1999 by Class Counsel and Special Counsel and Public Citizen, Inc. that basically covered the period October 1998 - October 1999.

TRUSTEES FOR THE BOWLING-PFIZER  
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME AND FUNDS BALANCE

FOR THE FOUR MONTHS ENDED APRIL 30, 2000

UNAUDITED

INCOME - INVESTMENT INTEREST	\$ 341,930
RESEARCH PROGRAMS - COSTS	<u>634,504</u>
EXPENSES:	
Supervisory Panel	319,357 (1)
Trustees' fees and expenses	103,575
Professional fees	12,070
Administrative office	<u>140,452 (1)</u>
Total	<u>575,454</u>
NET CHANGE IN FUNDS BALANCE	(868,028) (2)
FUNDS BALANCE, DECEMBER 31, 1999	<u>17,898,753</u>
FUNDS BALANCE, APRIL 30, 2000	<u>\$ 17,030,725</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>1/1/00-12/31/00</u>	<u>1/1/00- 4/30/00</u>
<b>SUPERVISORY PANEL:</b>		
Panel members' compensation		\$ 213,060
Consultants' compensation		87,238
Travel expenses		17,210
Miscellaneous		<u>1,849</u>
Total		<u>\$ 319,357</u>
 <b>ADMINISTRATIVE OFFICE:</b>		
Rents	\$ 67,000	\$ 16,447
Office payroll	318,000	97,358
Payroll taxes	18,000	7,672
Employee benefits	24,000	6,559
Outside services	60,000	10,946
Printing and postage	12,000	1,236
General insurance	3,000	
Telephone	18,000	2,125
Office supplies and expense	12,000	1,503
Travel	6,000	
Depreciation	6,000	1,817
Miscellaneous	6,000	162
Administrative services income		<u>(5,373)</u>
Total	<u>\$ 550,000</u>	<u>\$ 140,452</u>

**TRUSTEES FOR THE BOWLING-PFIZER**  
**HEART VALVE SETTLEMENT FUNDS**

**BALANCE SHEET**

**AS OF DECEMBER 31, 1999**

**UNAUDITED**

**ASSETS**

CASH	\$ 255,734
U.S. TREASURY BILLS (Par Value \$18,703,000)	18,468,400
OTHER ASSETS	<u>21,672</u>
	<u>\$ 18,745,806</u>

**LIABILITIES AND FUNDS BALANCE**

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 847,053(1)
FUNDS BALANCE	<u>17,898,753</u>
	<u>\$ 18,745,806</u>

- (1) - Does not include any provision for fees and expenses relating to applications filed with the Court in November 1999 by Class Counsel and Special Counsel and Public Citizen, Inc. that basically covered the period October 1998 - October 1999.

TRUSTEES FOR THE BOWLING-PFIZER  
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME, BENEFIT PAYMENTS AND FUNDS BALANCE

FOR THE YEAR ENDED DECEMBER 31, 1999

UNAUDITED

INCOME - INVESTMENT INTEREST	<u>\$ 798,421</u>
BENEFIT PAYMENTS - VALVE REPLACEMENT SURGERY	<u>199,565</u>
RESEARCH PROGRAMS - COSTS	<u>1,828,430</u>
LITIGATION ATTORNEYS - FEES & EXPENSES	<u>987,322</u>
EXPENSES:	
Supervisory Panel	1,451,561 (1)
Trustees' fees and expenses	169,091
Professional fees	75,647
Administrative office	<u>422,122 (1)</u>
Total	<u>2,118,421</u>
CONTRIBUTION BY SHILEY INCORPORATED	<u>6,250,000</u>
NET CHANGE IN FUNDS BALANCE	1,914,683 (2)
FUNDS BALANCE, DECEMBER 31, 1998	<u>15,984,070</u>
FUNDS BALANCE, DECEMBER 31, 1999	<u>\$ 17,898,753</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>1/1/99-12/31/99</u>	<u>1/1/99-12/31/99</u>
<b>SUPERVISORY PANEL:</b>		
Panel members' compensation		\$ 671,940
Consultants' compensation		564,622
Travel expenses		201,732
Miscellaneous		<u>13,267</u>
Total		<u>\$ 1,451,561</u>
 <b>ADMINISTRATIVE OFFICE:</b>		
Rents	\$ 67,000	\$ 64,138
Office payroll	298,000	295,836
Payroll taxes	18,000	16,087
Employee benefits	21,000	21,579
Outside services	72,000	22,792
Printing and postage	36,000	5,460
General insurance	3,000	1,028
Telephone	24,000	13,699
Office supplies and expense	12,000	3,025
Travel	6,000	
Depreciation	7,000	5,452
Miscellaneous	12,000	806
Administrative services income		<u>(27,780)</u>
Total	<u>\$ 576,000</u>	<u>\$ 422,122</u>