UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

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

ELEVENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

COVERING PERIOD FROM JUNE 18, 1999 TO DECEMBER 22, 1999

SPECIAL MASTERS/TRUSTEES

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

AGENDA

ELEVENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

December 22, 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. Eleventh Report of the Special Masters/Trustees

B. Appendices to Court Report

1. Unaudited balance sheet as of October 31, 1999 and an unaudited statement of income, benefit payments and funds balance for the ten months ended October 31, 1999.

2. Independent auditor's report for the year ended December 31, 1998 from Deloitte & Touche, LLP.

UNITED STATES DISTRICT COURT

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

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

Your Special Masters/Trustees respectfully present their eleventh periodic report, covering activities from June 18, 1999 to December 22, 1999.

I. CONSULTATION FUND

As previously reported, final distributions from the Consultation Fund have been approved and sent to each qualified implantee and spousal claimant and the Consultation Fund has been closed. There are still checks on the Consultation Fund issued to qualified claimants aggregating more than $1,000,000 that 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. The Trustees have obtained the assistance of heart valve registries (both U.S. and foreign), other foreign governmental agencies, doctors and hospitals known to have assisted claimants in filing claims, researchers with claimant data

and foreign legal counsel who have previously assisted Class Counsel in the Settlement proceedings. In addition, assistance has been provided by other legal representatives, relatives of claimants and a CD Rom directory. A major problem is that many of the claimants are deceased and their next of kin do not have the same mailing address. Although progress has been made with some of the unnegotiated checks, this is a slow process particularly for the claimants in foreign countries. Follow-up correspondence has been sent with respect to all foreign claimants and is being completed for the U.S. claimants. The Trustees will utilize all reasonable means to locate these claimants or their beneficiaries.

II. PATIENT BENEFIT FUND

A. Amended Guidelines. On November 23, 1999, the Supervisory Panel approved *Amended Guidelines To Assess Patients With Bjork-Shiley Convexo-Concave Heart Valves For Elective Explantation* (herein "Amended Guidelines"). These have been presented to the Court for approval. The production of the Amended Guidelines has been a major objective of the Panel for two and a half years, and it carries out the promise made to the Court and the parties at the hearing on June 18, 1999, to propose updated guidelines by the end of the year. Credit must be given to Chairman J. Kermit Smith for this major accomplishment. Without his leadership, it would not have been done.

The Panel has benefitted from two years of experience with the 1997 Guidelines, continued intensive investigation, and the reports

from cohort studies in the Netherlands, the United Kingdom and the U. S. (MedicAlert). Those reports come from independent research by the principal investigators and their scientific colleagues. It has been an exemplary demonstration of international cooperation. The contributions of Dr. Yolanda van der Graaf of the Netherlands and Prof. Kenneth Taylor of the United Kingdom must be recognized with appreciation.

The data derived from these studies have been merged, bringing together the experience of 15,841 patients. That is a significant base for epidemiological calculations. Using the same methodology and the same scope of inquiry as was employed by the Panel and approved by the Court in 1997, the scientists of these three countries have agreed on what are the objective factors that must be considered in order to determine the risks of strut fracture and the risks of surgical replacement. The factors used to assess the risks of surgical replacement are the same factors used daily by the medical profession.

The Amended Guidelines contain significant changes from the 1997 Guidelines. One new predictive factor has been added to the six factors that in 1997 comprised the set of factors relevant to the determination of the risks of strut fracture. It is the gender of the patient. Females are close to half as likely to suffer a strut fracture as males. Although this consideration was not used in the 1997 Guidelines, the subsequent studies show that there is a remarkable difference of risk of strut fracture between male and female implantees.

Reexamination of the importance of the particular shop order from which a valve emerged has caused this factor to be amended. Rather than identifying 13 shop orders as high risk, the new formula divides all shop orders into three groups:

A. Shop orders with fractures of more than 5% of the valves.

B. Shop orders with more than 1% and less than 5% fractures.

C. Shop orders with less than 1% fractures.

Welders were a significant factor and remain so, but for 60° valves the difference between Group A and Group B became insignificant and these two Groups were combined. The result is that there are two Groups of welders in the proposed Amended Guidelines.

Underreporting of strut fractures (particularly aortic valves) was reexamined in the three cohort study. While the old standard for underreporting was based on the original Netherlands study, the new standard derives from the combined figures from the Netherlands and the United Kingdom. Further, an inflation factor (addition to reported fractures) of 10% is included in order to account for underreporting in the Netherlands and the United Kingdom.

In order to calculate life expectancy, new background mortality rates from competing causes of death were derived from actual experience with BSCC valve patients. These rates are now incorporated in the Amended Guidelines rather than the general population life tables. Different methodology has been used in patients with double valves by including the additive fracture rates of both valves.

The operative mortality rate was reduced from 6% to 3% at age 58 (on a curve showing lesser rates at younger ages and higher rates at older ages). This change came from the merger of the three cohort studies and the incorporation of published and unpublished recent mortality rates in reoperative patients.

The data shows that even with a 97% survival of replacement surgery, there are serious morbidities from replacement surgery, including stroke and other problems (terminal renal failure, pulmonary disability, among others). These morbidities are quantifiable and have such an impact on a person's life after surgery that they must be considered life-changing events affecting a person's ability to return to the presurgery state of health and well being, given any length of time to recover. (The Claims Administrator reported, for instance, that 2 of 10 implantees claiming benefits for surgical replacement suffered serious morbidity.) There is data in this regard from three studies of postsurgical events, but it is not extensive.

Members of the Panel used their long experience with morbidity, and it is the best medical judgment of the Supervisory Panel that the serious morbidity rate equals the mortality rate. At age 58, to provide for serious morbidity, a factor of 3% must be added. Taken together, these two factors, being 6% at age 58, emphasize operative outcome and are called reoperative risk.

The matter of a <u>meaningful</u> extension of life expectancy is addressed and taken into account by use of the 6% operative risk factor. The factor of a two-year extension of life is no longer

needed and is dropped. Any postsurgical gain (survival) is sufficient.

The experience of the last few years as observed by scientists in three countries demonstrates the crucial centrality of the patient's age at the time of replacement operation. Risk of strut fracture is shown to reduce with age, while risk of replacement operation increases with age. For this reason, the Panel decided that it was no longer scientifically reasonable to consider the old guidelines, whether promulgated by Pfizer-Shiley prior to 1997 or approved by the Court in 1997.

It has been determined that the median age of the Class is calculated to be 70 years. Half of the Class are younger than 70 and half are older than 70.

It is estimated (1) that the number of patients with 60 degree BSCC heart valves who are alive and will qualify for reoperation are:

1997 Guidelines	**Amended Guidelines**
No. alive: 38,936	No. alive 29,937
No. qualify: 385*	No. qualify: 1,042

* Does not include patients who met only the pre-1997 Guidelines (Shiley).

(2) that the number of patients with 70 degree BSCC heart valves who are alive and will qualify for reoperation are:

1997 Guidelines	Amended Guidelines
No. alive: 1,758	No. alive 1,348
No. qualify: 144*	No. qualify: 269

* Does not include patients who met only the pre-1997 Guidelines (Shiley).

For patients with 60 degree valves and those with 70 degree valves, approximately 92% who would have qualified under the 1997 Guidelines on August 1, 1997 would still qualify under the Amended Guidelines on January 1, 2000.

Prior to adoption by the Supervisory Panel, the Amended Guidelines were sent for comment to counsel for the parties and for Public Citizen, to health authorities in the Netherlands, the United Kingdom, Canada, Australia and France, and to Sweden. The only recipient who has commented adversely on the Amended Guidelines is Class Counsel, who declined to give approval.

B. Dissemination of Amended Guidelines. Once the Amended Guidelines are approved by the Court and the calculator database is updated, the Claims Administrator will be able to identify those Class members known to qualify for valve replacement benefits, both foreign and domestic. The Trustees and the Chairman of the Supervisory Panel are preparing a plan for informing these Class Members and their physicians (where known) promptly, advising that they should consult about valve replacement. In addition, a plan is prepared to advise selected physicians, hospitals and health officials about the Amended Guidelines, and to take other steps, so

that the information will be in the hands of Class Members. The Trustees will promptly submit for Court approval the forms of letters to carry out this notification. They will also honor the established practices about the means of notifying individual patients in Australia, Canada, France, the Netherlands, Sweden, and the United Kingdom.

C. Research. The Supervisory Panel's research program continues to be pursued along the lines previously reported to the Court, seeking a reliable diagnostic technique to detect and identify high risk valves. We cannot report any significant success at this time, but the search continues in order to make sure that no avenue with probable success is ignored. A brief review of the existing research projects follows.

Cal-Tech is seeking to develop an acoustic reporting device, or an acoustic vibrometer, and has contracted with the Mayo Clinic, which has developed the necessary tools for this purpose.

Vanderbilt University, working with Iowa University, is working on the recording of magnetic signals from the valve when placed in a transducer.

The researchers at Lawrence Livermore Nuclear Laboratories continue their pursuit of a way to refine the sounds coming from an implanted valve in order to distinguish an intact valve from one with a break in one leg of the outlet strut. This work is being carefully monitored by Panel members so that its promises can be made real.

Information System Laboratories, San Diego, is trying to do with external coils what Vanderbilt University is trying to do with detector positioned close to the valve.

The Edison Welding Group is continuing its metallurgical investigation of the weld and the outlet strut in order to determine whether there are discernible factors that would aid in identifying a high risk strut.

In addition to the search for a diagnostic technique to detect a high risk valve, the Panel has completed a follow-up study of the implantees who participated in the imaging studies at Beaumont, Stanford and Glasgow. The implantees were asked to fill out an extensive questionnaire, and responses have been received from 76% of them. The results are that their health status was not good. Over half had been hospitalized again during the period since valve replacement surgery. Many of this group of implantees are taking 7 to 10 cardiac drugs each.

D. Dutch Studies. The first and second Dutch BSCC cohort studies, which have been completed, began in 1989 and 1994, respectively. In both studies the risk of outlet strut fracture has been examined in relation to a number of patient and valve related risk factors. The findings of all these studies have been used to develop decision analytic models. The end results of both studies were scientific papers that have been published in peer-reviewed journals.

In June 1998 the Dutch team started to gather the follow-up data on the surviving Dutch BSCC recipients for the Third Dutch

BSCC follow-up study. This time the data have been gathered through the cardiothoracic surgeons. Currently, data from two Dutch hospitals still need to be collected.

In addition to the continued monitoring of the cohort, new research activities are being done in the Netherlands. A study examining the relevance of findings on MRIs of the brain of patients who experienced strut fracture is underway. In the pipeline are also studies on the risk of reoperation of the cohort and the association between manufacturing characteristics and the wear status of BSCC valves. Finally, the Dutch researchers have expressed their wish to externally validate the latest decision analytic model.

Dr. Yolanda van der Graaf presented the design of the planned MRI study: An occasional observation was brought to the attention of the Dutch researchers: a patient whose BSCC heart valve was replaced, because of a perivalvular leakage, was found to have suffered from brain hemorrhage. On the brain MRI round "black holes" (also found to be related to neurosurgery operations) were seen. The explanted BSCC valve showed a single leg separation. Results of a pilot study, performed after this occasional observation showed that nearly all BSCC patients with explanted BSCC valves showed artifacts on the brain MRI. Defects were largest in patients who experienced outlet strut fracture but also patients with single leg fractures and intact BSCC valves showed artifacts on the MRI. Artifacts were also present in the two patients with fractured Duromedics heart valves. There are several

reasons that might explain these findings. First, the "black holes" may be the result of paramagnetic defects due to embolization of tiny pieces of metal; second defects may be due to the surgical interventions (surgical tools, heart-lung machine); and third, defects may be due to minimal hemorrhages, possibly related to long term anticoagulant use. In the planned study (November 1999-November 2000) all these hypotheses will be tested.

E. Imaging Tests. The program to offer imaging tests at Penn State to implantees who qualify for valve replacement surgery is nearing approval. The cost of imaging ($1,875) and the associated expenses (travel, accommodations, meals, etc.) will be paid by the Patient Benefit Fund. This imaging is also available to those Class Members who do not qualify for valve replacement surgery, but they must pay the costs and the associated expenses of the procedure.

F. Independent Review of Research. Two organizations are working on independent review of all the research carried out to date about the BSCC heart valve, the risks of strut fracture, and the rate of operative risk, whether the studies were sponsored by Pfizer/Shiley or by the Panel. One organization is the Institute for Health Policy and Health Services Research at the University of Cincinnati (as previously reported), and the other is the Battelle Institute in Columbus, Ohio. The principals from both organizations are scheduled to have a joint conference in January 2000.

G. Repository. Some progress has been made on establishing the repository required by Section 5.4.4.3 of the Settlement Agreement, but there is much to be done. The Trustees and the Chairman of the Supervisory Panel conferred with Pfizer

representatives early in December, the principal subject of the discussion being about copyright and confidentiality. The Repository is to be publicly accessible, and the question of confidentiality is an important issue in light of the fact that Pfizer is confronted with litigation initiated by implantees who opted out, or by Class Members who have chosen to arbitrate their claims or take them to court. The Chairman awaits a statement from Pfizer disclosing their position. Thereafter, the Chairman must consult with Class Counsel to hear their position before developing a plan to present to the Court for approval.

H. Valve Replacement Surgery Claims and Fracture Claims. The Claims Administrator has received 445 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 445 claims, there are 73 (58 foreign) qualified outlet strut fracture claims, 36 (15 foreign) qualified single leg fracture claims and 56 (22 foreign) qualified valve replacement surgery claims. Some of the claimants have elected other courses of action rather than to receive the Settlement benefits. The remaining claims have been reviewed and they either do not qualify or additional information is needed and has been requested from the claimants.

The office of the Claims Administrator continues to fulfill requests to calculate estimated annual fracture rates under the

1997 Guidelines. As previously reported, 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, 59 have had their BSCC heart valves explanted, including 12 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 October 31, 1999, the total balance of cash and cash equivalents was $19,424,588. This amount takes into account net interest earned from January 28, 1992 through October 31, 1999, in the aggregate amount of $20,528,253.

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

The Trustees have received the audit report for the year ended December 31, 1998 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 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 the Amended Guidelines as separately submitted, and

(c) approve or provide direction with respect to each of the Appendices to this Report, and

(d) fix the date of the next Report.

Respectfully submitted,

Dated: December 22, 1999

_____
Hon. Robert L. Black, Jr.

_____
Peter J. Strauss, Esq.

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF OCTOBER 31, 1999

UNAUDITED

ASSETS

CASH	$ 152,386
U.S. TREASURY BILLS (Par Value $)	19,272,202
OTHER ASSETS	16,446
	$ 19,441,034

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	$ 629,364(1)
FUNDS BALANCE	18,811,670
	$ 19,441,034

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

TRUSTEES FOR THE BOWLING-PFIZER HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME, BENEFIT PAYMENTS AND FUNDS BALANCE

FOR THE TEN MONTHS ENDED OCTOBER 31, 1999

UNAUDITED

INCOME:	
Investment interest	$ 623,546
Miscellaneous	19,969
Total	643,515
BENEFIT PAYMENTS - VALVE REPLACEMENT SURGERY	198,765
RESEARCH PROGRAMS	1,097,570
LITIGATION ATTORNEYS - FEES & EXPENSES	987,321(1)
EXPENSES:	
Supervisory Panel	1,214,559(2)
Trustees' fees and expenses	139,684
Professional fees	72,732
Administrative office	355,284(2)
Total	1,782,259
CONTRIBUTION BY SHILEY INCORPORATED	6,250,000
NET CHANGE IN FUNDS BALANCE	2,827,600(1)
FUNDS BALANCE, DECEMBER 31, 1998	15,984,070
FUNDS BALANCE, OCTOBER 31, 1999	$ 18,811,670

(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

	BUDGET 1/1/99-12/31/99	ACTUAL 1/1/99-10/31/99
SUPERVISORY PANEL:		
Panel members' compensation		$ 531,140
Consultants' compensation		501,635
Travel expenses		169,228
Miscellaneous		12,556
Total		$ 1,214,559
ADMINISTRATIVE OFFICE:		
Rents	$ 67,000	$ 55,179
Office payroll	298,000	229,546
Payroll taxes	18,000	13,467
Employee benefits	21,000	17,431
Outside services	72,000	15,312
Printing and postage	36,000	3,644
General insurance	3,000	1,028
Telephone	24,000	12,356
Office supplies and expense	12,000	1,998
Travel	6,000	
Depreciation	7,000	4,543
Miscellaneous	12,000	780
Total	$ 576,000	$ 355,284

Deloitte & Touche

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

Statements of Assets, Liabilities and Fund Balance - Modified Cash Basis as of December 31, 1998 and 1997 and Statements of Income, Expenses and Benefit Payments and Change in Fund Balance - Modified Cash Basis for the Years Ended December 31, 1998 and 1997 and Independent Auditors' Report

Deloitte Touche Tohmatsu

Deloitte & Touche

Deloitte & Touche LLP
250 East Fifth Street
P.O. Box 5340
Cincinnati, Ohio 45201-5340

Telephone: (513) 784-7100

INDEPENDENT AUDITORS' REPORT

Bowling - Pfizer Heart Valve Litigation Settlement Fund:

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, 1998 and 1997 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, 1998 and 1997 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 21, 1999

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

STATEMENTS OF ASSETS, LIABILITIES AND FUND BALANCE - MODIFIED CASH BASIS AS OF DECEMBER 31, 1998 AND 1997

	1998	1997
ASSETS		
CASH	$ 208,449	$ 150,658
INVESTMENTS (Note 3):		
Consultation Fund	-	3,605,202
Patient Benefit Fund	16,677,092	12,588,169
Total Investments	16,677,092	16,193,371
TAX REFUND RECEIVABLE (Note 6)		1,419,837
OTHER ASSETS (Note 2)	27,489	25,793
TOTAL ASSETS	$16,913,030	$17,789,659
LIABILITIES AND FUND BALANCE		
ACCOUNTS PAYABLE AND ACCRUED EXPENSES (Note 2)	$ 928,960	$ 995,967
Total Liabilities	928,960	995,967
FUND BALANCE (Note 1):		
Consultation Fund	-	4,918,388
Patient Benefit Fund	15,984,070	11,875,304
Total Fund Balance	15,984,070	16,793,692
TOTAL LIABILITIES AND FUND BALANCE	$16,913,030	$17,789,659

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, 1998 AND 1997

	1998	1997
INCOME:		
Settlement payments by Pfizer/Shiley (Note 1)	$ 6,250,000	$ 6,250,000
Net investment income	883,172	1,480,771
Income tax refunds (Note 6)		1,650,389
Miscellaneous income (Note 6)		169,440
Total income	7,133,172	9,550,600
EXPENSES AND BENEFIT PAYMENTS:		
Benefit payments - Consultation Fund (Note 2)	4,645,760	42,963,554
Benefit payments - valve replacement surgery	29,152	43,279
Research programs	1,315,031	1,002,147
Litigation attorneys - fees and expenses (Note 2)		737,765
Supervisory panel expenses (Note 1)	1,163,262	1,513,398
Trustees' fees and expenses	142,165	206,563
Notification expense	160,173	
Professional fees (Note 5)	53,387	58,130
Research Management Group		63,230
Other administrative expenses	433,864	467,682
Total expenses and benefit payments	7,942,794	47,055,748
DECREASE IN FUND BALANCE	(809,622)	(37,505,148)
FUND BALANCE, BEGINNNG OF YEAR	16,793,692	54,298,840
FUND BALANCE, END OF YEAR	$15,984,070	$ 16,793,692

See notes to modified cash basis financial statements.

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

NOTES TO MODIFIED CASH BASIS FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 1998 AND 1997

1. ORGANIZATION AND GENERAL INFORMATION

The Bowling-Pfizer Heart Valve Litigation Settlement Fund (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. At December 31, 1998 the Consultation Fund had distributed $91,718,314 to claimants.

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 and September 1998, respectively, to the Patient Benefit Fund.

The research activities of the Patient Benefit Fund are supervised by a Supervisory Panel (Panel). The Panel, subject to Court approval, shall adopt and amend 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.

Settlement Payments - All Consultation Fund claims submitted by each claimant were reviewed for qualification by the Fund and payments of qualified claims were approved by the Court.

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, 1998 and 1997 consist of U.S. Treasury Bills and are carried at cost plus accrued interest. The market value of such investments was approximately $16,678,000 and $16,206,000, at December 31, 1998 and 1997, 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:

1999	$ 64,113
2000	67,260
2001	67,260
2002	67,260
2003	67,260
Thereafter	16,815
Total	$ 349,968

5. RELATED PARTY TRANSACTIONS

One trustee of the Fund was 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 in 1997.

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 1998 or 1997.

The Fund filed claims for refunds for 1993, 1994, 1995 and 1996 based upon this ruling. Refunds and returned estimated payments 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 recorded an additional $1,262,325 in refunds and $157,512 in interest relating to those tax years in 1997. These amounts were received in 1998. The interest is included in miscellaneous income in the financial statements.

* * * * * *