

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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

SECOND REPORT OF THE SPECIAL MASTERS/TRUSTEES
COVERING PERIOD FROM FEBRUARY 28, 1995 TO JULY 6, 1995

SPECIAL MASTERS/TRUSTEES

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

AGENDA

SECOND REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

July 6, 1995
2:00 P.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. Second Report of the Special Masters/Trustees
- B. Appendices to Court Report
 - 1. Schedule of Status of Consultation Fund Claims Received.
 - 2. Combined unaudited balance sheet as of May 31, 1995 and an unaudited statement of income, benefit payments and funds balance for the five months ended December 31, 1995 for the Consultation Fund and the Patient Benefit Fund.

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

SECOND REPORT OF THE SPECIAL MASTERS/TRUSTEES

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

Your Special Masters/Trustees respectfully present their second periodic report, covering activities from February 28, 1995 to July 6, 1995.

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.

On November 25, 1994 the Court ordered the Special Masters/Trustees to hold in reserve at least twenty-five percent (25%) of the Consultation Fund for the purposes of future payment of attorney's fees and expenses to Class Counsel. The Trustees determined that the initial payments to those claimants who filed a claim form on or before October 31, 1994 would be \$1,500.00 to qualified implantees and \$250.00 to qualified spouses.

The Trustees received 9,860 claims for the Consultation Fund on or before October 31, 1994, and 1,342 claims have been received since then. As of June 26, 1995, substantially all claims received as of October 31, 1994 that were complete have been processed by the Trustees' Office, with 7,053 claims being approved and 1,034 denied. There have been 6,851 payments to implantees totalling \$10,276,500 and 4,757 payments to spouses totalling \$1,189,250. A schedule relating to the claims is appended as Appendix 1.

The Trustees mailed a reminder to approximately 7,600 persons who had not returned a Consultation Fund claim form whose names were in the database of potential Class Members that had been received from Class Counsel. This is the database that was used for the initial mailing of the notice and proof of claim form. Due to some difficulty in merging this database with the database for claims received, some persons who had already filed claims received the second mailing. As the result of this mailing, approximately 800 additional claims were received.

The Trustees desire that as many Class Members as possible participate in the benefits provided by the Settlement Agreement. They are concerned that the number of claims received for the Consultation Fund is not greater. As a result, the Trustees hereby request that the Court extend the deadline from July 1, 1995 to December 31, 1995 for filing Consultation Fund claims in order that more Class Members have the opportunity to participate in the Fund. Class Counsel and Counsel for Defendants have been advised of this request.

If the filing deadline is extended, the Trustees propose that a second payment be made to those claimants who filed their claim on or before October 31, 1994 and that an initial payment would be made to those claimants who filed their claim between November 1, 1994 and July 1, 1995 that would be equal to the two payments to those who filed their claim by October 31, 1994. These payments would be made as soon as practical after the approval of the extension of the deadline.

After the total number of eligible claimants is known and after providing for those fees and expenses that are directed by the Court to be paid out of the Consultation Fund, the final distribution will be made. The balance in the class member portion of the Consultation Fund (after providing for fees and expenses) will be divided so that all eligible class member claimants shall have been paid equally. Likewise, the balance in the spousal

portion of the Consultation Fund (after providing for fees and expenses) will be divided so that all eligible spousal claimants shall have been paid equally.

II. PATIENT BENEFIT FUND

Under Section 5 of the Settlement Agreement, the Patient Benefit Fund was established for the following purposes, briefly stated: to conduct research on the diagnosis of the risks of strut fracture and the risks of surgical replacement of valves, to establish guidelines for diagnosis and valve replacement, and to reimburse Class Members for the expenses of diagnosis and valve replacement that comply with the guidelines.

A. Supervisory Panel. As previously reported, the Supervisory Panel decided to fund the following initial research projects: (a) the second phase of a cohort study of implantees in the Netherlands; (b) a cohort study for implantees in the UK; (c) a program of aortic valve imaging at Glasgow; (d) an opportunistic program at Glasgow; (e) an initial valve imaging program at Stanford; and (f) to seek a modified proposal for a "feinfocus" x-ray study at Hershey. The proposals and budgets for these research projects are currently under financial and contractual review and will be presented for approval of the Court when these processes are satisfactorily completed. Agreement has been reached for the cohort studies in the Netherlands (except that some budgetary issues remain), for the UK, and for the modified study at Hershey. Negotiations continue for the imaging studies at Glasgow and Stanford. Also, several other proposals for services that are

necessary to support these primary research projects are under financial and contractual review.

Every contract for research and for support services will be presented to the Court for approval and will not be effective until approved.

The Supervisory Panel met on March 30, 31 and April 1, 1995 in Cincinnati since the last report to the Court and have conferred by telephone as needed. In addition, there have been meetings of the Panel's subcommittees. The Supervisory Panel has been diligently exploring other potential research projects.

On June 19, 1995 J. Kermit Smith and Dr. Donald C. Harrison met with representatives of RWTH KLINIKUM in Aachen, Germany. The RWTH group had recently commenced imaging patients with the "feinfocus" equipment and to date seven patients have been imaged, with the studies being supported by Shiley Incorporated. Messrs. Smith and Harrison were highly impressed with the people, equipment and the facility and believe that Aachen should become a clinical study site in Europe similar to Stanford and Glasgow. The Supervisory Panel had deferred taking over this study program from Shiley Incorporated due to difficulties initially encountered with the "feinfocus" equipment and ECG gating; however, these problems now seem to be resolved. The Supervisory Panel will give further consideration to this program.

B. Guidelines Committee. The nine persons selected by the Supervisory Panel, recommended by the Trustees and approved by the Court to serve on the Guidelines Committee to consider and

recommend to the Supervisory Panel guidelines for the use of diagnostic techniques and for replacement surgery have agreed to serve on the Committee. The first meeting of the newly formed Guidelines Committee will be held on July 7 and 8, 1995 in Dallas, Texas.

C. Valve Replacement Surgery Claims and Fracture Claims. The issue that was addressed after the last report to the Court regarding the motion for interpretation of the Settlement Agreement to clarify benefits available for a person whose valve has suffered a single leg fracture has not yet been resolved. On March 29, 1995 the Court appointed J. Kermit Smith as Special Master to assist in resolving this issue between Class Counsel and Counsel for Defendants. This process has not been concluded.

The Claims Administrator has been processing claims for valve replacement surgery and fracture claims. However, certain valve replacement surgery claims involving a patient's valve which had suffered a single leg fracture cannot be finalized until the benefits issue for these valves is resolved.

III. FINANCIAL INFORMATION

At May 31, 1995, the total balance of cash and cash equivalents was \$85,938,456 for the Consultation Fund (class member portion and spousal portion) and \$11,705,590 for the Patient Benefit Fund. These amounts include net interest earned from January 28, 1992 through May 31, 1995, in the aggregate amount of \$10,988,164 for the Consultation Fund and \$385,582 for the Patient

Benefit Fund. A combined unaudited balance sheet as of May 31, 1995 and an unaudited statement of income, benefit payments and funds balance for the period ended May 31, 1995 is attached as Appendix 2.

The expenses of the Supervisory Panel, the Trustees' compensation and expenses and the professional fees have been, or will be (for accrued items), approved by the Court. The expenses of the Research Management Group (RMG) commenced on April 1, 1995. The Trustees hereby request that the Court approve the expenses for the RMG presented on Schedule 1 of Appendix 2. The expenses relating to rents and the compensation and benefits concerning the research managers have previously been approved by the Court. A budget for the RMG will be submitted for approval by the Court for expenses subsequent to May 31, 1995. The expenses of the Administrative Office are within the budgeted amounts previously approved by the Court.

IV. COMMUNICATIONS

The pamphlet or brochure to be prepared by Class Counsel and Counsel for Defendants that will inform Class Members about their rights and benefits under the Settlement Agreement cannot be completed until the single leg fracture issue is resolved. When ready, it will be sent to all physicians, medical associations and officials, hospitals, and patients known to Counsel or to the Special Masters/Trustees.

V. APPROVALS

Your honor, the Trustees request that the Court approve this Report and the actions specifically referred to herein, and approve or provide further direction with respect to each of the Appendices to this Report.

Respectfully submitted,

Dated: July 6, 1995

Hon. Robert L. Black, Jr.

Peter J. Strauss, Esq.

TRUSTEES FOR THE BOWLING PFIZER HEART VALVE SETTLEMENT FUNDS

STATUS OF CONSULTATION FUND CLAIMS AS OF JUNE 26, 1995

Claims received as of October 31, 1994	9,860
Claims Approved	7,053
Claims Pending	1,773
Claims Denied	1,034
Claims Paid	6,851

	<u>Implantees</u>	<u>\$ Amount</u>	<u>Spouses</u>	<u>\$ Amount</u>	<u>Total</u>
Group1	1421	\$ 2,131,500	1088	\$ 272,000	\$ 2,403,500
Group2	531	796,500	379	94,750	891,250
Group3	906	1,359,000	658	164,500	1,523,500
Group4	616	924,000	444	111,000	1,035,000
Group5	567	850,500	400	100,000	950,500
Group6	642	963,000	419	104,750	1,067,750
Group7	496	744,000	315	78,750	822,750
Group8	222	333,000	152	38,000	371,000
Group9	577	865,500	324	81,000	946,500
Group10	153	229,500	93	23,250	252,750
Group11	720	1,080,000	485	121,250	1,201,250
Totals	<u>6,851</u>	<u>\$ 10,276,500</u>	<u>4,757</u>	<u>\$ 1,189,250</u>	<u>\$ 11,465,750</u>

Claims received November 1, 1994 through June 26, 1995 1,342

Of the claims received as of October 31, 1994, substantially all that were complete have been processed. Those claims that were not complete are shown above as pending, and the needed information is being requested from the claimants.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF MAY 31, 1995

UNAUDITED

ASSETS

CASH:

Consultation Fund	\$ 97,022
Patient Benefit Fund	63,619

U.S. TREASURY BILLS:

Consultation Fund (Par Value \$86,600,000)	85,841,434
Patient Benefit Fund (Par Value \$11,762,000)	11,641,971

OFFICE FURNITURE AND EQUIPMENT - NET:

Research Management Group	59,125
Administrative Office	15,459

OTHER ASSETS

27,856

\$ 97,746,486

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

Supervisory Panel Members' Compensation	\$ 128,900
Other	114,701

FEDERAL TAXES PAYABLE

176,020

Total Liabilities

419,621

FUNDS BALANCE

97,326,865

\$ 97,746,486

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME, BENEFIT PAYMENTS AND FUNDS BALANCE

FOR THE FIVE MONTHS ENDED MAY 31, 1995

UNAUDITED

INTEREST INCOME:

U.S. Treasury Bills:	
Consultation Fund	\$ 2,093,344
Patient Benefit Fund	282,654
Other:	
Consultation Fund	11,291
Patient Benefit Fund	<u>562</u>
Total	<u>2,387,851</u>

BENEFIT PAYMENTS:

Consultation Fund:	
Implantees	7,068,000
Spouses	<u>796,500</u>
Total	<u>7,864,500</u>

EXPENSES:

Supervisory Panel (1)	633,616
Trustees' compensation and expenses	129,483
Professional fees	53,809
Research Management Group (1)	72,569
Administrative Office (1)	<u>149,110</u>
Total	<u>1,038,587</u>

PROVISION FOR FEDERAL TAXES 534,300

NET CHANGE IN FUNDS BALANCE \$ (7,049,536)

FUNDS BALANCE, DECEMBER 31, 1994 104,376,401

FUNDS BALANCE, MAY 31, 1995 \$ 97,326,865

(1) - See Schedule 1 herewith.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

SCHEDULE OF EXPENSES

FOR THE FIVE MONTHS ENDED MAY 31, 1995

UNAUDITED

SUPERVISORY PANEL:

Panel members' compensation	\$ 490,900
Consultants' compensation	24,664
Travel and other expenses	<u>118,052</u>
Total	<u>\$ 633,616</u>

RESEARCH MANAGEMENT GROUP:

Rents	\$ 5,644
Office payroll	42,234
Payroll taxes	3,391
Employee benefits	6,739
Travel	1,624
Printing and postage	3,237
Telephone	243
Office supplies and expense	449
Depreciation	5,375
Miscellaneous	<u>3,633</u>
Total	<u>\$ 72,569</u>

ADMINISTRATIVE OFFICE:

Rents	\$ 15,513
Office payroll	76,726
Payroll taxes	6,824
Employee benefits	3,733
Outside services	15,930
Printing and postage	16,374
General insurance	3,238
Telephone	4,651
Office supplies and expense	4,087
Depreciation	979
Miscellaneous	<u>1,055</u>
Total	<u>\$ 149,110</u>