

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

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

---

THIRTEENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING PERIOD FROM JUNE 27, 2000 TO DECEMBER 13, 2000

---

SPECIAL MASTERS/TRUSTEES

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

**AGENDA**

**THIRTEENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES**

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

December 13, 2000  
11:00 A.M.

Hon. Herman J. Weber

1. Introductory remarks by Judge Weber.
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 Weber.

## TABLE OF CONTENTS

- A. Thirteenth Report of the Special Masters/Trustees
- B. Appendices to Court Report
  - 1. Unaudited balance sheet as of October 31, 2000 and an unaudited statement of income and funds balance for the ten months ended October 31, 2000.
  - 2. Independent Auditors' Report for the year ended December 31, 1999.
  - 3. Proposal of Deloitte & Touche for auditing services for the year ending December 31, 2000.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

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

---

THIRTEENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES  
COVERING PERIOD FROM JUNE 27, 2000 TO DECEMBER 13, 2000

---

SPECIAL MASTERS/TRUSTEES

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

**AGENDA**

**THIRTEENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES**

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

December 13, 2000  
11:00 A.M.

Hon. Herman J. Weber

1. Introductory remarks by Judge Weber.
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 Weber.

## TABLE OF CONTENTS

- A. Thirteenth Report of the Special Masters/Trustees
- B. Appendices to Court Report
  - 1. Unaudited balance sheet as of October 31, 2000 and an unaudited statement of income and funds balance for the ten months ended October 31, 2000.
  - 2. Independent Auditors' Report for the year ended December 31, 1999.
  - 3. Proposal of Deloitte & Touche for auditing services for the year ending December 31, 2000.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

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

---

THIRTEENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

---

To the Honorable Herman J. Weber, Judge, United States District Court:

Your Special Masters/Trustees respectfully present their thirteenth periodic report, covering activities from June 27, 2000 to December 13, 2000. This is the first periodic report made to Judge Herman J. Weber, to whom the case was reassigned after the recusal of Judge Spiegel.

**I. CONSULTATION FUND**

There remain checks on the Consultation Fund issued to qualified claimants aggregating approximately \$800,000 that have not been negotiated and are outstanding. As previously reported, the total approved distributions were \$6,147 each for implantees and \$1,009 each for spouses of implantees resulting in a total amount of \$91,718,314 sent to claimants.

The Trustees continue to attempt to locate those claimants who have checks outstanding and unnegotiated, and to pay them. As previously reported 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. The names and addresses of these claimants have also been provided to Class Counsel. A major problem is that many of the claimants are deceased and their next of kin do not have the same mailing address. The Trustees will continue to utilize all reasonable means to locate these claimants or their beneficiaries.

## **II. PATIENT BENEFIT FUND**

**A. 2000 Amended Guidelines.** Pursuant to the Court's order of March 8, 2000 (Document 1440) that the Trustees provide to Class Counsel and Special Counsel the materials used in designing the 2000 Amended Guidelines, the Trustees and the Chairman of the Supervisory Panel delivered those materials that were controlled by the Panel and used in guideline design, under a confidentiality agreement. These materials did not include the Shiley research database, which is owned by Defendant Pfizer. That database was delivered to Class Counsel on August 30, 2000, after both parties had signed a protective order (signed copy was filed September 5, 2000 as Document 1547, under the Court's order of July 18, 2000 approving the protective order, Document 1503.)



Dissemination of the 2000 Amended Guidelines has been completed in accordance with the procedures outlined in the Trustees' Twelfth Report.

B. Research. The Supervisory Panel met in Cincinnati, as the Court knows, on December 5 and 6, 2000. This Report covers the activities of the Panel since the Twelfth Report plus the actions taken and matters decided at the Panel meeting. Class and Special Counsel and Counsel for Defendants were present and had full opportunity to participate in the discussions on December 5, 2000.

The Epidemiology Committee held a conference in London, England, September 25 and 26, 2000, attended by scientists and physicians from United Kingdom, the Netherlands, Australia, Canada and Sweden. Trustee Robert L. Black, Special Counsel James T. Capretz and John T. Johnson, Counsel for Defendants Robert B. Conley, and Counsel for Public Citizen Brian Wolfman, all attended and participated in the discussion. The purpose of the conference was to review the prior epidemiological research forming the foundation for the guidelines and to elicit comments and criticisms, particularly from those persons who had no prior association with the development and design of the guidelines.

At the December 2000 Panel meeting, the report of the Epidemiological Subcommittee resulted in a series of decisions. A feasibility study to determine the advisability of proceeding with a cohort study of implantees in Poland and the Scandinavian countries was authorized. Dr. Ron Brookmeyer will continue his investigation of the latest data on those risk factors included in

the Guidelines, with attention being paid to the factors of age, underreporting and gender. While there are less fractures being reported in recent years than in the 1980s, there are also fewer implantees still alive, and the rate of fracture should be reexamined. Dr. William Blot will continue his investigation into effect of rewelding or reworking of valves during the manufacturing processes. The work of both Dr. Brookmeyer and Dr. Blot, our expert consultants, will maintain their surveillance of the latest data.

The need to make the Guidelines "user friendly" was discussed, and it was the consensus of the Panel that the manner of communicating the impact of the Guidelines shall be carefully considered when the next guideline amendment is approved.

The proposal from Dr. Yolanda van der Graaf to continue monitoring the Dutch cohort for another two years (retroactive to May 2000) was approved. Her project researching significance of "artifacts" disclosed in MRI scans of the brains of implantees is continuing.

Dr. Tom Ivey, reporting for the Guidelines Committee, stated that in the absence of significant new data about the risk factors used in the Guidelines, there is no need to consider amending them at this moment. It is clear that this report in no way precludes further guideline amendments in the future.

The Imaging and Acoustics Committee conferred in Pasadena, California, October 26 and 27, 2000. The conference was attended by the principal investigators (and their associates) of the

several research projects under way, two independent consultants, and Trustee Peter J. Strauss. Also attending were Special Counsel James T. Capretz and John T. Johnson, and Counsel for Defendants Robert B. Conley.

The emphasis continues on research to develop effective and useable acoustic techniques for the identification of defective or high risk valves. As to the pursuit of passive acoustic techniques, the project at Lawrence Livermore National Laboratories has been terminated, and by reason of the unresolved controversy over the impartiality of Dr. Allen Eberhardt (he has served as an expert witness for Pfizer in BSCC heart valve litigation), no project has been authorized at Structural Acoustics, Inc. The Panel does not discard the possibility of returning to passive acoustics in the future because the development of new technology proceeds unabated.

The research project at BioQuantetics, Inc., to develop an active acoustic technique using vibro-acoustography to identify high risk valves continues to hold encouraging promise. This project is important to the Class, and its scientific goals and milestones for the year 2001 should be clear. The first step of this project began in May, 2000, and it has now been authorized by the Panel to continue into the next steps to be completed in 2001, subject to appropriate adjustments to the proposed budget.

The project using an electromagnetic acoustic transponder was originally under the aegis of Vanderbilt University working in conjunction with researchers at Iowa State University. Dr. John P.

Wikswow, the principal investigator at Vanderbilt, has reported that the technique being developed at Iowa, known as EMAT, has much greater promise of success than the Vanderbilt technique, known as SQUID. The reason is that it has been demonstrated to Dr. Wikswow's satisfaction that EMAT can be tuned to discriminate between single leg separation valves and intact valves, whereas SQUID cannot be so tuned. At his suggestion, the contract with Vanderbilt is being terminated and a new contract (and protocol) with Iowa State was approved in principle, subject to a revised budget and clear goals and milestones for the year 2001.

After considerable discussion with Class Counsel, who initially opposed any project to study the effect of what is known as the "hook deflection test," and the withdrawal of the Trustees' initial application for approval, a revised proposal was agreed upon and thereafter approved by the Court. This research will be pursued by the Imperial College School of Medicine at Hammersmith Hospital. The "hook deflection test" was a procedure used for a limited period of time at one step in the manufacture of BSCC heart valves, whereby the outlet strut was weighted and stressed. The Dutch and British studies developed data that suggested that those valves that had been submitted to two or more hook deflection tests were many times more likely to fracture than valves not so tested. However, the data was so sparse that a study of 1100 of Pfizer's manufacturing records will be necessary before any conclusions could be reached.

Edison Welding Institute proposed three new studies, and the Panel approved two. One will study outlet strut fracturing process, and the other seeks improved frequency analysis for determination of damage in heart valves. These projects are closely linked and will have only one budget to achieve considerable savings.

The Panel wants the project at EWI to be coordinated with a metallurgical research study proposed by Dr. Pat Lawford of the United Kingdom. The first phase of her study was approved with the requirement that the principal investigators of both studies meet and work together. The other phases of her proposal need clarification. The two investigators should attend the next Panel meeting together with their reports on progress to date.

The proposed project at Information Systems Laboratories (ISL), using a coil to induce an electronic beam to detect the status of a valve, raised a number of questions to be answered before approval can be given. The Panel will engage a specialist for consultation on this project.

The Imaging and Acoustics Subcommittee recommended adoption of a new proposal (made the day before) by the University of Cincinnati Institute for Health Policy and Health Services Research, to continue their present contract in order to create a database with web-based system of abstracts of scientific and medical articles pertinent to the BSCC valve. This database will be of great benefit for Panel investigators and the medical profession. The project was approved subject to modifications

required by the Panel and the negotiation of the budget and a review of both indexing and instructions for its use.

C. Independent Review of Research. At the December 2000 meeting of the Supervisory Panel, Dr. Robert L. Ludke, Ph.D., presented the Preliminary Final report of the U.C. Institute For Health Policy and Health Services Research, being an independent review of all research on BSCC heart valves, whether conducted by Pfizer, Shiley or the Panel. The Chairman assigned each Subcommittee to review those aspects of this extensive report that impinge on their jurisdiction. It was agreed that further conference with Dr. Ludke and his associates will be necessary for a thorough understanding of the criteria used by the Institute and the consequences of the recommendations.

D. Imaging Test. The program to offer an imaging test of Class Members' valves at the Hershey Institute of Penn State has imaged 9 Class Members to date, who qualify for replacement surgery benefits under the 2000 Amended Guidelines (costs fully paid), and no Class Members who do not qualify. One of the patients received an imaging grade of 4 (probable SLS) and subsequently had her BSCC heart valve explanted. The explanted valve was examined by L. Raymond & Associates and the outlet strut was found to be intact.

E. Repository. As previously reported, the Repository is being established. The documents that will be included are being scanned and indexed. This process is ongoing.

F. Valve Replacement Surgery Claims and Fracture Claims. The Claims Administrator has received in excess of 460 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 claims received, there are: 78 (60 foreign) qualified outlet strut fracture claims not including three reported fractures that have not been documented; 37 (15 foreign) qualified single leg fracture claims; and 73 (25 foreign) qualified valve replacement surgery claims including 8 previous nonqualifying replacement surgeries that now qualify under the 2000 Amended Guidelines. The total of these validated claims is 188. 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 has fulfilled requests to calculate estimated annual fracture rates under the 2000 Amended Guidelines for 1,642 BSCC heart valves. In addition, a review of the valve replacement surgery claims and the Consultation Fund claims was conducted in order to identify those implantees who may qualify for valve replacement surgery benefits under the 2000 Amended Guidelines. There are 336 implantees who may qualify

excluding those known to have had their BSCC heart valves explanted. The Claims Administrator has delivered to Class Counsel the names and addresses of these 336 implantees to be used for the mailing of the Court approved notification letter pursuant to Order of the Court entered November 21, 2000 (Document 1576).

G. Benefits under Guidelines. The Trustees' Motion For Reconsideration of Order On Benefits (Document 1541) addresses the Order (Document 1528) in which the Court held that the 1977 Guidelines shall continue in effect for those implantees who qualify for surgical replacement benefits even though they may not qualify under the 2000 Amended Guidelines (or subsequent amendments thereto). We believe the issue was fully briefed just before Judge Spiegel recused himself. The Motion remains unresolved.

### III. MOTION TO REMOVE

The appeal by Class Counsel to the Court of Appeals for the Sixth Circuit from the District Court's denial of their motion to remove three members of the Supervisory Panel has been settled and withdrawn, by agreement of the parties.

### IV. FINANCIAL INFORMATION

At October 31, 2000, the total balance of cash and cash equivalents was \$22,262,282. This amount takes into account net interest earned from January 28, 1992 through October 31, 2000, in the aggregate amount of \$21,582,043.



Attached as Appendix 1 are the following: an unaudited balance sheet as of October 31, 2000 and an unaudited statement of income and funds balance for the ten months ended October 31, 2000 (which includes the budgeted amounts for expenses for the administrative office for the period January 1, 2000 through December 31, 2000).

Attached as Appendix 2 is a copy of the Independent Auditors' Report for the year ended December 31, 1999.

Attached as Appendix 3 is a copy of the proposal of Deloitte & Touche for auditing services for the year ending December 31, 2000. The Trustees recommend that the Court approve the proposal.

#### **V. 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 have met with Class Counsel throughout the period.

**VI. 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 13, 2000

---

Hon. Robert L. Black, Jr.

---

Peter J. Strauss, Esq.

**TRUSTEES FOR THE BOWLING-PFIZER**  
**HEART VALVE SETTLEMENT FUNDS**

**BALANCE SHEET**

**AS OF OCTOBER 31, 2000**

**UNAUDITED**

**ASSETS**

CASH	\$ 117,969
U.S. TREASURY BILLS (Par Value \$22,485,000)	22,144,313
OTHER ASSETS	<u>30,095</u>
	<u><u>\$ 22,292,377</u></u>

**LIABILITIES AND FUNDS BALANCE**

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 598,655 (1)
FUNDS BALANCE	<u>21,693,722</u>
	<u><u>\$ 22,292,377</u></u>

- (1) - Does not include any provision for fees and expenses for Class Counsel and Special Counsel and Public Citizen, Inc. for the period since October 1999.

**TRUSTEES FOR THE BOWLING-PFIZER**  
**HEART VALVE SETTLEMENT FUNDS**

**STATEMENT OF INCOME AND FUNDS BALANCE**

**FOR THE TEN MONTHS ENDED OCTOBER 31, 2000**

**UNAUDITED**

INCOME - INVESTMENT INTEREST	\$ 878,268
RESEARCH PROGRAMS - COSTS	<u>1,367,359</u>
LITIGATION ATTORNEYS - FEES & EXPENSES	<u>324,385</u>
EXPENSES:	
Supervisory Panel	1,103,950 (1)
Trustees' fees and expenses	238,604
Professional fees	73,090
Administrative office	<u>363,911 (1)</u>
Total	<u>1,779,555</u>
CONTRIBUTION BY PFIZER INC.	<u>6,250,000</u>
NET CHANGE IN FUNDS BALANCE	3,656,969 (2)
FUNDS BALANCE, DECEMBER 31, 1999	<u>18,036,753</u>
FUNDS BALANCE, OCTOBER 31, 2000	<u>\$ 21,693,722</u>

(1) - See Schedule 1 herewith.

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

**TRUSTEES FOR THE BOWLING-PFIZER**  
**HEART VALVE SETTLEMENT FUNDS**

**SCHEDULE OF EXPENSES**  
**UNAUDITED**

	<u>BUDGET</u> <u>1/1/00-12/31/00</u>	<u>ACTUAL</u> <u>1/1/00-10/31/00</u>
<b>SUPERVISORY PANEL:</b>		
Panel members' compensation		\$ 584,780
Consultants' compensation		168,896
Travel expenses		141,600
Miscellaneous		4,299
Notification expenses		<u>204,375</u>
Total		<u>\$ 1,103,950</u>
<b>ADMINISTRATIVE OFFICE:</b>		
Rents	\$ 67,000	\$ 56,115
Office payroll	318,000	245,541
Payroll taxes	18,000	14,382
Employee benefits	24,000	19,170
Outside services	60,000	16,660
Printing and postage	12,000	5,946
General insurance	3,000	714
Telephone	18,000	6,560
Office supplies and expense	12,000	4,662
Travel	6,000	
Depreciation	6,000	3,851
Miscellaneous	6,000	284
Administrative services income		<u>(9,974)</u>
Total	<u>\$ 550,000</u>	<u>\$ 363,911</u>

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

*Statements of Assets, Liabilities and Fund Balance  
- Modified Cash Basis as of December 31, 1999  
and 1998 and Statements of Income, Expenses  
and Benefit Payments and Change in Fund  
Balance - Modified Cash Basis for the Years  
Ended December 31, 1999 and 1998 and  
Independent Auditors' Report*



## 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, 1999 and 1998 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 auditing standards generally accepted in the United States of America. 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 accounting principles generally accepted in the United States of America.

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, 1999 and 1998 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 6, 2000

## BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

### STATEMENTS OF ASSETS, LIABILITIES AND FUND BALANCE - MODIFIED CASH BASIS AS OF DECEMBER 31, 1999 AND 1998

---

	1999	1998
<b>ASSETS</b>		
CASH	\$ 255,422	\$ 208,449
INVESTMENTS (Note 3)	18,468,400	16,677,092
OTHER ASSETS (Note 2)	<u>21,672</u>	<u>27,489</u>
 TOTAL ASSETS	 <u>\$18,745,494</u>	 <u>\$16,913,030</u>
<b>LIABILITIES AND FUND BALANCE</b>		
ACCOUNTS PAYABLE AND ACCRUED EXPENSES (Note 2)	\$ 708,741	\$ 928,960
 FUND BALANCE (Note 1)	 <u>18,036,753</u>	 <u>15,984,070</u>
 TOTAL LIABILITIES AND FUND BALANCE	 <u>\$18,745,494</u>	 <u>\$16,913,030</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, 1999 AND 1998

	1999	1998
INCOME:		
Settlement payments by Pfizer/Shiley (Note 1)	\$ 6,250,000	\$ 6,250,000
Net investment income	798,421	883,172
Total income	<u>7,048,421</u>	<u>7,133,172</u>
EXPENSES AND BENEFIT PAYMENTS:		
Benefit payments - Consultation Fund (Note 2)		4,645,760
Benefit payments - valve replacement surgery	199,565	29,152
Research programs	1,690,430	1,315,031
Litigation attorneys - fees and expenses (Note 2)	987,322	
Supervisory panel expenses (Note 1)	1,451,561	1,163,262
Trustees' fees and expenses	169,091	142,165
Notification expense		160,173
Professional fees	75,647	53,387
Other administrative expenses	422,122	433,864
Total expenses and benefit payments	<u>4,995,738</u>	<u>7,942,794</u>
INCREASE (DECREASE) IN FUND BALANCE	2,052,683	(809,622)
FUND BALANCE, BEGINNING OF YEAR	<u>15,984,070</u>	<u>16,793,692</u>
FUND BALANCE, END OF YEAR	<u>\$ 18,036,753</u>	<u>\$ 15,984,070</u>

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, 1999 AND 1998**

---

### **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 (BSCC) 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 BSCC heart valve and replace it with another prosthetic valve.

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 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.

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 was paid, after fees and expenses, equally to all qualified Plaintiff spouses. At December 31, 1999 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 annually in 1996 through 2000 to the Patient Benefit Fund.

## 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 5) 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, 1999 and 1998 consist of U.S. Treasury Bills and are carried at cost plus accrued interest. The market value of such investments was approximately \$18,482,000 and \$16,678,000, at December 31, 1999 and 1998, 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:

2000	\$ 67,260
2001	67,260
2002	67,260
2003	67,260
2004	16,815
	<hr/>
Total	<u>\$285,855</u>

## 5. 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 1999 or 1998.

\* \* \* \* \*

2000 NOV 21 PM 1:51

**Deloitte  
& Touche**

October 24, 2000

Trustees of the Bowling-Pfizer  
Heart Valve Litigation Settlement Fund  
525 Vine Street, Suite 2300  
Cincinnati, Ohio 45202

Dear Sirs:

We are pleased to serve as independent accountants and auditors for the Bowling-Pfizer Heart Valve Litigation Settlement Fund (the "Fund"). Mr. J. David Bergmann will be responsible for the services that we perform for the Fund. He will be assisted by Michael Saemann, audit manager. Mr. Bergmann will, as he considers necessary, call on other individuals with specialized knowledge, either in this office or elsewhere in our firm, to assist in the performance of our services.

While auditing and reporting on the Fund's annual financial statements for the year ending December 31, 2000, is the service that we are to provide under this engagement letter, we would also be pleased to assist the Fund on issues as they arise throughout the year. Hence, we hope that the Fund will call Mr. Bergmann whenever management believes he can be of assistance.

We will perform this engagement subject to the terms and conditions set forth herein.

#### **AUDIT OF FINANCIAL STATEMENTS**

Our audit of the Fund's financial statements for the year ending December 31, 2000, will be conducted in accordance with auditing standards generally accepted in the United States of America.

We will plan and perform our audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether caused by error or fraud. However, because of the characteristics of fraud, particularly those involving concealment and falsified documentation (including forgery), a properly planned and performed audit may not detect a material misstatement. Therefore, an audit conducted in accordance with auditing standards generally accepted in the United States of America is designed to obtain reasonable, rather than absolute, assurance that the financial statements are free of material misstatement. An audit is not designed to detect error or fraud that is immaterial to the financial statements.

An audit includes obtaining an understanding of internal control sufficient to plan the audit and to determine the nature, timing, and extent of audit procedures to be performed. An audit is not designed to provide assurance on internal control or to identify reportable conditions.

An audit includes examining, on a test basis, evidence supporting the 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.

The objective of our audit is the expression of an opinion on the fairness of the presentation of the Fund's financial statements in conformity with the modified cash basis of accounting, in all material respects. Our ability to express an opinion, and the wording of our opinion, will, of course, be dependent on the facts and circumstances at the date of our report. If, for any reason, we are unable to complete the audit or are unable to form or have not formed an opinion, we may decline to express an opinion or decline to issue a report as a result of this engagement. If we are unable to complete our audit or if our auditors' report requires modification, the reasons therefor will be discussed with management and the Board of Trustees.

### **MANAGEMENT'S RESPONSIBILITY**

The financial statements are the responsibility of management. In this regard, management has the responsibility for, among other things, establishing and maintaining effective internal control over financial reporting, for identifying and ensuring that the Fund complies with the laws and regulations applicable to its activities, for properly recording transactions in the accounting records, for adjusting the financial statements to correct material misstatements, for making appropriate accounting estimates, for safeguarding assets, for the overall accuracy of the financial statements and their conformity with the modified cash basis of accounting, and for making all financial records and related information available to us.

We will make specific inquiries of the Fund's management about the representations embodied in the financial statements. As part of our audit procedures, we will request that management provide us with a representation letter acknowledging management's responsibility for the preparation of the financial statements and affirming management's belief that the effects of any uncorrected financial statement misstatements aggregated by us during the current audit engagement and pertaining to the latest period presented are immaterial, both individually and in the aggregate, to the financial statements taken as a whole. We will also request that management confirm certain representations made to us during our audit. The responses to those inquiries and related written representations of management required by auditing standards generally accepted in the United States of America are part of the evidential matter that we will rely on as auditors in forming our opinion on the Fund's financial statements. Because of the importance of management's representations, the Fund agrees to release and indemnify Deloitte & Touche LLP and its personnel from all claims, liabilities, and expenses relating to our services under this engagement letter attributable to any misrepresentation by management.

If the Fund intends to publish or otherwise reproduce in any document our report on the Fund's financial statements, or otherwise make reference to Deloitte & Touche LLP in a document that contains other information in addition to the audited financial statements (e.g., in a periodic filing with a regulator, in a debt or equity offering circular or in a private placement memorandum), thereby associating Deloitte & Touche LLP with such document, the Fund agrees that Bowling-Pfizer Heart Valve Litigation Settlement Fund management will provide us with a draft of the document to read and obtain our approval for the inclusion or incorporation by reference of our report, or the reference to Deloitte & Touche LLP, in such document before the document is printed and distributed. The inclusion or incorporation by reference of our report in any such document

would constitute the reissuance of our report. The Fund also agrees that Fund management will notify us and obtain our approval prior to including our report on an electronic site.

Our engagement to perform the services described above does not constitute our agreement to be associated with any such documents published or reproduced by or on behalf of the Fund. Any request by the Fund to reissue our report, to consent to its inclusion or incorporation by reference in an offering or other document, or to agree to its inclusion on an electronic site, will be considered based on the facts and circumstances existing at the time of such request. The estimated fees outlined herein do not include any services that would need to be performed in connection with any such request; fees for such services (and their scope) would be subject to our mutual agreement at such time and would be described in a separate engagement letter.

#### **OTHER COMMUNICATIONS ARISING FROM THE AUDIT**

In connection with the planning and the performance of our audit, auditing standards generally accepted in the United States of America require that certain matters be communicated to the Board of Trustees. We will report directly to the Board of Trustees any fraud of which we become aware that involves senior management, and any fraud (whether caused by senior management or other employees) of which we become aware that causes a material misstatement of the financial statements. We will report to senior management any fraud perpetrated by lower level employees of which we become aware that does not cause a material misstatement of the financial statements; however, we will not report such matters directly to the Board of Trustees, unless otherwise directed by the Board of Trustees.

We will inform the appropriate level of management of the Fund and determine that the Board of Trustees is adequately informed with respect to illegal acts that have been detected or have otherwise come to our attention in the course of our audit, unless the illegal act is clearly inconsequential.

We will also report directly to the Fund's management and the Board of Trustees matters coming to our attention during the course of our audit that we believe are reportable conditions. Reportable conditions are significant deficiencies in the design or operation of internal control that could adversely affect the Fund's ability to record, process, summarize, and report financial data consistent with the assertions of management in the financial statements.

We may also have other comments for management on matters we have observed and possible ways to improve the efficiency of the Fund's operations or other recommendations concerning internal control.

With respect to these other communications, it is our practice to discuss all comments, if appropriate, with the level of management responsible for the matters, prior to their communication to the Board of Trustees.

#### **COORDINATION OF THE AUDIT**

Our audit work will be completed during September and October. Assistance to be supplied by your personnel, including preparation of schedules and analyses of accounts, will be communicated to Mr. R. Wayne Smith, Administrator.

We are, of course, available to assist you in other areas that might arise.

## FEES

We estimate that our total fees for this audit will be \$12,100 including expenses.

Based on the anticipated timing of the work, our fees will be billed as audit fieldwork is being performed. Payment of the billing is expected to be within 30 days. We will notify you promptly of any circumstances we encounter that could significantly affect our estimate.

\* \* \* \* \*

If the above terms are acceptable to you and the services outlined are in accordance with your understanding, please sign the copy of this letter in the space provided and return it to us.

Yours truly,

*Deloitte & Touche LLP*

Accepted and agreed to by Bowling-Pfizer Heart Valve  
Litigation Settlement Fund.

By: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_