

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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

FOURTH REPORT OF THE SPECIAL MASTERS/TRUSTEES
COVERING PERIOD FROM OCTOBER 26, 1995 TO JUNE 14, 1996

SPECIAL MASTERS/TRUSTEES

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

AGENDA

FOURTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

June 14, 1996
11:30 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. Fourth Report of the Special Masters/Trustees

- B. Appendices to Court Report
 - 1. Unaudited balance sheet as of April 30, 1996 and an unaudited statement of income, benefit payments and funds balance for the four months ended April 30, 1996 which includes the budgeted amounts for expenses for the period January 1, 1996 through December 31, 1996.
 - 2. Unaudited financial statements for the year ended December 31, 1995.
 - 3. Independent auditor's report for the years ended December 31, 1994 and 1993 and the period January 23, 1992 (date of inception) to December 31, 1992 from Deloitte & Touche.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

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

FOURTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

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

Your Special Masters/Trustees respectfully present their fourth periodic report, covering activities from October 26, 1995 to June 14, 1996.

I. CONSULTATION FUND

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.

Originally, October 31, 1994 was fixed as the initial deadline for filing Consultation Fund claims, and July 1, 1995 was fixed as the "final" deadline. However, because far fewer claims were filed than had been expected and because the Court desired that as many

Class Members as possible participate in the Consultation Fund distributions, and for other reasons set forth in the Third Report of the Special Masters/Trustees, the final deadline was extended to December 31, 1995, and then to March 31, 1996. While this last deadline was fair and reasonable for Class members resident in the United States, it became clear that this deadline was neither fair nor reasonable for those not resident in the United States. The reason was that the information brochure explaining benefits and rights under the Settlement Agreement had to be translated into thirteen languages and distributed in twenty-six countries. The completion of these procedures consumed so much time that the Special Masters/Trustees applied for an extension of sixty days for nonresident Class Members, and on March 29, 1996, the Court extended the deadline for filing proofs of claim by Class Members who are not resident in the United States from March 31, 1996 to May 31, 1996. (Document 832.)

The payment of a final distribution in equal amounts to Class Members will be delayed until the number of eligible claimants is determined. As promptly as practicable, application will be made to the Court for approval of a process for that final and complete distribution in equal amounts to eligible implantees from the implantee portion of the Consultation Fund and in equal parts to eligible spouses from the spousal portion of the Fund.

Proofs of claim postmarked on or before the applicable deadline will be considered for approval. Experience has demonstrated that claims that are timely posted around the world

may not be delivered to the Settlement office in Cincinnati until weeks later.

There has been a total of \$37,270,750 paid to date for implantee and spousal claims. As of June 5, 1996 there had been 15,136 claims received and there were 1,351 claims that had not been completely processed.

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 valve replacement surgeries, and to create a publicly accessible repository of appropriate information concerning the status of research and the risks of valve fracture and valve replacement.

A. Research Program. The Supervisory Panel is now conducting the research that it deems appropriate for the investigation of diagnostic techniques and valve replacement surgery, and for the consideration of changes in the replacement guidelines. Shiley Incorporated had maintained certain research while the Panel was considering what lines to pursue, and now that the Panel has taken over certain of the research projects initiated by Shiley, the Panel has, with the Court's approval, reimbursed Shiley for the costs of maintaining those projects. The total reimbursement was

\$2,584,277, which may be compared with the amount of \$3,546,630 that Shiley first demanded for reimbursement.

The Panel's research program includes three lines of investigation: epidemiological, radiographic and acoustical. No other non-invasive technologies have been discovered despite an extensive search. The proposals for new research projects that have been approved by the Supervisory Panel or are still under consideration basically look to improvement and refinement of the existing three lines of investigation. The Supervisory Panel has not reached any conclusions that are clinically significant to Class Members. The current reports from investigators are preliminary and do not rise to the level of a medical certainty. The Panel strongly believes that the release of any so called "progress report" would be premature and could be confusing without extensive explanations that would offer nothing of value to Class Members. We do not want to take any action that would do more harm than good. The Panel continues to press hard to move the projects along to appropriate conclusions, but it will be counterproductive to enforce a rigid schedule.

In epidemiological research, two cohort studies are being conducted, the first in the Netherlands and the second in the United Kingdom. They will not be completed until late 1997. A feasibility study of patients registered in MedicAlert (mainly U.S. residents), is in process of completion, without any assurance that a timely study could evolve from that. Three expert epidemiologist are working on mechanisms to refine the risks of strut fracture and

the risks of replacement surgery (both mortality and morbidity) under a program developed by the Epidemiological Committee of the Panel.

Radiographic studies are nearing completion at Stanford and at the Western Infirmary in Glasgow. These studies, when supplemented by the study at the William Beaumont Hospital (Michigan) that was completed by Shiley, should eventually produce imaging data on about 1,000 patients. This will be sufficient to allow the Panel to reach conclusions about the advisability of using radiographic data as a diagnostic technique to identify valves with high risk of strut fracture. The possibility of conducting a similar study in Aachen, Germany, has been abandoned.

In addition to the imaging of patients, valves have been implanted in sheep and studied for a number of years. Included are intact valves, valves with a clinical single leg fracture and valves with an induced fracture. These studies will reveal important data about the physical and chronological connections between single leg fractures and total outlet strut fractures.

Acoustical research has been conducted either jointly with radiographic studies or in parallel with them. The Shiley plan for acoustical diagnosis of a single leg fracture was well conceived but produced less than satisfactory results by reason of faulty execution. Nevertheless, the initial investigative steps produced data that is highly promising. The Supervisory Panel is now pursuing with two contractors (and possibly a third) studies to determine the usefulness of acoustical techniques as a diagnostic

tool, and hopes to have reports in hand in about three months.

The Panel has not deemed it wise to carry on research beyond the current status of the metallurgical characteristics of the valve, or any bioengineering research.

The Johnson Pilot Study arose from a Court Order that Pfizer/Shiley produce for Special Counsel John T. Johnson their manufacturing records on condition that the disclosure was approved by the Supervisory Panel. The Panel decided on a Pilot Study limited to the production and delivery of 1,000 records, of which 400 have been copied and delivered. The Pilot Study has been delayed by a dispute about the costs of copying the manufacturing records and by Mr. Johnson's recent back operation. The Panel has not received any report of significance at this time.

At the request of the French Ministry of Health, the Chairman and Jamie L. Hirsch of the Research Management Group made a presentation on the state of the research program to a meeting including representatives of the Ministry of Health, French cardiac surgeons and cardiologists. The Panel remains open to considering a French research project if the Ministry of Health deems it appropriate to make a proposal. It was said that out of about 7,000 aortic valves implanted in French patients, five strut fractures have been reported.

B. Guidelines Committee. As previously reported, the Guidelines Committee has met twice. On the basis of the research data submitted to and considered by it at the second meeting in

November 1995, the Guidelines Committee decided not to recommend any change in the guidelines for replacement surgery. The Supervisory Panel accepted this interim conclusion as reasonable under the circumstances, but the Panel has determined to furnish the Guidelines Committee with updated reports from the three lines of investigation in due time before the next meeting of the Guidelines Committee now scheduled for early October 1996 in Vienna, Austria (in conjunction with an international meeting of cardiac surgeons and cardiologists). After that meeting, the Guidelines Committee will be restructured as a subcommittee of the Supervisory Panel, consisting of three Panel members, and with certain former members of the Guidelines Committee as consultants.

C. Valve Replacement Surgery Claims and Fracture Claims. As previously reported, the Claims Administrator has been processing claims for valve replacement surgery and strut fracture claims. As of June 10, 1996, two hundred fifty-four Patient Benefit Fund claims have been received. There are forty-three qualified outlet strut fracture claims, twenty-eight qualified single leg fracture claims and thirty-three qualified valve replacement surgery claims. Based upon information presently available, one hundred thirty-five claims do not qualify and additional information is needed for fifteen of the claims.

On May 24, 1996 the Trustees reimbursed Pfizer Inc. from the Patient Benefit Fund for their payment of medical expenses for qualifying valve replacement surgeries since January 23, 1992 in

the amount of \$610,505.26. In addition, there are two claims that have not been finalized with the claimants' insurance companies that may require reimbursement in the future.

III. FINANCIAL INFORMATION

At April 30, 1996, the total balance of cash and cash equivalents was \$64,980,435 for the Consultation Fund (class member portion and spousal portion) and \$9,623,463 for the Patient Benefit Fund. These amounts include net interest earned from January 28, 1992 through April 30, 1996, in the aggregate amount of \$14,610,128 for the Consultation Fund and \$936,586 for the Patient Benefit Fund.

A combined unaudited balance sheet as of April 30, 1996 and an unaudited statement of income, benefit payments and funds balance for the four months ended April 30, 1996 which includes the budgeted amounts for expenses for the period January 1, 1996 through December 31, 1996, is attached as Appendix 1. Unaudited financial statements for the year ended December 31, 1995 are attached as Appendix 2.

The Trustees have received the audit report for the years ended December 31, 1994 and 1993 and the period January 23, 1992 (date of inception) to December 31, 1992 from Deloitte & Touche. A copy of their independent auditor's report is attached as Appendix 3.

IV. COMMUNICATIONS

The information brochure prepared by Class Counsel and Counsel for Defendants was distributed in the United States and Canada in January 1996, and after translation into thirteen languages, it was distributed in twenty-six other countries in March 1996. As noted above, the unavoidable delay in producing brochures in other languages resulted in an extension to May 31, 1996 of the deadline for filing Consultation Fund proofs of claim by Class Members not resident in the United States. At this time, no further mass communication with Class members is contemplated until there is a duly approved change in the guidelines for replacement surgery. Meanwhile, the Claims Administrator and the Bowling office are in almost daily contact with individual Class Members.

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: June 14, 1996

Hon. Robert L. Black, Jr.

Peter J. Strauss, Esq.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF APRIL 30, 1996

UNAUDITED

ASSETS

CASH:

Consultation Fund	\$ 793,913
Patient Benefit Fund	71,081

U.S. TREASURY BILLS:

Consultation Fund (Par Value \$64,950,000)	64,186,522
Patient Benefit Fund (Par Value \$9,612,000)	9,552,382

OFFICE FURNITURE AND EQUIPMENT - NET:

Research Management Group	46,342
Administrative Office	13,195

OTHER ASSETS

29,845

\$ 74,693,280

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 552,229 (1)
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FEDERAL TAXES PAYABLE	<u>50,000</u>
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Total Liabilities	602,229
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FUNDS BALANCE	<u>74,091,051 (1)</u>
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\$ 74,693,280

- (1) - Does not include the liability to Shiley Incorporated/Pfizer Inc. for Patient Benefit Fund benefits paid on behalf of the Settlement Fund and the liability to Shiley/Pfizer for the interim costs for the research programs that were taken over by the Supervisory Panel. Also, does not consider the fees and expenses of Class Counsel.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME, BENEFIT PAYMENTS AND FUNDS BALANCE

FOR THE FOUR MONTHS ENDED APRIL 30, 1996

UNAUDITED

	<u>BUDGET</u>	<u>ACTUAL</u>
	<u>1/1/96-12/31/96</u>	<u>1/1/96-4/30/96</u>
INTEREST INCOME:		
Consultation Fund		\$ 1,133,033
Patient Benefit Fund		<u>174,361</u>
Total		<u>1,307,394</u>
BENEFIT PAYMENTS:		
Consultation Fund:		
Implantees		2,139,000
Spouses		<u>418,000</u>
Total		2,557,000
Patient Benefit Fund:		
Valve Replacement Surgery		<u>44,685</u>
Total		<u>2,601,685</u>
RESEARCH PROGRAMS:	<u>\$6,976,000</u>	<u>337,277</u>
EXPENSES:		
Supervisory Panel (1)	2,075,000	443,855
Trustees' fees and expenses	350,000	78,588
Professional fees	170,000	35,189
Research Management Group (1)	517,000	142,064
Administrative Office (1)	592,000	165,445
Notification expense	<u>200,000</u>	<u>73,041</u>
Total	<u>\$3,904,000</u>	<u>938,182</u>
PROVISION FOR FEDERAL TAXES		<u>150,000</u>
NET CHANGE IN FUNDS BALANCE		(2,719,750)
FUNDS BALANCE, DECEMBER 31, 1995		<u>76,810,801</u>
FUNDS BALANCE, APRIL 30, 1996		<u>\$ 74,091,051 (2)</u>

(1) - See Schedule 1 herewith.

(2) - See note (1) on the Balance Sheet herewith.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

SCHEDULE OF EXPENSES
UNAUDITED

	<u>BUDGET</u>	<u>ACTUAL</u>
	<u>1/1/96-12/31/96</u>	<u>1/1/96-4/30/96</u>
SUPERVISORY PANEL:		
Panel members' compensation	\$1,000,000	\$ 269,300
Guidelines Committee compensation	240,000	250
Consultants' compensation	410,000	122,541
Travel and other expenses	<u>425,000</u>	<u>51,764</u>
Total	<u>\$2,075,000</u>	<u>\$ 443,855</u>
RESEARCH MANAGEMENT GROUP:		
Rents	\$ 62,000	\$ 19,656
Office payroll	200,000	60,716
Payroll taxes	21,000	5,673
Employee benefits	63,000	16,151
Outside services	12,000	
Computer and telephone support	51,000	15,200
Travel	60,000	4,627
Printing and postage	24,000	12,205
General insurance	3,000	
Telephone	6,000	899
Research supplies	3,000	
Office supplies and expense	9,000	1,611
Depreciation		4,300
Miscellaneous	<u>3,000</u>	<u>1,026</u>
Total	<u>\$ 517,000</u>	<u>\$ 142,064</u>
ADMINISTRATIVE OFFICE:		
Rents	\$ 48,000	\$ 14,000
Office payroll	290,000	72,669
Payroll taxes	30,000	7,108
Employee benefits	20,000	8,453
Outside services	96,000	30,272
Printing and postage	54,000	17,105
General insurance	6,000	
Telephone	24,000	9,808
Office supplies and expense	12,000	1,462
Depreciation		819
Miscellaneous	<u>12,000</u>	<u>3,749</u>
Total	<u>\$ 592,000</u>	<u>\$ 165,445</u>

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF DECEMBER 31, 1995

UNAUDITED

ASSETS

CASH:

Consultation Fund	\$ 351,400
Patient Benefit Fund	167,939

U.S. TREASURY BILLS:

Consultation Fund (Par Value \$66,650,000)	66,408,269
Patient Benefit Fund (Par Value \$10,912,000)	10,861,909

OFFICE FURNITURE AND EQUIPMENT - NET:

Research Management Group	54,125
Administrative Office	14,014

TAX REFUND RECEIVABLE 100,000

OTHER ASSETS 30,619

\$ 77,988,275

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES \$ 1,177,474(1)

FUNDS BALANCE 76,810,801(1)

\$ 77,988,275

- (1) - Does not include the liability to Shiley Incorporated/Pfizer Inc. for Patient Benefit Fund benefits paid on behalf of the Settlement Fund and the liability to Shiley/Pfizer for the interim costs for the research programs that were taken over by the Supervisory Panel. Also, does not consider the fees and expenses of Class Counsel.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME, BENEFIT PAYMENTS AND FUNDS BALANCE

FOR THE YEAR ENDED DECEMBER 31, 1995

UNAUDITED

INTEREST INCOME:

Consultation Fund	\$ 4,593,566
Patient Benefit Fund	<u>659,859</u>
Total	<u>5,253,425</u>

BENEFIT PAYMENTS:

Consultation Fund:	
Implantees	25,539,000
Spouses	<u>2,787,250</u>
Total	28,326,250

Patient Benefit Fund:	
Valve Replacement Surgery	<u>116,534</u>
Total	<u>28,442,784</u>

RESEARCH PROGRAMS

479,472

EXPENSES:

Supervisory Panel (1)	1,701,256
Trustees' compensation and expenses	313,532
Special Master-SLF compensation and expenses	20,367
Professional fees	156,284
Research Management Group (1)	352,966
Administrative Office (1)	442,364
Notification expense	<u>10,000</u>

2,996,769

PROVISION FOR FEDERAL TAXES

900,000

NET CHANGE IN FUNDS BALANCE

(27,565,600)

FUNDS BALANCE, DECEMBER 31, 1994

104,376,401

FUNDS BALANCE, DECEMBER 31, 1995

\$ 76,810,801 (2)

(1) - See Schedule 1 herewith.

(2) - See note (1) on the Balance Sheet herewith.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

SCHEDULE OF EXPENSES
UNAUDITED

SUPERVISORY PANEL:

	<u>ACTUAL</u>
	<u>1/1/95-12/31/95</u>
Panel members' compensation	\$ 1,057,633
Guidelines Committee compensation	144,462
Consultants' compensation	179,633
Travel and other expenses	319,528
Total	<u>\$ 1,701,256</u>

RESEARCH MANAGEMENT GROUP:

	<u>BUDGET (1)</u>	<u>ACTUAL</u>
	<u>4/1/95-12/31/95</u>	<u>4/1/95-12/31/95</u>
Rents	\$ 42,644	\$ 37,149
Office payroll	161,234	156,235
Payroll taxes	17,391	17,365
Employee benefits	24,739	27,720
Computer and telephone support	39,000	34,200
Travel	65,624	27,303
Advertising		10,983
Printing and postage	18,237	18,943
General insurance		600
Telephone	3,243	4,168
Office supplies and expense	6,449	8,396
Depreciation	5,375	9,675
Miscellaneous	9,633	229
Total	<u>\$ 393,569</u>	<u>\$ 352,966</u>

ADMINISTRATIVE OFFICE:

	<u>BUDGET (2)</u>	<u>ACTUAL</u>
	<u>1/1/95-12/31/95</u>	<u>1/1/95-12/31/95</u>
Rents	\$ 48,000	\$ 35,992
Office payroll	235,000	216,749
Payroll taxes	27,000	16,556
Employee benefits	18,000	11,872
Outside services	96,000	83,357
Printing and postage	54,000	44,562
General insurance	8,000	3,294
Telephone	24,000	15,604
Office supplies and expense	12,000	10,374
Depreciation		2,424
Miscellaneous	18,000	1,580
Total	<u>\$ 540,000</u>	<u>\$ 442,364</u>

- (1) - Represents the actual expenses for April and May, 1995 plus the amounts budgeted for the period June 1 through December 31, 1995.
- (2) - Represents the four quarterly budgets for the period January 1 through December 31, 1995.



**BOWLING-PFIZER HEART VALVE
LITIGATION SETTLEMENT FUND**

**Statement of Assets, Liabilities and Fund Balance -
Modified Cash Basis as of December 31, 1994, 1993
and 1992 and Statements of Revenue and Settlement
Payments in Excess of Expenses and Benefit
Payments and Change in Fund Balance - Modified
Cash Basis for the Years Ended December 31, 1994,
1993 and the Period January 23, 1992 (Date of
Inception) to December 31, 1992 and Independent
Auditor's Report**



INDEPENDENT AUDITORS' REPORT

Bowling - Pfizer Heart Valve Litigation Settlement Fund
525 Vine Street, Suite 1300
Cincinnati, Ohio 45202

We have audited the accompanying statements of assets, liabilities and fund balance - modified cash basis of the Bowling - Pfizer Heart Valve Litigation Settlement Fund (the "Fund") as of December 31, 1994, 1993 and 1992 and the related statements of revenue and settlement payments in excess of expenses and benefit payments and change in fund balance - modified cash basis for the years ended December 31, 1994 and 1993 and the period January 23, 1992 (Date of Inception) to December 31, 1992. These financial statements are the responsibility of the Fund's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with generally accepted auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As described in Note 2 to the financial statements, these financial statements were prepared on the modified cash basis of accounting, which is a comprehensive basis of accounting other than generally accepted accounting principles.

In our opinion, such financial statements present fairly, in all material respects, the assets, liabilities and fund balance of the Fund as of December 31, 1994, 1993 and 1992 and its revenue and settlement payments in excess of expenses and benefit payments and changes in fund balance for the years ended December 31, 1994 and 1993 and the period January 23, 1992 (Date of Inception) to December 31, 1992 on the basis of accounting described in Note 2.

Deloitte & Touche LLP

October 20, 1995

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

STATEMENTS OF ASSETS, LIABILITIES AND FUND BALANCE - MODIFIED CASH BASIS AS OF DECEMBER 31, 1994, 1993 AND 1992

	1994	1993	1992
ASSETS			
CASH	\$ 268,530	\$ 112,114	\$ 268,501
INVESTMENTS (Note 3):			
Consultation Fund	91,312,971	82,660,934	81,089,604
Patient Benefit Fund	12,006,135	<u>82,660,934</u>	<u>81,089,604</u>
Total Investments	103,319,106	82,660,934	81,089,604
INTEREST RECEIVABLE (Note 2)	945,621	112,169	456,133
TAX REFUND RECEIVABLE (Notes 2,6)	108,280		
OTHER ASSETS (Note 2)	<u>46,177</u>		
TOTAL ASSETS	<u>\$104,687,714</u>	<u>\$82,885,217</u>	<u>\$81,814,238</u>
LIABILITIES AND FUND BALANCE			
ACCOUNTS PAYABLE AND ACCRUED EXPENSES (Note 2)	\$ 311,313	\$ 1,162	\$ 12,667
TAXES PAYABLE (Note 6)		<u>83,273</u>	<u>558,487</u>
Total Liabilities	<u>311,313</u>	<u>84,435</u>	<u>571,154</u>
FUND BALANCE (Note 1):			
Consultation Fund	92,345,628	82,800,782	81,243,084
Patient Benefit Fund	12,030,773	<u>82,800,782</u>	<u>81,243,084</u>
Total Fund Balance	<u>104,376,401</u>	<u>82,800,782</u>	<u>81,243,084</u>
TOTAL LIABILITIES AND FUND BALANCE	<u>\$104,687,714</u>	<u>\$82,885,217</u>	<u>\$81,814,238</u>

See notes to financial statements.

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

STATEMENTS OF REVENUE AND SETTLEMENT PAYMENTS IN EXCESS OF EXPENSES AND BENEFIT PAYMENTS AND CHANGE IN FUND BALANCE - MODIFIED CASH BASIS FOR THE YEARS ENDED DECEMBER 31, 1994 AND 1993 AND THE PERIOD JANUARY 23, 1992 (DATE OF INCEPTION) TO DECEMBER 31, 1992

	1994	1993	1992
INCOME:			
Settlement payments by Pfizer/Shiley (Note 1)	\$ 22,500,000		\$80,000,000
Net Investment Income	<u>3,670,661</u>	<u>\$ 2,600,093</u>	<u>2,715,141</u>
Total Income	<u>26,170,661</u>	<u>2,600,093</u>	<u>82,715,141</u>
EXPENSES AND BENEFIT PAYMENTS:			
Benefit payments - Consultation Fund (Note 2)	2,406,500		
Supervisory panel expenses (Note 1)	571,593		
Notification expense	407,606		900,000
Trustees' fees and expenses	93,428	8,251	12,667
Professional fees (Note 5)	44,954	11,764	
Other administrative expenses	99,241	1,107	903
Provision for income taxes (Note 6)	<u>971,720</u>	<u>1,021,273</u>	<u>558,487</u>
Total expenses and benefit payments	<u>4,595,042</u>	<u>1,042,395</u>	<u>1,472,057</u>
INCREASE IN FUND BALANCE	21,575,619	1,557,698	81,243,084
FUND BALANCE, BEGINNING OF YEAR	<u>82,800,782</u>	<u>81,243,084</u>	<u> </u>
FUND BALANCE, END OF YEAR	<u>\$104,376,401</u>	<u>\$82,800,782</u>	<u>\$81,243,084</u>

See notes to financial statements.

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

NOTES TO MODIFIED CASH BASIS FINANCIAL STATEMENTS

1. ORGANIZATION AND GENERAL INFORMATION

The Bowling-Pfizer Heart Valve Litigation Settlement Fund (the Fund) is the result of a settlement between Pfizer Inc. (Pfizer) and its wholly-owned subsidiary Shiley Incorporated (Shiley) and a class of plaintiffs (Plaintiffs) consisting of all persons who were alive on January 23, 1992 with a Bjork-Shiley convexo-concave (C/C) heart valve still implanted, and their spouses on that date, except those persons who filed valid and timely requests for exclusion from the class.

The Settlement requires that Pfizer/Shiley pay a minimum of \$165 million to the Fund to settle the claims of the Plaintiffs. Certain provisions exist whereby Pfizer may be required to pay additional amounts to the Fund based on certain criteria as defined in the Settlement. The minimum Settlement is allocated between the "Patient Benefit Fund" (\$75 million) and the "Consultation Fund" (\$90 million).

The Patient Benefit Fund is to be used for: research and development of diagnostic techniques to identify implantees who may have a significant risk of strut fracture and to make such diagnostic techniques available to plaintiff implantees; research concerning the characterization and/or reduction of the risks of valve replacement surgery; and payment of covered expenses for qualifying surgery to explant due to the risk of strut fracture, a Plaintiff implantee's C/C heart valve and replace it with another prosthetic valve.

The Consultation Fund, initially \$80,000,000 for Plaintiff implantees, is intended to provide Plaintiff implantees with funds to obtain medical and psychological consultation as they deem best. It is to be divided equally among Plaintiff implantees after paying or providing for fees and expenses to be paid out of the implantee portion of the Fund. In addition, \$10,000,000 was paid into the Fund which is to be paid, after fees and expenses, equally to all Plaintiff spouses.

The terms of the Settlement require Pfizer/Shiley to initially deposit \$12,500,000 into the Patient Benefit Fund. Additionally, beginning on the second anniversary of the final approval of the Settlement, Pfizer/Shiley is required to make annual deposits into the Patient Benefit Fund of not less than \$6,250,000 until a total of \$75,000,000 has been paid.

Pfizer/Shiley paid \$80 million to the Consultation Fund in 1992 and paid \$10 million to the Consultation Fund in 1994. In addition, in 1994 Pfizer/Shiley also paid \$12,500,000 to the Patient Benefit Fund.

As of October 20, 1995 the Fund had received Consultation Fund proof of claim forms from 12,238 potential claimants. Of this number, 11,033 claims had been processed and 9,154 had been approved as valid claims under the Settlement Agreement.

The research activities of the Patient Benefit Fund are supervised by a Supervisory Panel (Panel). The Panel, subject to Court approval, shall adopt guidelines for the use of diagnostic testing techniques and for valve replacement surgery. Also, the Panel will create a publicly accessible repository of information concerning the status of the research and the risks of valve fracture and of valve replacement. The Panel is made up of six members who are recognized scientific or medical experts and one member who is not a scientist or physician.

2. SIGNIFICANT ACCOUNTING POLICIES

Basis of Accounting - The Fund prepares its financial statements on the modified cash basis of accounting. Therefore, it records interest receivable for interest earned not yet received, taxes receivable (payable) and accounts payable for expenses when incurred rather than when paid (modified cash basis). Under this basis all settlement payments by Pfizer/Shiley are recognized when received and all benefit payments and Plaintiffs' counsel fees and expenses are recognized when paid rather than when incurred. Additionally, the "Amounts due to Pfizer/Shiley" will be recognized when paid rather than when incurred.

Settlement Payments by Pfizer/Shiley - All Consultation Fund claims submitted by each claimant are reviewed for qualification by the Fund and payments of qualified claims are approved by the Court. The Fund commenced the payment of an initial distribution to Consultation Fund claimants in 1994. The total number of eligible claimants has not yet been determined.

Amounts due to Pfizer/Shiley - The Fund has agreed to reimburse Pfizer/Shiley for certain medical expense payments made for qualifying valve replacement surgeries. These medical expense payments were made by Pfizer/Shiley for qualifying surgeries that occurred after January 23, 1992 and before the Fund commenced processing valve replacement surgery claims. The Fund has agreed to contract for, and continue certain research programs that were initiated by Shiley Incorporated. In addition, the Fund has agreed to reimburse Pfizer/Shiley for the reasonable costs of maintaining these research programs from the date of the appointment of the Supervisory Panel until the dates that the research programs come under the control of the Supervisory Panel. These amounts will be paid to Pfizer/Shiley after review by the Fund and approval by the Court. These amounts will be reported as a distribution when paid by the Fund. Management has estimated the total amount due to Pfizer/Shiley to be approximately \$1,700,000 as of December 31, 1994 for these two categories of costs to the Patient Benefit Fund.

Other Assets - Other Assets represents prepaid insurance, minor office furniture and computer equipment used by the Fund.

3. INVESTMENTS

Investments at December 31, 1994, 1993 and 1992 consist of U.S. Treasury Bills and are carried at cost. The market value of such investments was approximately \$104,284,000, \$82,811,000 and \$81,584,000, at December 31, 1994, 1993 and 1992, respectively.

4. OPERATING LEASES

The Fund leases its office facilities under an agreement classified as an operating lease from an unrelated litigation settlement fund. Effective July 1, 1994 the lease was amended and assigned to the Fund for the period April 1, 1996 through March 31, 1999. Total future minimum lease and sublease payments due are as follows:

1996	\$ 39,803
1997	53,071
1998	53,071
1999	<u>13,268</u>
Total	<u>\$ 159,213</u>

5. RELATED PARTY TRANSACTIONS

One trustee of the Fund is a partner of the law firm that provides miscellaneous services to the Fund. Payments of professional fees to this firm, approved by the Court, amounted to \$18,818 in 1994. No fees were paid to this law firm in 1993 or 1992.

6. TAX STATUS

For Federal income tax purposes, the Fund is treated as a taxable complex trust, a "Designated Settlement Fund" under Section 468(B) of the IRC. The Fund is required to pay taxes on the excess of interest income earned over expenses incurred for the administration of the Fund. The settlement payments by Pfizer/Shiley, benefit payments and Plaintiffs' counsel fees and expenses are not taxable transactions.

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