

**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, 2010**

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, 2010.

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, 2010.

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 119 unique patients, collected a total of 177 blood draws obtained lung tissue explanted from 54 PPH patients, lung tissue from 2 “warm autopsies” and tissue from 26 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. These articles, abstracts and publications are listed in Exhibit “B” hereto.

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. For example, the PHBI initiative has discovered:

- Differences in the expression of certain genes between males and females with PPH, which may explain why women are so much more predisposed to getting PPH than men;
- New genetic mutations in patients who already have a previously described mutation (referred to as the “second hit” phenomenon). Previously, this had been shown to occur in certain cancers, but had only been suspected to occur in PPH; and
- Specific proteins produced by the bone marrow, which point to PPH as actually being a systemic disease, a discovery that could lead to new treatments.

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

Approximately 30 institutions have thus far made grant submissions in response to the NIH grant announcement.

During 2010, 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 as a result of the Tenth Amendment to the Settlement Agreement, CMREF initiated new grant making activities during 2010 that went beyond its continuing support of PHBI. These new grant making activities involved:

- Funding the start-up of “*Pulmonary Circulation*,” a unique journal published by the Pulmonary Vascular Research Institute that is focused on providing peer reviewed scientific articles regarding PPH;
- Funding a project by the Pulmonary Hypertension Association (“PHA”) to provide medical education regarding Primary Pulmonary Hypertension 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 the patients who contract the disease.

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.

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

Respectfully submitted,

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

/s/ Peter Panteleo, _____
PETER PANTELEO, 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, 2010 was filed electronically this __ day of April, 2011 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 __ day of April, 2011, 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:

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Dated: April __, 2011

/s/ **Michael D. Fishbein**
MICHAEL D. FISHBEIN