

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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

TENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES
COVERING PERIOD FROM DECEMBER 16, 1998 TO JUNE 18, 1999

SPECIAL MASTERS/TRUSTEES

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

AGENDA

TENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

June 18, 1999
10:30 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.

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- A. Tenth Report of the Special Masters/Trustees

- B. Appendices to Court Report
 - 1. Unaudited balance sheet as of April 30, 1999 and an unaudited statement of income and funds balance for the four months ended April 30, 1999.

 - 2. Unaudited balance sheet as of December 31, 1998 and an unaudited statement of income, benefit payments and funds balance for the year ended December 31, 1998.

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IN RE: : Case No. C-1-91-256
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TENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

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

Your Special Masters/Trustees respectfully present their tenth periodic report, covering activities from December 16, 1998 to June 18, 1999.

I. CONSULTATION FUND

As previously reported, under Section 6 of the Settlement Agreement, the Consultation Fund, initially \$80,000,000, is intended to provide Claimants with funds to obtain medical and psychological consultation as they deem best. It is to be divided equally among Claimants after paying or providing for fees and expenses to be paid out of this Fund. In addition, a \$10,000,000 fund was established to be paid, after fees and expenses, equally among all Claimants who are spouses of Class Members.

As previously reported, final distributions have been approved and sent to each qualified implantee and spousal claimant. The Consultation Fund has been closed as of August 31, 1998. Checks on

the Consultation Fund issued to qualified claimants aggregating more than \$1,000,000 have not been negotiated and are outstanding. The Trustees continue to attempt to locate those claimants who have checks outstanding and unnegotiated, and to pay them. Although progress has been made with some of the previously reported unnegotiated checks, there are now additional unnegotiated checks resulting from the final distributions. A comprehensive report regarding this issue will be presented at the next report of the Trustees.

II. PATIENT BENEFIT FUND

A. Supervisory Panel Meeting. The Supervisory Panel met on Tuesday, June 8, 1999, with Class Counsel, Counsel for Defendants, Counsel for Public Citizen, the Panel's consultants, the principal investigators of the cohort studies in The Netherlands and the United Kingdom, and a representative of UK's Medical Device Agency. The focus of the full day meeting was the 1997 Guidelines and their prospective improvement. Class Counsel presented five resolutions about the Guidelines, and these were discussed at length. In addition, all persons present engaged in open and frank discussion of the several issues that were raised about the Guidelines. It is fair to say that every one had full opportunity to speak and that the communication was positive. Counsel also had an opportunity to present their views at the Supervisory Panel meeting on March 9, 1999.

B. Dissemination of 1997 Guidelines. The Claims Administrator has identified 174 Class Members qualifying for surgical benefits of their BSCC valves under the new 1997 Guidelines (whose valves have not already been explanted). Sixty-seven of these are U.S. residents, and the Court has already approved the letters that inform their physicians of this qualification so that the patient can decide in consultation with his or her doctor whether to have the valve replaced. Four of these sixty-seven implantees have had their BSCC valves replaced. In addition to those sixty-seven implantees, there are twenty-one who meet the qualifications under the Shiley guidelines (1995) that were incorporated in the 1997 Guidelines, and a mailing has been sent to all of them, using the same method as was used with all the other qualifiers. The Supervisory Panel and the Claims Administrator do not intrude on the intimate personal relationship between the patient and his or her doctor.

There are 107 foreign Class Members identified by the Claims Administrator as qualifying for valve replacement benefits under the 1997 Guidelines, but an Australian implantee has since had his valve replaced. They are located in 22 different countries. The Trustees recommend to the Court that the Chairman of the Supervisory Panel and the Claims Administrator use the same methods of communication that were used in the U.S.A. to send out information about the 1997 Guidelines in order to advise these 106 foreign Class Members of their options. The Chairman of the Supervisory Panel has been told many times and with great emphasis

that direct communication with patients (implantees) is prohibited in Australia, Canada, France, the Netherlands, Sweden, and the United Kingdom. The medical authorities in those countries believe that information about heart valves and other matters of personal health must be communicated by the treating physician, not by third parties. This will mean that no direct communication will be made to those who reside in those countries. The established lines of communication will be used. The Chairman of the Supervisory Panel and the Claims Administrator are prepared to do that immediately.

C. Research. The Supervisory Panel's research program continues along the several lines previously reported as well as along some new lines. The search continues for a reliable diagnostic technique to detect and identify high risk valves. Delays have been encountered by reason of the necessity to negotiate research contracts with some institutions, particularly those of higher learning. The sticking points have been ownership of new techniques and discoveries, publication rights and procedures, and confidentiality of data supplied to the researcher by the Supervisory Panel. One example is the contract with Vanderbilt University for investigation into a new, noninvasive way to identify a break in one leg of the outlet strut by electromagnetic technique. Considerable time was expended in order to make clear to the people at Vanderbilt University that the economic benefit of inventions and discoveries must belong to the Class, that the Supervisory Panel must review all publications, and that data it supplies must be kept confidential.

The data being developed by the epidemiological projects is being merged for the purpose of improving the reliability of the data that constitutes the foundation of the 1997 Guidelines. No technique has been discovered that will identify specific valves with high risk of fracture, and the Panel has relied on epidemiological studies. Three studies are underway, being those in The Netherlands, the UK and Medic Alert in the U.S. The first two studies are examining Shiley's manufacturing records, and all three are using standard epidemiological methods. The data developed by all three will be merged by the middle of August 1999, in preparation for a meeting of the Supervisory Panel in September 1999, the purpose of which will be to consider refinements and improvements of the Panel's Guidelines, if any.

The cooperation of the Dutch and British researchers has been exemplary. They have come together with American researchers in London for meetings in October 1998 and May 1999 to coordinate their work for the purposes of refining the epidemiological data and making it as accurate as scientific methods can provide. Dr. Yolanda van der Graaf of The Netherlands has already delivered to the Chairman of the Supervisory Panel a disk containing the Dutch data. This willingness to share scientific findings across national lines should be acknowledged with appreciation.

The Supervisory Panel is sponsoring a follow-up study of the implantees who participated in the imaging studies previously conducted at Beaumont, Stanford and Glasgow. The study was conducted by mailing an extensive questionnaire covering a range of

items related to the experiences of the implantees since the imaging was completed. A concerted effort was made to elicit replies, and there is now a 75% response. The answers to the questionnaires are now being tabulated for the Panel's consideration.

As to acoustic research, a meeting was held in Cincinnati on June 3, 1999 of investigators and support personnel from Lawrence Livermore National Laboratories, ERI and Vanderbilt University. The purpose of this meeting was to review and discuss acoustic projects being conducted, coordinate the work, refine the efforts, and give direction to the ongoing research. The project at Vanderbilt University, a new one, will search into an area indicated by the title of the project, which is "Electromagnetic and Acoustic Techniques for Non-Invasive Detection and Catheter-Based Confirmation of Outlet Strut Fracture in the Bjork-Shiley Heart Valve." The negotiation for this work is in process of completion, being complicated by the fact that the principal investigator desires to use techniques developed at and owned by Iowa State University. Officials at that university have raised questions about contract provisions. Negotiations continue.

Three studies are under way to review the rate of operative mortality after surgical replacement of a BSCC valve, under the guidance of Dr. Tom Ivey. In addition to his own study, Drs. Scott Page and Eugene Blackstone are at work on different aspects of this item. The point is to determine whether the rate of operative mortality used in the 1997 Guidelines can be confirmed or must be

changed.

The Supervisory Panel has approved three proposals to investigate different methods of detecting a single leg fracture or break in the outlet strut of a BSCC valve. One of these originated with Dr. van der Graaf of The Netherlands; it is designed to research the possibility of detecting a single leg break by MRI scanning of the brain to find paramagnetic defects. The study will commence in September 1999.

Edison Welding of Columbus is under contract to bring practical metallurgical experience to bear on the cause or causes of failure of the weld or fusion of the outlet strut of a BSCC valve. Their work will be coordinated with Dr. Pat Lawford of the University of Sheffield (UK), who has extensive experience in this field.

The third project is at the California Institute of Technology, which is under contract to investigate the application of Doppler ultrasound for diagnostics of outlet strut resonance of a single leg fracture in a BSCC valve.

D. Imaging Tests. The Supervisory Panel continues to look for an institution to carry out two imaging programs. One is for implantees with valves that have been identified as high risk valves under the 1997 Guidelines. The other program is to make imaging available for all other implantees, at their cost. Negotiations with Stanford University, which did one of the original three imaging studies, were canceled due to circumstances unacceptable to the Panel. Negotiations are now proceeding with

Penn State to do these two programs. In addition, Massachusetts General Hospital has indicated an interest in discussing this work, since the principal investigator who ran the imaging program at Stanford is now at Mass General.

E. Independent Review of Research. A contract has been negotiated with the Institute for Health Policy and Health Services Research at the University of Cincinnati to make an independent review of all the research carried on to date about the BSCC heart valve, the risks of strut fracture, and the rate of operative mortality, whether sponsored by Pfizer/Shiley or by the Panel. The Chairman of the Panel is seeking another organization to supplement the work of the UC Institute.

F. Repository. There is a great deal of work to be done before the Repository will be in place and operative. The Court has approved the repository document adopted by the Panel in March 1999, but that is not the end of the matter. That document was very general in its description of the contents of the Repository. It did not include those manufacturing records known as abbreviated Device History Records (DHRs). At the March 1999 meeting of the Supervisory Panel, Class and Special Counsel proposed to include DHRs, and Counsel for Defendants opposed that idea. The Supervisory Panel, after full consideration, decided that it did not wish to have the DHRs included in the Repository, but in the interest of fairness, the Panel voted to request the Court to order the Defendants to keep all manufacturing records (including abbreviated DHRs) until the termination of the Patient Benefit

Fund, and in the meantime, to make the same available to the Panel for research purposes, and to physicians for medical purposes for individual Class Members upon signed authorization of the Class Member. The Panel's position is more fully set out in the Trustees' Motion For An Order To The Defendants To Maintain All BSCC Heart Valve Manufacturing Records Until the Disposition Of The Patient Benefit Fund, Making Them Available For Research And Medical Purposes. The contents of the Repository cannot be determined until the resolution of this difference of opinion.

Further, the Chairman of the Panel must consult with Class Counsel and Counsel for Defendants about removing the confidential classification of specific documents and data. There is a considerable volume of material in the Supervisory Panel's office in California that accumulated under the supervision of the (now dissolved) Research Management Group that has to be catalogued, indexed and scanned.

G. Valve Replacement Surgery Claims and Fracture Claims. The Claims Administrator has received 424 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 424 claims, there are 68 qualified outlet strut fracture claims, ³⁵54 qualified single leg fracture claims and ⁵⁴35

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 continues to fulfill requests to calculate estimated annual fracture rates under the 1997 Guidelines. A review of the valve replacement surgery claims and the Consultation Fund claims shows that there have been identified 226 implantees who may qualify for valve replacement surgery benefits under those Guidelines. Of these implantees, 57 have had their BSCC heart valves explanted, including 10 whose valve replacements occurred after the 1997 Guidelines were approved and 4 whose prior valve replacements also qualified under the 1997 Guidelines.

III. FINANCIAL INFORMATION

At April 30, 1999, the total balance of cash and cash equivalents was \$15,252,524. This amount includes net interest earned from January 28, 1992 through April 30, 1999, in the aggregate amount of \$20,152,063.

Attached as Appendix 1 are the following: an unaudited balance sheet as of April 30, 1999 and an unaudited statement of income and funds balance for the four months ended April 30, 1999 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 1999 through December 31, 1999).

Attached as Appendix 2 are the following: an unaudited balance sheet as of December 31, 1998 and an unaudited statement of income, benefit payments and funds balance for the year ended December 31, 1998 (which includes the budgeted amounts for expenses for the administrative office for the year ended December 31, 1998).

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' office are also in contact with Class Counsel and Counsel for Defendants.

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 18, 1999

Hon. Robert L. Black, Jr.

Peter J. Strauss, Esq.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF APRIL 30, 1999

UNAUDITED

ASSETS

CASH	\$ 308,422
U.S. TREASURY BILLS (Par Value \$15,042,000)	14,944,102
OTHER ASSETS	<u>25,396</u>
	<u>\$ 15,277,920</u>

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 956,258(1)
FUNDS BALANCE	<u>14,321,662</u>
	<u>\$ 15,277,920</u>

- (1) - Does not include any provision for fees and expenses relating to applications filed with the Court in November 1998 by Class Counsel and Special Counsel and Public Citizen, Inc. that basically covered the period October 1997 - October 1998.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME AND FUNDS BALANCE
FOR THE FOUR MONTHS ENDED APRIL 30, 1999

UNAUDITED

INCOME - INVESTMENT INTEREST	\$ <u>247,356</u>
RESEARCH PROGRAMS - COSTS	<u>497,157</u>
LITIGATION ATTORNEYS - FEES & EXPENSES	<u>791,175</u> (1)
EXPENSES:	
Supervisory Panel (2)	400,230
Trustees' fees and expenses	54,650
Professional fees	26,569
Administrative office (2)	<u>141,483</u>
Total	<u>622,932</u>
NET CHANGE IN FUNDS BALANCE	(1,663,908) (1)
FUNDS BALANCE, DECEMBER 31, 1998	<u>15,985,570</u>
FUNDS BALANCE, APRIL 30, 1999	<u>\$ 14,321,662</u>

- (1) - See note (1) on Balance Sheet herewith.
(2) - See Schedule 1 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- 4/30/99</u>
SUPERVISORY PANEL:		
Panel members' compensation		\$ 183,540
Consultants' compensation		155,764
Travel expenses		57,474
Miscellaneous		<u>3,452</u>
Total		<u>\$ 400,230</u>
 ADMINISTRATIVE OFFICE:		
Rents	\$ 67,000	\$ 19,822
Office payroll	298,000	90,948
Payroll taxes	18,000	7,371
Employee benefits	21,000	6,267
Outside services	72,000	4,870
Printing and postage	36,000	422
General insurance	3,000	1,328
Telephone	24,000	7,317
Office supplies and expense	12,000	1,014
Travel	6,000	
Depreciation	7,000	1,817
Miscellaneous	<u>12,000</u>	<u>307</u>
Total	<u>\$ 576,000</u>	<u>\$ 141,483</u>

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF DECEMBER 31, 1998

UNAUDITED

ASSETS

CASH	\$ 209,949
U.S. TREASURY BILLS (Par Value \$16,842,000)	16,677,092
OTHER ASSETS	<u>27,489</u>
	<u>\$ 16,914,530</u>

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 928,960(1)
FUNDS BALANCE	<u>15,985,570</u>
	<u>\$ 16,914,530</u>

- (1) - Does not include any provision for fees and expenses relating to applications filed with the Court in November 1998 by Class Counsel and Special Counsel and Public Citizen, Inc. that basically covered the period October 1997 - October 1998.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME, BENEFIT PAYMENTS AND FUNDS BALANCE

FOR THE YEAR ENDED DECEMBER 31, 1998

UNAUDITED

INCOME - INVESTMENT INTEREST	<u>\$ 884,672</u>
BENEFIT PAYMENTS:	
Consultation Fund:	
Implantees	4,194,375
Spouses	<u>451,385</u>
Total	4,645,760
Patient Benefit Fund:	
Valve Replacement Surgery	<u>29,152</u>
Total	<u>4,674,912</u>
RESEARCH PROGRAMS - COSTS	<u>1,315,031</u>
EXPENSES:	
Supervisory Panel (1)	1,323,435
Trustees' fees and expenses	142,165
Professional fees	53,387
Administrative office (1)	<u>433,864</u>
Total	<u>1,952,851</u>
CONTRIBUTION BY SHILEY INCORPORATED	<u>6,250,000</u>
NET CHANGE IN FUNDS BALANCE	(808,122) (2)
FUNDS BALANCE, DECEMBER 31, 1997	<u>16,793,692</u>
FUNDS BALANCE, DECEMBER 31, 1998	<u><u>\$ 15,985,570</u></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>1/1/98-12/31/98</u>	<u>1/1/98-12/31/98</u>
SUPERVISORY PANEL:		
Panel members' compensation		\$ 643,304
Consultants' compensation		353,885
Travel expenses		147,470
Miscellaneous		18,603
Notification expenses		<u>160,173</u>
Total		<u>\$ 1,323,435</u>
 ADMINISTRATIVE OFFICE:		
Rents	\$ 54,000	\$ 48,205
Office payroll	298,000	276,644
Payroll taxes	18,000	15,238
Employee benefits	18,000	18,740
Outside services	96,000	24,615
Printing and postage	48,000	28,108
General insurance	3,000	823
Telephone	24,000	12,474
Office supplies and expense	12,000	2,029
Travel	6,000	
Depreciation	4,000	5,714
Miscellaneous	<u>12,000</u>	<u>1,274</u>
Total	<u>\$ 593,000</u>	<u>\$ 433,864</u>