

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE: DIET DRUGS
(PHENTERMINE/FENFLURAMINE/
DEXFENFLURAMINE) PRODUCTS LIABILITY
LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO: SHEILA BROWN, ET
AL. V. AMERICAN HOME PRODUCTS CORPORATION

CIVIL ACTION
No. 99-20593

**ANNUAL REPORT OF THE CARDIOVASCULAR MEDICAL RESEARCH AND
EDUCATION FUND, INC. FOR THE YEAR ENDED DECEMBER 31, 2011**

I. INTRODUCTION

The Class Action Settlement Agreement in the above referenced litigation authorized the creation of the Cardiovascular Medical Research & Education Fund, Inc. (“CMREF” or “the Fund”) for purposes of financing “medical research related to treatment and cure of Primary Pulmonary Hypertension....” See Bylaws of the Cardiovascular Medical Research & Education Fund, Inc. at § 2.B (appended as Exhibit “B” to the Fifth Amendment approved by the Court in Pretrial Order No. 2677). The original version of the Settlement Agreement provided \$25 million in funding for CMREF. See Settlement Agreement at §IV.A.3.a. The Tenth Amendment to the Settlement Agreement, approved by the Court on July 2, 2010, provided an additional \$12.5 million in funding for CMREF. See *In re Diet Drugs*, 2010 WL 2735414 at *3 (E.D.Pa. July 2, 2010).

Under its Court-approved Bylaws, CMREF is required to furnish an annual report to the Court following the close of the Foundation’s fiscal year. *Id.* at § 6.N(I). This is the Annual Report of the CMREF for the year ended December 31, 2011.

II. FINANCIAL REPORT

Attached as Exhibit “A” to this Annual Report are the compiled financial statements of the CMREF prepared by the Certified Public Accountants employed by the Fund. These financial statements show the assets and liabilities of the CMREF, the principal changes in assets and liabilities, the revenue and receipts of the Fund, and the expenses and disbursements made by the Fund for the fiscal year ended December 31, 2011.

III. GRANT ACTIVITIES

Efforts to uncover the causes of PPH have heretofore been handicapped by the lack of appropriate human lung tissues for histological, immunohistological, gene microarray, proteomic, metabolic and cell culture studies. Therefore, in the period prior to 2010 the primary funding initiatives of the CMREF were devoted to the creation and funding of what ultimately became known as the Pulmonary Hypertension Breakthrough Initiative (“PHBI”), a consortium of 13 highly distinguished, university-affiliated medical institutions devoted to acquiring and preserving lung tissue and blood samples from PPH patients for appropriate scientific study.

Funded by annual grants from CMREF, the PHBI consortium has implemented a novel, collaborative research model in which Transplant and Preparation Centers (“TPCs”) harvest and preserve explanted lung tissues and blood samples from PPH and control patients undergoing lung transplantation. Under the study protocols adopted by the PHBI, prepared cells, lung tissue and blood harvested by the TPCs are stored and managed by Processing Centers at the University of Pennsylvania, University of Colorado and the University of Alabama. Associated relevant clinical data are maintained by the Data Coordinating Center (DCC) at the University of

Michigan. The stored clinical specimens and relevant clinical data are distributed to researchers and used for research designed to better understand PPH.

Thus far, PHBI has enrolled 143 unique patients, collected a total of 190 blood draws obtained lung tissue explanted from 65 PPH patients, lung tissue from 2 “warm autopsies” and tissue from 34 failed donor (i.e., control) lungs. In addition, numerous articles and abstracts have been published and submitted for publication based, in whole or in part, on the biologic material collected by PHBI.

The research presented by the PHBI has been “groundbreaking” and “has produced novel and exciting discoveries about the molecular basis of PPH.” *See Diet Drugs*, 2010 WL 2735414 at *3.

During 2010, in recognition of the potential value of the biological materials and information gathered by PHBI, the National Institutes of Health (“NIH”) announced its intention to make “RO3” grants to utilize “available human biospecimens collected by the Pulmonary Hypertension Breakthrough Initiative (PHBI) ... to investigate mechanistic research questions in lung vascular biology, including validating hypotheses of pulmonary arterial hypertension (PAH) pathogenesis” and solicited proposals for such grants from the medical/scientific community.¹ NIH received a significant number of proposals in response to this solicitation. NIH made nine RO3 grants in September, 2011 and plans to announce a second round of grants on July 1, 2012. Moreover, the PHBI network is in the process of applying to NIH for an “R24” grant to fund the continued banking and procurement of data, tissues and blood that has to date been funded exclusively by CMREF.

¹ *See*: <http://www07.grants.gov/search/search.do?&mode=VIEW&oppId=58400>.

During 2011, CMREF continued to provide support for the ongoing scientific research efforts of the PHBI. However, with the advent of NIH grants to fund further research based on the materials developed by PHBI and with the influx of additional funds to CMREF as a result of the Tenth Amendment to the Settlement Agreement, during 2011 CMREF continued other grant-making activities that were first commenced in 2010 and initiated new grant-making activities that went well beyond the continuing support of PHBI. These grant-making activities involved:

- ▶ Funding the start-up of a unique journal by the Pulmonary Vascular Institute (“PVI”) devoted to publishing research and providing educational information regarding PPH;
- ▶ Funding a project by the Pulmonary Hypertension Association (“PHA”) to provide medical education regarding PPH in pediatric patients;
- ▶ Investigating the feasibility of developing and funding a cooperative, multi-center research project designed to investigate methods to address right heart failure, which is the condition inevitably produced by PPH that actually causes the death of nearly all of the patients who contract the disease;
- ▶ Funding the development of a right ventricular assistance device by the CircuLite Company to treat right heart failure in PPH patients;
- ▶ Providing funding to the PHA for “Barst Grants” to support the further development of pediatric pulmonary hypertension research and the engagement of younger researchers in the field and to facilitate the connection of those researchers with more senior experts through mentorship opportunities; and
- ▶ Soliciting requests for proposals from qualified academic medical centers with the ability to coordinate and conduct a clinical study evaluating right ventricular function in patients with pulmonary hypertension, its adaptive and maladaptive responses, and the effects of therapy.

CMREF is pleased with the progress made by its grantees and believes that they will continue

to produce research and provide education that will facilitate a better understanding of PPH that will in turn lead to improved treatments for those who suffer from this disease.

Respectfully submitted,

/s/ John Newman, M.D.
JOHN NEWMAN, M.D., PRESIDENT

/s/ Peter Panteleo.
PETER PANTALEO, SECRETARY

/s/ Michael D. Fishbein
MICHAEL D. FISHBEIN, TREASURER

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing Annual Report of the Cardiovascular Medical Research and Education Fund, Inc. for the Year Ended December 31, 2011 was filed electronically this 11th day of June, 2012 and is available for viewing and downloading from the ECF System of the United States District Court for the Eastern District of Pennsylvania.

The undersigned further certifies that on this 11th day of June, 2012, he caused a true and correct paper copy of the Joint Motion to be served upon each of the following via United States first-class mail, addressed as follows:

Orran L. Brown, Esquire
BROWN GREER, PLC
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Special Master
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Philadelphia, PA 19103

/s/ Michael D. Fishbein
MICHAEL D. FISHBEIN

Exhibit “A”

**THE CARDIOVASCULAR MEDICAL RESEARCH
AND EDUCATION FUND, INC.
(A non-profit organization)**

FINANCIAL STATEMENTS

DECEMBER 31, 2011

THE CARDIOVASCULAR MEDICAL RESEARCH AND EDUCATION FUND, INC.
DECEMBER 31, 2011

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Independent Accountants' Compilation Report

To the Board of Trustees
The Cardiovascular Medical Research and Education Fund, Inc.
Philadelphia, Pennsylvania

We have compiled the accompanying statement of financial position of the Cardiovascular Medical Research and Education Fund, Inc. (a non-profit organization) as of December 31, 2011, and the related statements of activities and cash flows for the year then ended. We have not audited or reviewed the accompanying financial statements and, accordingly, do not express an opinion or provide any assurance about whether the financial statements are in accordance with accounting principles generally accepted in the United States of America.

Management is responsible for the presentation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America and for designing, implementing, and maintaining internal control relevant to the preparation and fair presentation of the financial statements.

Our responsibility is to conduct the compilation in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants. The objective of a compilation is to assist management in presenting financial information in the form of financial statements without undertaking to obtain or provide any assurance that there are no material modifications that should be made to the financial statements.

Heffler, Radtich & Savitta, LLP

Philadelphia, Pennsylvania
May 8, 2012

THE CARDIOVASCULAR MEDICAL RESEARCH AND EDUCATION FUND, INC.
STATEMENT OF FINANCIAL POSITION
DECEMBER 31, 2011

ASSETS

Cash and Cash Equivalents	\$ 9,507,556
Dividend Income Receivable	40,507
Investments	<u>8,876,843</u>

TOTAL ASSETS

\$ 18,424,906

LIABILITIES

Accrued Excise Tax	\$ 1,343
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NET ASSETS

Unrestricted Net Assets	<u>\$ 18,423,563</u>
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TOTAL LIABILITIES AND NET ASSETS

\$ 18,424,906

See accompanying notes and independent accountants' compilation report.

THE CARDIOVASCULAR MEDICAL RESEARCH AND EDUCATION FUND, INC.
STATEMENT OF ACTIVITIES
FOR THE YEAR ENDED DECEMBER 31, 2011

UNRESTRICTED REVENUE	
Dividend Income	\$ 211,913
Interest Income	99,629
Capital Gain	22,452
Unrealized Loss on Investments	(204,002)
Total Unrestricted Revenue	<u>129,992</u>
 EXPENSES	
Management & General	
Advertising	2,446
Bank Charges	225
Insurance	7,677
Meeting Reimbursement	57,702
Office Supplies	6,999
Payroll	25,000
Professional Fees - Accounting	7,500
Professional Fees - Website	1,400
Taxes - Excise Tax	6,680
Taxes - Payroll	2,032
Telephone	2,426
Payroll Service Charges	1,700
Program Services	
Awards & Grants	4,094,811
Payroll	25,000
Taxes - Payroll	2,032
Total Expenses	<u>4,243,630</u>
DECREASE IN UNRESTRICTED NET ASSETS	(4,113,638)
UNRESTRICTED NET ASSETS, BEGINNING OF YEAR	<u>22,537,201</u>
UNRESTRICTED NET ASSETS, END OF YEAR	<u>\$ 18,423,563</u>

See accompanying notes and independent accountants' compilation report.

THE CARDIOVASCULAR MEDICAL RESEARCH AND EDUCATION FUND, INC.
STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED DECEMBER 31, 2011

Cash flows from operating activities	
Decrease in Net Assets	\$ (4,113,638)
Adjustments to reconcile increase in Net Assets to net cash used in operating activities:	
Unrealized Loss on Investments	\$ 204,002
Increase in dividend income receivable	(20,969)
Decreased in prepaid excise tax	5,337
Increased in accrued excise tax	<u>1,343</u>
Net Cash used in operating activities	<u>(3,923,925)</u>
Cash flows from investing activities	
Proceeds from sale of Investments	11,000,000
Purchase of Investments	<u>(5,007,204)</u>
Net Cash used in investing activities	<u>5,992,796</u>
Net Increase in Cash and Cash Equivalents	2,068,871
Cash and Cash Equivalents, Beginning of Year	<u>7,438,685</u>
Cash and Cash Equivalents, End of Year	<u>\$ 9,507,556</u>

See accompanying notes and independent accountants' compilation report.

**THE CARDIOVASCULAR MEDICAL RESEARCH AND EDUCATION FUND, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2011**

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Nature of Activities

The Cardiovascular Medical Research and Education Fund (the Fund) is a non-profit organization exempt from federal income taxes under Section 501(c)(3) of the Internal Revenue Code. The Fund has been established to carry out part of the Nationwide Class Action Settlement Agreement ("Settlement Agreement") with American Home Products Corporation. The Settlement Agreement requires the creation of the Fund to carry out medical research and education related to the treatment and cure of primary pulmonary hypertension, a disease which is nearly always fatal.

Basis of Accounting

The accompanying financial statements have been prepared on the accrual basis of accounting in accordance with generally accepted accounting principles.

Financial Statement Presentation

The Organization is required to report information regarding its financial position and activities according to three classes of net assets: unrestricted net assets, temporarily restricted net assets, and permanently restricted net assets.

Contributions

Contributions are required to be reported as unrestricted, temporarily restricted, or permanently restricted support depending on the existence and/or nature of any donor restrictions.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

Cash and Cash Equivalents

For purposes of the statement of cash flows, the Organization considers all unrestricted highly liquid investments with a maturity of three months or less to be cash equivalents.

THE CARDIOVASCULAR MEDICAL RESEARCH AND EDUCATION FUND, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2011

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Income Taxes

The Fund is exempt from federal income taxes under section 501(c)(3) of the Internal Revenue Code (IRC) and, accordingly, has made no provision for federal income taxes in the accompanying financial statements. As a Private Foundation, the Fund is subject to federal excise tax on net investment income as defined by the IRC. The Organization's Federal Exempt Organization Return of Private Foundation for years 2009, 2010 & 2011 are subject to examination by the IRS, generally for three years after they were filed.

NOTE 2 - CONCENTRATION OF CREDIT RISK

The Fund maintains the majority of its cash balances at one financial institution. This account significantly exceeds federally insured limits. Management of the Fund does not believe it is exposed to significant credit risk with this financial institution.

NOTE 3 - SET-ASIDE DISTRIBUTION

The Fund is required to distribute 5% of its net assets to specific projects each year in order to avoid incurring excise tax. Such distributions are recognized at the time that the unconditional promises to give by the Fund are made. The Fund met its requirements with respect to required distributions for the year ended December 31, 2011.

NOTE 4 - INVESTMENTS

Investments in marketable securities are carried at fair value based on quoted prices in active markets (all level 1 measurements) and consist of the following at December 31, 2011:

Government & Agency Bond	3,019,600
Short-Term Bond Fund	<u>5,857,243</u>
Total Investments	<u>\$ 8,876,843</u>