

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

WESTERN DIVISION

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

SEVENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES
COVERING PERIOD FROM JUNE 4, 1997 TO DECEMBER 5, 1997

SPECIAL MASTERS/TRUSTEES

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

AGENDA

SEVENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

In Re: Bowling-Pfizer Litigation

Case No. C-1-91-256

December 5, 1997
2:30 P.M.

Hon. S. Arthur Spiegel

1. Introductory remarks by Judge Spiegel.
2. Report of the Special Masters/Trustees.
3. Comments from Counsel:
 Class Counsel.
 Counsel for Defendants.
4. Questions and comments from those in attendance.
5. Request for date of next report of Trustees.
6. Closing remarks of Judge Spiegel.

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- A. Seventh Report of the Special Masters/Trustees

- B. Appendices to Court Report
 - 1. Unaudited balance sheet as of October 31, 1997 and an unaudited statement of income, benefit payments and funds balance for the ten months ended October 31, 1997.

 - 2. Independent auditor's report for the years ended December 31, 1996 and 1995 from Deloitte & Touche, LLP.

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

SEVENTH REPORT OF THE SPECIAL MASTERS/TRUSTEES

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

Your Special Masters/Trustees respectfully present their seventh periodic report, covering activities from June 4, 1997 to December 5, 1997.

I. CONSULTATION FUND

Under Section 6 of the Settlement Agreement, the Consultation Fund, initially \$80,000,000, is intended to provide Claimants with funds to obtain medical and psychological consultation as they deem best. It is to be divided equally among Claimants after paying or providing for fees and expenses to be paid out of this Fund. In addition, a \$10,000,000 fund was established to be paid, after fees and expenses, equally among all Claimants who are spouses of Class Members. The final deadlines for filing Consultation Fund claims were March 31, 1996 for Class Members resident in the United States, and May 31, 1996, for Class Members resident in all other countries.

The Trustees received 15,907 proof of claim forms from implantee claimants. All of these claims have been processed and 13,334 have been approved. The other 2,573 have been rejected for various reasons (such as, lack of reasonable proof of an implanted BSCC valve, implantation of another type of heart valve, death or removal of the BSCC valve before January 23, 1992, etc.).

The approved distributions are as follows: \$5,835 to implantees and \$962 to spouses of implantees. To date \$87,015,477 has been distributed to implantees and spouses of implantees from the Consultation Fund. There is in excess of \$3,500,000 remaining in the Fund. It is likely that final nominal distributions will be paid to both implantees and spouses of implantees. It is anticipated that the eventual total amount paid to implantees and spouses will be substantially equivalent to the \$90,000,000 originally paid into the Fund by Defendants.

Whether another and final distribution will be made from the Consultation Fund will depend primarily on the settlement of Federal income tax matters. It will be remembered that the Trustees 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 received refunds of taxes related to a net operating loss carryback for 1993 and a refund of 1996 estimated tax payments. In addition, amended returns were filed for 1994 and 1995. The Fund has received notification from the Internal Revenue

Service of a tax audit to be performed. It is not feasible to exhaust the fund until these tax matters are put to rest.

II. PATIENT BENEFIT FUND

Under Section 5 of the Settlement Agreement, the Patient Benefit Fund was established for the following purposes, briefly stated: to conduct research on the diagnosis of the risks of strut fracture and the risks of surgical replacement of valves, to establish guidelines for valve replacement surgeries, and to create a publicly accessible repository of appropriate information concerning the status of research and the risks of valve fracture and valve replacement.

A. Guidelines. The Special Masters/Trustees presented to the Court, on June 4, 1997, the Supervisory Panel's Revised Final Draft of the Guidelines to Assess Patients with Bjork-Shiley Convexo-Concave Heart Valves for Elective Explantation ("Supervisory Panel's Guidelines") (Doc.1096). After a hearing on that date and the submission of memoranda ("briefs"), responses and replies relating to the comments and criticisms of Class and Special Counsel and Amicus Public Citizen, the Court approved the Supervisory Panel's Guidelines as presented (August 28, 1997, Doc.1130).

The Supervisory Panel met October 2 through 4, 1997, and established a program of research consisting of twelve projects. Most of these are in their formative states, and as each new research contract is developed and approved by the Supervisory

Panel, we will seek approval of the Court in accordance with established procedures. Three of the twelve projects are the ongoing epidemiological studies in The Netherlands, United Kingdom and United States. The purpose of the research is to discover new scientific and medical data that, in accordance with expectations, will improve and refine the Supervisory Panel's Guidelines.

The Supervisory Panel is at work on the dissemination of its Guidelines and has created "Dear Doctor" and "Dear Patient" letters now approved by this Court (Doc.1162) for mailing in the United States. This will be accomplished as soon as practicable. The Chairman is consulting with the regulatory authorities in other countries so as to disseminate the Guidelines worldwide. He plans a trip next week for consultation in The Netherlands and the United Kingdom about Guideline dissemination, as well as the ongoing epidemiological studies in those countries. We will communicate with officials in all other countries where Class Members reside. Members of the Supervisory Panel are preparing an article about the Guidelines to be submitted to one of the leading U.S. medical journals. A brief notice will be published in appropriate periodicals.

B. Repository. As previously reported, the Chairman of the Supervisory Panel has sought the advice and counsel of Class Counsel, Counsel for Defendants, Counsel for Amici, and persons with appropriate knowledge and skill, concerning the publicly accessible repository of information about research and the risks of valve failure and replacement. The Supervisory Panel will be

working on the development of a proposal for consideration of the Court at a later date.

C. Valve Replacement Surgery Claims and Fracture Claims. The Claims Administrator has received 360 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 360 claims, there are 54 qualified outlet strut fracture claims, 34 qualified single leg fracture claims and 39 qualified valve replacement surgery claims. Some of the claimants have elected other courses of action rather than to receive the Settlement benefits. The remaining 233 claims have been reviewed and they either do not qualify or additional information is needed and has been requested from the claimants.

The computer system in the Trustees' office has been upgraded in order to implement the new guidelines for valve replacement surgery. Software will soon be installed which will include 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 new guidelines.

III. FINANCIAL INFORMATION

At October 31, 1997, the total balance of cash and cash equivalents was \$3,823,345 for the Consultation Fund (class member portion and spousal portion) and \$12,823,679 for the Patient Benefit Fund. These amounts include net interest earned from January 28, 1992 through April 30, 1997, in the aggregate amount of \$17,311,480 for the Consultation Fund and \$1,524,266 for the Patient Benefit Fund.

Attached as Appendix 1 are the following: an unaudited balance sheet as of October 31, 1997 and an unaudited statement of income, benefit payments and funds balance for the ten months ended October 31, 1997 (which includes the budgeted amounts for expenses for the Research Management Group and the administrative office for the period January 1, 1997 through December 31, 1997).

The Trustees have received the audit report for the years ended December 31, 1996 and 1995 from Deloitte & Touche, LLP. A copy of their independent auditor's report is attached as Appendix 2.

IV. COMMUNICATIONS

The Claims Administrator and the Trustees' office are in daily contact with individual Class Members, and as noted above, the Supervisory Panel will disseminate information about its Guidelines for the benefit of Class Members.

V. APPROVALS

Your honor, the Special Masters/Trustees request that the Court:

- (a) approve this report, and
- (b) approve other actions specifically referred to in this Report, 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 5, 1997

Hon. Robert L. Black, Jr.

Peter J. Strauss, Esq.

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

BALANCE SHEET

AS OF OCTOBER 31, 1997

UNAUDITED

ASSETS

CASH:

Consultation Fund	\$ 99,915
Patient Benefit Fund	47,127

U.S. TREASURY BILLS:

Consultation Fund (Par Value \$3,765,000)	3,723,430
Patient Benefit Fund (Par Value \$12,952,000)	12,776,552

OTHER ASSETS

23,485

\$ 16,670,509

LIABILITIES AND FUNDS BALANCE

ACCOUNTS PAYABLE AND ACCRUED EXPENSES	\$ 511,586(1)
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FUNDS BALANCE

16,158,923

\$ 16,670,509

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

TRUSTEES FOR THE BOWLING-PFIZER
HEART VALVE SETTLEMENT FUNDS

STATEMENT OF INCOME, BENEFIT PAYMENTS AND FUNDS BALANCE

FOR THE TEN MONTHS ENDED OCTOBER 31, 1997

UNAUDITED

INCOME:

Investment interest:	
Consultation Fund	\$ 947,675
Patient Benefit Fund	348,807
Miscellaneous	<u>11,928</u>
Total	<u>1,308,410</u>

BENEFIT PAYMENTS:

Consultation Fund:	
Implantees	38,371,263
Spouses	<u>4,535,214</u>
Total	42,906,477

Patient Benefit Fund:	
Valve Replacement Surgery	<u>36,978</u>
Total	<u>42,943,455</u>

RESEARCH PROGRAMS 550,760

LITIGATION ATTORNEYS-FEES & EXPENSES 737,765 (1)

EXPENSES:

Supervisory Panel (2)	1,156,851
Trustees' fees and expenses	181,413
Professional fees	53,204
Research Management Group (2)	64,652
Administrative office (2)	<u>398,291</u>
Total	<u>1,854,411</u>

PROVISION FOR FEDERAL TAXES (388,064)

CONTRIBUTION BY SHILEY INCORPORATED 6,250,000

NET CHANGE IN FUNDS BALANCE (38,139,917)

FUNDS BALANCE, DECEMBER 31, 1996 54,298,840

FUNDS BALANCE, APRIL 30, 1997 \$ 16,158,923

- (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

	<u>BUDGET</u>	<u>ACTUAL</u>
	<u>1/1/97-12/31/97</u>	<u>1/1/97-10/31/97</u>
SUPERVISORY PANEL:		
Panel members' compensation		\$ 691,640
Guidelines Committee compensation		39,491
Consultants' compensation		258,425
Travel and other expenses		167,295
Total		\$ 1,156,851
RESEARCH MANAGEMENT GROUP:		
Rents	\$ 62,000	\$ 25,174
Office payroll	84,000	18,826
Payroll taxes	8,000	2,610
Employee benefits	12,000	1,021
Outside services	12,000	1,015
Computer and telephone support	24,000	625
Travel	12,000	
Printing and postage	24,000	5,992
General insurance	3,000	
Telephone	12,000	2,678
Research supplies and expense	12,000	3,662
Office supplies and expense	9,000	2,369
Depreciation	8,000	
Miscellaneous	3,000	680
Total	\$ 285,000	\$ 64,652
ADMINISTRATIVE OFFICE:		
Rents	\$ 54,000	\$ 47,309
Office payroll	298,000	211,709
Payroll taxes	24,000	13,798
Employee benefits	24,000	12,814
Outside services	102,000	48,911
Printing and postage	54,000	44,399
General insurance	6,000	1,357
Telephone	24,000	10,249
Office supplies and expense	12,000	1,967
Travel	6,000	
Depreciation	4,000	2,048
Miscellaneous	12,000	3,730
Total	\$ 620,000	\$ 398,291



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

**Statements of Assets, Liabilities and Fund Balance -
Modified Cash Basis as of December 31, 1996 and
1995 and Statements of Income, Expenses and Benefit
Payments and Change in Fund Balance - Modified
Cash Basis for the Years Ended December 31, 1996
and 1995 and Independent Auditor's Report**



INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying statements of assets, liabilities and fund balance - modified cash basis of the Bowling - Pfizer Heart Valve Litigation Settlement Fund (the "Fund") as of December 31, 1996 and 1995 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, 1996 and 1995 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 10, 1997

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

STATEMENTS OF ASSETS, LIABILITIES AND FUND BALANCE - MODIFIED CASH BASIS AS OF DECEMBER 31, 1996 AND 1995

	1996	1995
ASSETS		
CASH	\$ 8,947	\$ 528,682
INVESTMENTS (Note 3):		
Consultation Fund	45,657,075	66,408,269
Patient Benefit Fund	9,050,071	10,861,909
Total Investments	54,707,146	77,270,178
TAX REFUND RECEIVABLE (Notes 2,6)	293,636	100,000
OTHER ASSETS (Note 2)	67,303	92,476
TOTAL ASSETS	<u>\$55,077,032</u>	<u>\$77,991,336</u>
LIABILITIES AND FUND BALANCE		
ACCOUNTS PAYABLE AND ACCRUED EXPENSES (Note 2)	\$ 778,192	\$ 1,177,474
Total Liabilities	778,192	1,177,474
FUND BALANCE (Note 1):		
Consultation Fund	45,990,235	66,956,949
Patient Benefit Fund	8,308,605	9,856,913
Total Fund Balance	54,298,840	76,813,862
TOTAL LIABILITIES AND FUND BALANCE	<u>\$55,077,032</u>	<u>\$77,991,336</u>

See notes to 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, 1996 AND 1995

	1996	1995
INCOME:		
Settlement payments by Pfizer/Shiley (Note 1)	\$ 6,250,000	
Net investment income	3,299,943	\$ 5,253,426
Total Income	<u>9,549,943</u>	<u>5,253,426</u>
EXPENSES AND BENEFIT PAYMENTS:		
Benefit payments - Consultation Fund (Note 2)	13,383,250	28,319,250
Benefit payments - valve replacement surgery	639,969	116,534
Research programs	4,399,354	479,471
Litigation attorneys - fees and expenses (Note 2)	11,073,946	
Supervisory panel expenses (Note 1)	1,321,251	1,707,538
Trustees' fees and expenses	193,928	313,532
Special master - SLF fees and expenses		20,367
Professional fees (Note 5)	85,672	156,284
Research Management Group	358,070	351,861
Other administrative expenses	485,311	441,128
Notification expense	124,214	10,000
Provision for income taxes (Note 6)		900,000
Total expenses and benefit payments	<u>32,064,965</u>	<u>32,815,965</u>
DECREASE IN FUND BALANCE	(22,515,022)	(27,562,539)
FUND BALANCE, BEGINNING OF YEAR	<u>76,813,862</u>	<u>104,376,401</u>
FUND BALANCE, END OF YEAR	<u>\$54,298,840</u>	<u>\$ 76,813,862</u>

See notes to financial statements.

BOWLING-PFIZER HEART VALVE LITIGATION SETTLEMENT FUND

NOTES TO MODIFIED CASH BASIS FINANCIAL STATEMENTS

1. ORGANIZATION AND GENERAL INFORMATION

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

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

The Patient Benefit Fund is to be used for: research and development of diagnostic techniques to identify implantees who may have a significant risk of strut fracture and to make such diagnostic techniques available to Plaintiff implantees; research concerning the characterization and/or reduction of the risks of valve replacement surgery; and payment of covered 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 to the Patient Benefit Fund.

As of October 10, 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 13,334 had been approved as valid claims under the Settlement Agreement. At December 31, 1996 the Consultation Fund had distributed \$44,109,000 to claimants. As of October 10, 1997 total payments to Plaintiff implantees and Plaintiff spouses was \$86,679,790. The Consultation Fund will be liquidated upon resolution of the federal income tax matters described in Note 6, by distributing available funds to all approved claimants.

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 has agreed to reimburse Pfizer/Shiley for certain medical expense payments made for qualifying valve replacement surgeries. These medical expense payments were made by Pfizer/Shiley for qualifying surgeries that occurred after January 23, 1992 and before the Fund commenced processing valve replacement surgery claims. The Fund has agreed to contract for, and continue certain research programs that were initiated by Shiley Incorporated. In addition, the Fund has agreed to reimburse Pfizer/Shiley for the reasonable costs of maintaining these research programs from the date of the appointment of the Supervisory Panel until the dates that the research programs come under the control of the Supervisory Panel. These amounts will be paid to Pfizer/Shiley after review by the Fund and approval by the Court. These amounts will be reported as a distribution when paid by the Fund. 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 in 1996 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, 1996 and 1995 consist of U.S. Treasury Bills and are carried at cost plus accrued interest. The market value of such investments was approximately \$54,809,000 and \$77,316,000, at December 31, 1996 and 1995, respectively.

4. OPERATING LEASES

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

1997	\$ 66,071
1998	53,071
1999	<u>13,268</u>
Total	<u>\$ 132,410</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 \$14,422 and \$34,064 in 1996 and 1995.

6. TAX STATUS

For Federal income tax purposes, the Fund is treated as a taxable complex trust, a "Designated Settlement Fund" under Section 468(B) of the 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 1996.

The Fund has filed amended returns for 1994 and 1995 claiming refunds of approximately \$1,370,000 based upon this ruling. The Fund has chosen not to record these amounts at December 31, 1996 due to notification from the Internal Revenue Service of a tax audit to be performed. The Fund will record the refunds, if any, when the tax audit is completed and settled.

* * * * *