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, 2006

I. INTRODUCTION

The Class Action Settlement 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 CMREF is required to furnish an annual report to the Court within 120 days from 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, 2006.

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 reports show the assets and liabilities of the CMREF as of the end of the Fund's fiscal year, the principal changes in assets and liabilities, the revenue and receipts of the Fund, and the expenses and

disbursements made by the Fund.

III. GRANTEE ACTIVITIES

As set forth in the previous Annual Reports filed by the Fund, CMREF has sponsored a nationwide group of researchers with the main goal of uncovering the causes and pathogenesis of Idiopathic Pulmonary Arterial Hypertension (IPAH)[1] in pursuit of the prevention and cure of this disease. A main priority of the group is to establish Transplant and Preparation Centers ("TPCs") to provide and bank explanted lung tissues and blood samples from IPAH and other lung transplant patients to be used for research. Prepared cells, lung tissue and blood from the TPCs will be stored and managed by Processing Centers at the University of Pennsylvania, Johns Hopkins and the University of Alabama. Associated relevant clinical data will be maintained by the Data Coordinating Center (DCC) at the University of Michigan. The stored clinical specimens and relevant clinical data will be distributed to researchers within the network and used for yet to be defined research designed to better understand IPAH.

The principal investigators (PI) and other representatives of the funded institutions met in Detroit, Michigan on April 6, 2006, to create the infrastructure by which the group would operate and to determine a plan of action for the coming year. Specific aims agreed upon by the participants were as follows: (1) Create an infrastructure that meets the needs of the network; (2) Define an efficient and effective communication system; (3) Create the process by which tissue collection and sample processing can be standardized across transplant sites, while striking a balance between standardization and flexibility that accommodates unique site challenges; (4)

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[1] "Idiopathic Pulmonary Arterial Hypertension" is the nomenclature currently used by the medical profession to describe Primary Pulmonary Hypertension.

Define the type and quantity of tissue (including control tissue) required to meet the current research requests of the network and to bank for future research; (5) Define the patient population to be studied to ensure that every collected lung is eligible and that every eligible lung is collected; and (6) Determine the definition of a successful transplant. It was voted that the group would be called the Pulmonary Hypertension Breakthrough Initiative or PHBI.

The following Committees and/or Working Groups have been formed by PHBI and their responsibilities defined. Committee positions may be rotated among the network participants on an annual basis:

STEERING COMMITTEE: The Steering Committee consists of all PI awardees with Vallerie McLaughlin, M.D. (University of Michigan) as Chair and Mark Geraci, M.D. (University of Colorado) as Co-Chair. The responsibilities of committee chairs include: (1) Conduct the monthly (currently bi-monthly) Steering Committee teleconference; (2) Facilitate the conduct of network related activities (agreements, protocol development, dissemination of network related documents, etc.); and (3) act as liaison between the Steering Committee members and the Research Advisory Committee (RAC) of the CMREF where necessary.

EXECUTIVE COMMITTEE: The Chair and Co-Chair of the Steering Committee along with one member each from a Transplant, Processing and Research Center will make up this committee to be convened as necessary in order to address issues requiring expediency.

CLINICAL PROTOCOL DEVELOPMENT WORKING GROUP: Consisting of a member from the DCC and 2-3 Transplant Centers, representatives are responsible for the development of the Clinical Protocol. The Clinical Database has been developed by the DCC.

TISSUE PROCESSING PROTOCOL WORKING GROUP: This committee consists of representatives from all Processing Centers, 1-2 Transplant Centers and 1-2 Research Centers and has been responsible for developing Tissue and Blood Processing Protocol(s).

TISSUE UTILIZATION COMMITTEE: Consisting of representatives from all Processing Centers and one each from the Transplant and Research Centers, this group is responsible for developing a process by which researchers outside of the

network can apply for the use of PHBI tissue, blood and/or data for the purpose of research. The committee will review applications for merit, adequate funding and proper regulatory oversight, prior to allocation of PHBI resources.

Highlights of the past year's accomplishments by the Pulmonary Hypertension Breakthrough Initiative include:

ANNUAL INVESTIGATOR MEETING - CHICAGO SEPTEMBER 2006: This 2 day meeting was attended by both PIs and Study Coordinators. Working sessions included an overview of study conduct and data collection procedures presented by the DCC for the Study Coordinators and a Tissue Processing demonstration and discussion conducted for the Transplant Centers representatives by the TPC. The PIs met to discuss problems and issues encountered thus far. Topics covered included the definition of successful transplant, the consideration of appropriate disease specific and non-diseased control lung tissue and the necessary processes required to begin collecting blood in order for research to commence.

MATERIAL TRANSFER AGREEMENT (MTA): As a general rule, institutions are required to sign an agreement with any provider of materials (biological samples or data) before a transfer can take place. A unified Material Transfer Agreement (based on the NIH Uniform Biological Material Transfer Agreement) was drafted by the CMREF attorneys. After input was sought from each participating institution's legal department, all PHBI members have agreed to the provisions of the MTA. This MTA does not specifically address terms of confidentiality and/or non-disclosure. A separate non-disclosure agreement will be drafted and signed by all PHBI participants in the near future.

DEVELOPMENT OF CTOOLS WEBSITE: This website was created and is maintained by the DCC. It is an advanced web-based collaboration environment, accessible to all PHBI participants, where announcements can be made, resources shared, and study documents stored and archived. It is anticipated that it will become a useful tool for developing training modules that utilize a variety of media. This will be important to maintain consistency at sites during the course of changes in personnel.

PROTOCOL(S) DEVELOPMENT:

Clinical Protocol - Developed with the input from all PHBI members, this protocol defines the overall study design, selection and enrollment of subjects, inclusion criteria, study interventions, clinical and laboratory data to be collected, data management processes, quality assurance and project time line.

Tissue Processing Protocol(s) - This complex set of protocols, which is in near final form, describes in detail the processes by which tissue and blood is collected, processed and distributed. The Tissue Processing Protocol is at this time being beta tested by all transplant centers prior to the acquisition of IPAH lung tissue. The first version of a Blood Protocol has been finalized. When subject enrollment begins, the collection of blood products will allow the PHBI researchers to begin their work.

DATABASE DEVELOPMENT: The data collection tool or Case Report Forms (CRF) and database have been completed and are now in beta-testing. The tool contains 21 separate CRFs and over 300 points of data to be entered electronically by the transplant site via a secure HIPAA and GCP compliant web-based system.

SHIPPING AND TRACKING SYSTEM DEVELOPMENT: These systems have not yet been developed as a finalized protocol is required. A barcode tracking system will be developed and employed by the DCC to monitor sample transfer from the Transplant Centers to the various end users. This will be an important QA step for assuring sample viability and accountability.

DEVELOPMENT OF AN INDEPENDENT QUALITY ASSURANCE COMMITTEE (IQAC): The concept of this committee is to provide outside (unbiased) oversight of the conduct of the PHBI activities, ensuring data integrity and overall credibility. The proposal was supported by a majority of the Steering Committee members. It was presented to the RAC of the CMREF and approved with modifications. A document was created defining the roles and responsibilities of the Steering Committee, the DCC, the RAC and the proposed IQAC. The formation of this committee is pending.

The CMREF is pleased with the progress made by its grantees in establishing the Pulmonary Hypertension Breakthrough Initiative and continues to believe that it will produce research that will facilitate a better understanding of IPAH that will lead to an improved treatments and a better prognosis for those who suffer from this disease.

Dated: May 21, 2007

JOSEPH LOSCALZO, M.D., PH.D., PRESIDENT

STUART LAND, ESQUIRE, SECRETARY

MICHAEL D. FISHBEIN, ESQUIRE, TREASURER

CERTIFICATE OF SERVICE

I, Michael D. Fishbein, Esquire, do hereby certify that a true and correct copy of the attached Annual Report of the Cardiovascular Medical Research and Education Fund, Inc. for the Year Ended December 31, 2006, was filed electronically this 21st day of May, 2007 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 a true and correct copy has been served upon the following, via United States Postal Service, first class mail:

Peter L. Zimroth, Esquire
Steven G. Reade, Esquire
ARNOLD & PORTER
399 Park Avenue
New York, NY 10022

Gregory P. Miller
Special Discovery Master
MILLER, ALFANO & RASPANTI
1818 Market Street, Suite 3402
Philadelphia, PA 19103

MICHAEL D. FISHBEIN, ESQUIRE

Exhibit “A”

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

FINANCIAL STATEMENTS

DECEMBER 31, 2006

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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, 2006, and the related statements of activities and cash flows for the year then ended, in accordance with Statements on Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants.

A compilation is limited to presenting in the form of financial statements information that is the representation of the Trustees. We did not audit or review the accompanying financial statements and, accordingly, do not express an opinion or any other form of assurance on them.

Heffler, Radetich & Saitta, LLP

Philadelphia, Pennsylvania
May 1, 2007

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2589 Boyce Plaza Road ▪ Pittsburgh, PA 15241

THE CARDIOVASCULAR MEDICAL RESEARCH AND EDUCATION FUND, INC.
STATEMENT OF FINANCIAL POSITION
DECEMBER 31, 2006

ASSETS		
Cash and Cash Equivalents	$	7,924,357
Dividend Income Receivable		34,206
Investments		15,791,746
TOTAL ASSETS	$	23,750,309
LIABILITIES		
Accrued Excise Tax	$	2,848
NET ASSETS		
Unrestricted Net Assets		23,747,461
TOTAL LIABILITIES AND NET ASSETS	$	23,750,309

See accompanying notes and accountants' report

THE CARDIOVASCULAR MEDICAL RESEARCH AND EDUCATION FUND, INC.
STATEMENT OF ACTIVITIES
FOR THE YEAR ENDED DECEMBER 31, 2006

REVENUE		
Dividend Income	$	938,000
Interest Income		91,178
Gain on Sales of Investments		15,625
Unrealized Gain on Investments		54,693
Total Revenue		1,099,496
EXPENSES		
Management & General		
Bank Charges		14,200
Computer Repairs		95
Insurance		4,734
Meeting Reimbursement		55,784
Miscellaneous		864
Office Supplies		651
Payroll		26,025
Payroll Service Charges		766
Penalties		160
Professional Fees - Accounting		8,000
Professional Fees - Website		411
Taxes - Excise Tax		10,448
Taxes - Payroll		2,118
Telephone		3,356
Program Services		
Awards & Grants		2,749,525
Payroll		26,025
Professional Fees - Consulting		81,200
Taxes - Payroll		2,118
Total Expenses		2,986,480
DECREASE IN NET ASSETS		(1,886,984)
NET ASSETS, BEGINNING OF YEAR		25,634,445
NET ASSETS, END OF YEAR	$	23,747,461

See accompanying notes and accountants' report

THE CARDIOVASCULAR MEDICAL RESEARCH AND EDUCATION FUND, INC.
STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED DECEMBER 31, 2006

Cash flows from operating activities		
Decrease in Net Assets	$	(1,886,984)
Adjustments to reconcile decrease in Net Assets to net cash used in operating activities:		
Unrealized gain on Investments		(54,693)
Gain on Sale of Investments		(15,625)
Decrese in dividend Income Receivable		23,412
Increase in accrued expenses		203
Net cash used in operating activities		(1,933,687)
Cash flows from investing activities		
Proceeds from sale of Investments		8,000,000
Net cash provided by investing activities		8,000,000
Net increase in cash and cash equivalents		6,066,313
Cash and cash equivalents at beginning of year		1,858,044
Cash and cash equivalents at end of year	$	7,924,357

See accompanying notes and accountants' report

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 Fund applies the provisions of Statement of Financial Accounting Standards (SFAS) No. 117, "Financial Statements of Not-for-Profit Organizations." Under SFAS No. 117, 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

The Fund also applies the provisions of SFAS No. 116, "Accounting for Contributions Received and Contributions Made." Under SFAS No. 116, such 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.

Investments

Investments in marketable securities are stated at fair value. All gains and investment income are unrestricted. Investments at December 31, 2006 are maintained in a short term bond portfolio.

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.

NOTE 2 - **CONCENTRATION OF CREDIT RISK**

The Fund maintains its cash balances at various financial institutions. These accounts, at times, may exceed federally insured limits.

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. For the year ended December 31, 2006, in accordance with Section 4942 (f)(2)(c) of the Internal Revenue Code, the Fund has elected to "set-aside" its required distribution. The calculated "set-aside" distribution is $1,281,855. Such distributions will be recognized at such time as unconditional promises to give by the Fund are made.