

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

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

NINTH REPORT OF THE SPECIAL MASTERS/TRUSTEES
COVERING PERIOD FROM JUNE 10, 1998 TO DECEMBER 16, 1998

SPECIAL MASTERS/TRUSTEES

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

AGENDA

NINTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

December 16, 1998
10:00 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.

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- A. Ninth Report of the Special Masters/Trustees
- B. Appendices to Court Report
 - 1. Unaudited balance sheet as of October 31, 1998 and an unaudited statement of income, benefit payments and funds balance for the ten months ended October 31, 1998.
 - 2. Independent auditor's report for the year ended December 31, 1997 from Deloitte & Touche, LLP.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
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IN RE: : Case No. C-1-91-256
BOWLING-PFIZER LITIGATION : (Judge Spiegel)

NINTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

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

Your Special Masters/Trustees respectfully present their ninth periodic report, covering activities from June 10, 1998 to December 16, 1998.

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, the timing of a final distribution from the Consultation Fund was primarily dependent on the settlement of Federal income tax matters. The Trustees had

received a favorable revenue ruling regarding the taxability of the Settlement Fund (Fund) and the deductibility of certain expenses for Federal income tax purposes. Due to the revenue ruling, the Fund filed claims for refunds for 1993, 1994, 1995 and 1996. Refunds of \$681,700 were received by the Fund in 1997. The Internal Revenue Service completed their tax audits for these years in January 1998. The Fund subsequently received an additional \$1,262,325 in refunds and \$157,512 in interest relating to those tax years.

Final distributions have been approved and sent in the amounts of \$312 to each qualified implantee claimant and \$47 to each qualified spousal claimant. The total approved distributions are as follows: \$6,147 each for implantees and \$1,009 each for spouses of implantees resulting in a total amount of \$91,710,893 sent for 13,350 implantees and 9,563 spouses.

The Trustees now wish to terminate the Consultation Fund. However, checks on this Fund issued to qualified claimants aggregating more than \$1,000,000 have not been negotiated and are outstanding. Final efforts must be made to see that these claimants are duly paid, and a deadline fixed for terminating those claims that cannot be paid within a reasonable amount of time.

After expenditure of the Trustees' reasonable efforts to contact unpaid claimants, the Trustees will report to the Court, as follows: the Trustees' attempts to locate the qualified claimants who have checks outstanding and unnegotiated and to pay them; whether there are still claimants whose claims have not been paid

and the amount thereof; the Trustees' recommendation about termination of all the claims that cannot be paid at that time; and the Trustees' recommendation about the disposition of the funds representing the outstanding unnegotiated checks.

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 qualifying 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.

The responsibility to accomplish these purposes is given to the Supervisory Panel. The following report is based on the actions taken by the Panel up to and through its most recent meeting in Cincinnati on December 8, 1998.

A. Dissemination of 1997 Guidelines. There has been no further mass distribution of the Guidelines approved by the Court on August 28, 1997 (Document 1130), herein called the 1997 Guidelines. However, arrangements have now been completed for distribution in The Netherlands.

The Claims Administrator has identified 68 United States implantees who appear to qualify for surgical benefits under the 1997 Guidelines according to the information on file in the

Settlement Funds office. Subject to approval by Class Counsel, by Counsel for Defendants, and by the Court, a means has been prepared of informing the appropriate physicians about the qualification of the identified implantees, so that the matter can be discussed between patient and physician.

The article written by the Supervisory Panel for publication was submitted to the New England Journal of Medicine, but was rejected. It has since been submitted to the Journal of the American Medical Association, and there are indications that the article may not be accepted by that publication. If that is the case, the Panel plans to submit it next to the American Journal of Cardiology.

As previously reported, the Federal Food and Drug Administration has placed the Supervisory Panel's 1997 Guidelines on its web site.

B. Research. The Supervisory Panel has continued to pursue various means whereby the 1997 Guidelines can be revised for the benefit of the Class, and this effort leads in several directions.

The current identification of valves with a high risk of strut fracture has been based on epidemiological studies. The ongoing projects are three: the Dutch Cohort, the United Kingdom Cohort, and a study by Medic Alert of data from United States residents who have registered with that organization. The Panel's Epidemiology Subcommittee held a meeting in London, England, on October 29 and 30, 1998 to consider combining and pooling data obtained from these three studies with purpose to increase the precision of estimates

of the relative and absolute risks of mortality and of outlet strut fracture (OSF), to clarify valve-related and patient-related risk factors for OSF, to increase the precision of estimates of the relative and absolute risks of mortality following elective reoperations to replace BSCC valves, and to provide information useful for the improvement of the 1997 Guidelines. The representatives of these three studies agreed in principle to create a master data file and to arrange for the combined analysis of data from the three cohorts, and a formal agreement will be circulated for the signature of all parties. The expectation is that the research data file will be complete in about 18 months. The Chairman suggests that this is a major step forward for the benefit of the Class.

Almost 1,000 implantees have undergone imaging (x-ray) and acoustic studies at Beaumont, Stanford and Glasgow, and although these projects did not develop diagnostic techniques that meet the standards of medical reliability, they accumulated extensive clinical data. With the expectation that the Class will benefit, a follow-up study has been authorized so that information about these implantees will be brought up to date, particularly with respect to the occurrence of single leg separation and outlet strut fracture.

A project has been established at Stanford to offer reimaging evaluation to all mitral implantees (not aortic implantees) who qualify for benefits for surgical replacement of high risk valves under the 1997 Guidelines. Further, this service will be available

to all other implantees (those who do not qualify under the 1997 Guidelines) who wish to have their valves x-rayed at their cost.

Prior acoustic studies of the sounds of intact versus those with a single leg separation have not been successful in providing a high level of sensitivity and a low false-positive rate. In order to determine whether acoustic signals are indeed different for intact valves versus those with a single leg separation, the Panel found it necessary to carry out a study in an anechoic chamber (that is, a chamber where there are no extraneous sounds). Lawrence Livermore Laboratory is now engaged in this project, using a water tank located at the Naval Research Unit in San Diego, California. They have completed the first part of the five tasks in this project, and it will go forward under careful panel supervision.

Another research project to detect differences between implanted intact valves and valves with a single leg separation is being conducted by Information Systems Laboratories, Inc. This study utilizes magnetometry with external gradient coils to record magnetic signals and to determine whether there are detectable differences. This project is in the first stages of establishing its validity.

A different approach to detecting the differences may lie in the use of a catheter-based magnetic recording system, based on preliminary work accomplished without funding from the Supervisory Panel. The proposal made by Dr. John Wikswo of Vanderbilt University to the Panel was accepted, and the negotiation of a

contract was approved, the work to be done under close monitoring.

While past metallurgical studies have not produced any information of clinical use to the Class, the Panel is inquiring into a possible review of whether the Haynes 25 wire used in the outlet strut becomes increasingly brittle for any reason, such as the welding process or fatigue due to prolonged stress. A four-phase contract will be negotiated with the Ohio Welders Institute in Columbus, Ohio.

The studies conducted by the Cleveland Clinic seeking ways to improve the images obtained by x-ray have been terminated or concluded, without any results beneficial to the Class. The Supervisory Panel thinks that the pursuit of these studies was proper and necessary; they confirmed the Panel's decision not to pursue further cine imaging projects.

Dr. Tom Ivey's project to review operative mortality and morbidity includes three separate studies of data available at the Cleveland Clinic, Health Data Research, Inc., and medical records at Shiley about certain explantations.

Dr. Yolanda van der Graaf of Utrecht University in The Netherlands sent the Panel three proposals a few days before its recent meeting. Two of them will require further study and broader consideration, one for the creation of a web site and the other for the investigation of the cause of what is called "paramagnetic defects" in the MRI of an implantee who survived an outlet strut fracture. The Panel approved the negotiation of a two-year contract for study of the association between metallurgy and the

manufacturing characteristics of the valves and the study of a better estimation of prophylactic reoperation risks.

C. Independent Review of Research. In order to obtain an independent review of all the research carried out to date about the BSCC heart valve and the risks of strut fracture and of reoperative mortality, whether sponsored by Pfizer/Shiley or by the Supervisory Panel, five "think tanks" have been approached, but only two proposals have been elicited. Those are the Battelle Institute in Columbus and the Institute for Health Policy and Health Services Research at the University of Cincinnati. These two proposals were considered by the Panel and both were approved on condition the principals agree to a joint conference to discuss their independently conceived conclusions.

D. Repository. At the recent Panel meeting, a proposal for establishing the information repository required for the benefit of the Class was presented. It had been developed in lengthy consultations with Class Counsel and Counsel for Defendants. The Panel adopted the proposal and it will be presented to the Court for approval as soon as possible.

E. Valve Replacement Surgery Claims and Fracture Claims. The Claims Administrator has received 406 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 406 claims, there are 66 qualified outlet strut fracture claims, 35 qualified single leg fracture claims and 49 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.

As previously reported, the computer system in the Trustees' office has been upgraded in order to implement the 1997 guidelines. Software was installed which includes a data table consisting of selected manufacturing and implantation data derived from the Bjork-Shiley convexo-concave research data base of Shiley Incorporated. This data is needed to determine the eligibility of implantee Class Members for valve replacement surgery benefits under the Supervisory Panel's 1997 guidelines formula.

The office of the Claims Administrator continues to provide, upon requests, the estimated annual fracture rates under the 1997 guidelines. There are 8 known valve replacement surgeries that qualify for benefits under the 1997 guidelines formula, including 5 recent surgeries and 3 previous surgeries. By reviewing the valve replacement surgery claims and the Consultation Fund claims, there have been identified 227 implantees who may qualify for valve replacement surgery benefits under those guidelines. Of these implantees, 52 have already had their BSCC heart valves explanted.

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III. FINANCIAL INFORMATION

At October 31, 1998, the total balance of cash and cash equivalents was \$4,717,699 for the Consultation Fund (class member portion and spousal portion) and \$16,987,793 for the Patient Benefit Fund. These amounts include net interest earned from January 28, 1992 through October 31, 1998, in the aggregate amount of \$17,582,645 for the Consultation Fund and \$2,157,490 for the Patient Benefit Fund.

Attached as Appendix 1 are the following: an unaudited balance sheet as of October 31, 1998 and an unaudited statement of income, benefit payments and funds balance for the ten months ended October 31, 1998 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 1998 through December 31, 1998).

The Trustees have received the audit report for the year ended December 31, 1997 from Deloitte & Touche, LLP. A copy of their independent auditor's report is attached as Appendix 2.

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 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: December 16, 1998

Hon. Robert L. Black, Jr.

Peter J. Strauss, Esq.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF OCTOBER 31, 1998

UNAUDITED

ASSETS

CASH:

Consultation Fund	\$ 170,321
Patient Benefit Fund	23,701

U.S. TREASURY BILLS:

Consultation Fund (Par Value \$4,581,000)	4,547,378
Patient Benefit Fund (Par Value \$17,142,000)	16,964,092

OTHER ASSETS

<u>22,463</u>
<u>\$ 21,727,955</u>

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES

\$ 500,427(1)

FUNDS BALANCE

<u>21,227,528</u>
<u>\$ 21,727,955</u>

- (1) - Does not include any provision for fees and expenses relating to applications filed with the Court in November 1997 and November 1998 by Class Counsel and Special Counsel and Public Citizen, Inc. that basically covered the periods October 1996 - October 1997, and October 1997 - October 1998, respectively.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME, BENEFIT PAYMENTS AND FUNDS BALANCE

FOR THE TEN MONTHS ENDED OCTOBER 31, 1998

UNAUDITED

INCOME:

Investment interest:	
Consultation Fund	\$ 196,434
Patient Benefit Fund	523,666
Miscellaneous	<u>161,720</u>
Total	<u>881,820</u>

BENEFIT PAYMENTS:

Consultation Fund:	
Implantees	29,175
Spouses	<u>2,886</u>
Total	32,061

Patient Benefit Fund:	
Valve Replacement Surgery	<u>28,914</u>
Total	<u>60,975</u>

RESEARCH PROGRAMS

973,742

EXPENSES:

Supervisory Panel (1)	1,004,650
Trustees' fees and expenses	119,240
Professional fees	41,421
Administrative office (1)	<u>340,444</u>
Total	<u>1,505,755</u>

REFUNDS OF FEDERAL INCOME TAXES

1,262,325

CONTRIBUTION BY SHILEY INCORPORATED

6,250,000

NET CHANGE IN FUNDS BALANCE

5,853,673 (2)

FUNDS BALANCE, DECEMBER 31, 1997

15,373,855

FUNDS BALANCE, OCTOBER 31, 1998

\$ 21,227,528

(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>1/1/98-10/31/98</u>
SUPERVISORY PANEL:		
Panel members' compensation		\$ 427,064
Consultants' compensation		292,478
Travel expenses		114,588
Notification expenses		157,508
Miscellaneous		13,012
Total		\$ 1,004,650
 ADMINISTRATIVE OFFICE:		
Rents	\$ 54,000	\$ 40,593
Office payroll	298,000	215,252
Payroll taxes	18,000	12,733
Employee benefits	18,000	15,010
Outside services	96,000	32,921
Printing and postage	48,000	2,619
General insurance	3,000	900
Telephone	24,000	13,082
Office supplies and expense	12,000	1,934
Travel	6,000	
Depreciation	4,000	4,647
Miscellaneous	12,000	753
Total	\$ 593,000	\$ 340,444



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

*Statements of Assets, Liabilities and Fund Balance
- Modified Cash Basis as of December 31, 1997
and 1996 and Statements of Income, Expenses
and Benefit Payments and Change in Fund
Balance - Modified Cash Basis for the Years
Ended December 31, 1997 and 1996 and
Independent Auditor's Report*



INDEPENDENT AUDITORS' REPORT

Bowling - Pfizer Heart Valve Litigation Settlement Fund
525 Vine Street, Suite 805
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, 1997 and 1996 and the related statements of income, expenses and benefit payments and change in fund balance - modified cash basis for the years then ended. 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, 1997 and 1996 and its income, expenses and benefit payments and change in fund balance for the years then ended on the basis of accounting described in Note 2.

Deloitte & Touche LLP

October 9, 1998

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

STATEMENTS OF ASSETS, LIABILITIES AND FUND BALANCE - MODIFIED CASH BASIS AS OF DECEMBER 31, 1997 AND 1996

	1997	1996
ASSETS		
CASH	<u>\$ 150,658</u>	<u>\$ 8,947</u>
INVESTMENTS (Note 3):		
Consultation Fund	3,605,202	45,657,075
Patient Benefit Fund	<u>12,588,169</u>	<u>9,050,071</u>
Total Investments	16,193,371	54,707,146
TAX REFUND RECEIVABLE (Notes 2,6)	1,419,837	293,636
OTHER ASSETS (Note 2)	<u>25,793</u>	<u>67,303</u>
TOTAL ASSETS	<u>\$17,789,659</u>	<u>\$55,077,032</u>
LIABILITIES AND FUND BALANCE		
ACCOUNTS PAYABLE AND ACCRUED EXPENSES (Note 2)	\$ 995,967	\$ 778,192
Total Liabilities	<u>995,967</u>	<u>778,192</u>
FUND BALANCE (Note 1):		
Consultation Fund	4,918,388	45,990,235
Patient Benefit Fund	<u>11,875,304</u>	<u>8,308,605</u>
Total Fund Balance	<u>16,793,692</u>	<u>54,298,840</u>
TOTAL LIABILITIES AND FUND BALANCE	<u>\$17,789,659</u>	<u>\$55,077,032</u>

See notes to modified cash basis financial statements.

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

STATEMENTS OF INCOME, EXPENSES AND BENEFIT PAYMENTS AND CHANGE IN FUND BALANCE - MODIFIED CASH BASIS FOR THE YEARS ENDED DECEMBER 31, 1997 AND 1996

	1997	1996
INCOME:		
Settlement payments by Pfizer/Shiley (Note 1)	\$ 6,250,000	\$ 6,250,000
Net investment income	1,480,771	3,299,943
Income tax refunds (Note 6)	1,650,389	
Miscellaneous income (Note 6)	169,440	
Total Income	<u>9,550,600</u>	<u>9,549,943</u>
EXPENSES AND BENEFIT PAYMENTS:		
Benefit payments - Consultation Fund (Note 2)	42,963,554	13,383,250
Benefit payments - valve replacement surgery	43,279	639,969
Research programs	1,002,147	4,399,354
Litigation attorneys - fees and expenses (Note 2)	737,765	11,073,946
Supervisory panel expenses (Note 1)	1,513,398	1,321,251
Trustees' fees and expenses	206,563	193,928
Professional fees (Note 5)	58,130	85,672
Research Management Group	63,230	358,070
Other administrative expenses	467,682	485,311
Notification expense		124,214
Total expenses and benefit payments	<u>47,055,748</u>	<u>32,064,965</u>
DECREASE IN FUND BALANCE	(37,505,148)	(22,515,022)
FUND BALANCE, BEGINNING OF YEAR	<u>54,298,840</u>	<u>76,813,862</u>
FUND BALANCE, END OF YEAR	<u>\$ 16,793,692</u>	<u>\$ 54,298,840</u>

See notes to modified cash basis 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 medical 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 qualified 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 qualified Plaintiff spouses.

The terms of the Settlement required 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 \$80,000,000 to the Consultation Fund in 1992. In 1994 Pfizer/Shiley paid \$10,000,000 to the Consultation Fund and \$12,500,000 to the Patient Benefit Fund. Pfizer/Shiley also paid \$6,250,000 in October 1996 and 1997, respectively, to the Patient Benefit Fund.

As of December 31, 1997, the Fund had received Consultation Fund proof of claim forms from 15,907 potential implantee claimants. All of these claims had been processed and 13,350 had been approved as valid claims under the Settlement Agreement. At December 31, 1997 the Consultation Fund had distributed \$87,072,554 to claimants. As of October 9, 1998 total payments to Plaintiff implantees and Plaintiff spouses was \$87,104,615.

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) (see Note 6) 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" are recognized when paid rather than when incurred.

Settlement Payments - 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.

Amounts Due to Pfizer/Shiley - The Fund 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 agreed to contract for, and continue certain research programs that were initiated by Shiley Incorporated. In addition, the Fund 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 came under the control of the Supervisory Panel. These amounts were paid to Pfizer/Shiley after review by the Fund and approval by the Court. These amounts were reported as a distribution when paid by the Fund. These amounts were paid in full during 1996 and reported as benefit payments - valve replacement surgery and research programs in the statement of income, expenses and benefit payments and change in fund balance.

Litigation Attorneys - Fees and Expenses - Represents Court approved payments to Plaintiffs' counsel and to Public Citizen, Inc.

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

Estimates - The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts in the financial statements. Actual results could differ from the estimates.

3. INVESTMENTS

Investments at December 31, 1997 and 1996 consist of U.S. Treasury Bills and are carried at cost plus accrued interest. The market value of such investments was approximately \$16,206,000 and \$54,809,000, at December 31, 1997 and 1996, respectively.

4. OPERATING LEASES

The Fund leases its office facilities under an agreement classified as an operating lease from an unrelated party. Total future minimum lease payments due are as follows:

1998	\$ 54,670
1999	64,113
2000	67,260
2001	67,260
2002	67,260
Thereafter	<u>84,075</u>
Total	<u>\$ 404,638</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 \$14,851 and \$14,422 in 1997 and 1996.

6. TAX STATUS

For Federal income tax purposes, the Fund is treated as a taxable complex trust, a "Settlement Fund" under Section 468(B) of the Internal Revenue Code. 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 payment of Plaintiffs' counsel fees and expenses are not taxable transactions.

In March 1996, the Fund requested a ruling from the Internal Revenue Service, regarding the taxability of the Fund and the deductibility of certain disbursements from the Fund. In January 1997, the Fund received a favorable ruling regarding these issues and, consequently, recorded no tax provision for 1997 or 1996.

The Fund filed claims for refunds for 1993, 1994, 1995 and 1996 based upon this ruling. Refunds of \$681,700 were received by the Fund in 1997. The Internal Revenue Service completed their tax audits for these tax years in January 1998. The Fund subsequently received an additional \$1,262,325 in refunds and \$157,512 in interest relating to those tax years. The interest is included in miscellaneous income in the financial statements.

* * * * *