

UNITED STATE DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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IN RE: LUPRON MARKETING)
AND SALES PRACTICES)
LITIGATION)

MDL NO. 1430
MASTER FILE NO. 01- CV-10861-RGS

Re: CASE NO. 04-10175)

Hon. Richard G. Stearns

**MOTION TO CONSIDER DANA-FARBER/HARVARD CANCER CENTER
RESEACH PROPOSAL RE: TAP PHARACEUTICALS/LUPRON CY PRES
DISTRIBUTION**

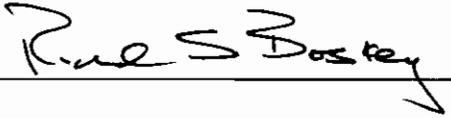
In response to the Court's May 19, 2009 "Memorandum and Order Regarding Disposition of Money Remaining in the Consumer Settlement Pool," Dana-Farber/Harvard Cancer Center respectfully submits this Motion for the Court to consider its prostate cancer research proposal. Dana-Farber/Harvard Cancer Center only recently became aware of the Court's willingness to accept research proposals regarding this matter and respectfully requests to be included in the Court's consideration.

In response to the May 19, 2009 Memorandum and Order, Dana-Farber/Harvard Cancer Center now submits detailed answers to the specific questions set forth by the Court along with additional budget and grant protocol information as part of its Research Proposal. Dana-Farber/Harvard Cancer Center remains available to answer any further questions the Court may have or provide any additional information the Court may desire.

Respectfully Submitted,

DANA-FARBER/HARVARD CANCER CENTER

BY: DANA-FARBER CANCER INSTITUTE, INC.

BY: 

Richard S. Boskey

Sr. Vice-President and General Counsel

Proposal for Disposition of Money Remaining in the Consumer Settlement Pool from Lupron® Marketing and Sales Practices Litigation

Submitted by

The Dana-Farber/Harvard Cancer Center

in collaboration with the Prostate Cancer Foundation

Introduction

The major purpose of the drug leuprolide acetate, or Lupron®, is to treat patients with prostate cancer. It is effective in prolonging survival in men with advanced prostate cancer, in palliating their symptoms and in curing patients with localized or locally advanced prostate cancer. In addition to its use as a prostate cancer drug, Lupron® may be used in the treatment of conditions such as endometriosis, uterine fibroids, and/or central precocious puberty.

Of the conditions cited above, prostate cancer is the most urgent public health challenge: one in six men will be diagnosed with this disease in their lifetime, and approximately 27,000 deaths resulting from prostate cancer are predicted in the U.S. in 2009, posing significant treatment and management challenges for both doctors and patients. While many patients may be cured either with surgery or with radiation, with or without hormonal therapies such as Lupron®, a substantial fraction of patients who receive treatment will have recurrences wherein the tumor metastasizes, and for such patients, no curative therapies are available. Moreover, the side effects of Lupron® are substantial and are being increasingly appreciated.

The Dana-Farber/Harvard Cancer Center (DF/HCC) and the Prostate Cancer Foundation (PCF) have each designed and implemented distinct and effective strategies to address the problems posed by prostate cancer. Specifically, the mission of the prostate cancer program and National Cancer Institute sponsored “Specialized Program of Research Excellence,” or SPORE, at DF/HCC is to encourage and promote collaborative and translational research that will lead to new approaches to the prevention, diagnosis, and treatment of prostate cancer. The mission of PCF is to end death and suffering from prostate cancer, by funding research that will hasten the development of a cure for prostate cancer.

These complementary visions have on occasion led to targeted collaborations between DF/HCC and PCF. Accordingly, leadership at DF/HCC and PCF respectfully submit below a joint plan for the disbursement of funds made available through the Consumer Settlement Pool resulting from Lupron®, marketing and sales practices litigation.

Background

Through this proposal, we seek to leverage the existing institutional infrastructure, funding mechanisms and relationships of the DF/HCC and the PCF to distribute, monitor and evaluate settlement funds annually, on a competitive basis, locally and nationally, to support large scale research collaborations in prostate cancer research, cutting-edge pilot

projects, develop promising young investigators, and train talented graduate students. For additional information about DF/HCC, PCF, and programs and initiatives that are funded by these organizations, refer to **Appendix A**. For a record of past grants and awards made by DF/HCC and PCF, refer to **Appendices B and C**, respectively.

The central and overarching goal of our jointly proposed program is to directly impact prostate cancer research and other Lupron®-treatable diseases and conditions. Specifically our program goals include the following objectives:

- To direct leftover Settlement Pool funds from Lupron® litigation to prostate cancer and other Lupron® treatable disease research initiatives of merit.
- To distribute Settlement Pool funds to prostate cancer and other Lupron® treatable disease researchers at the local, state and national level.
- To distribute Settlement Pool funds through existing organizational channels, which have demonstrated effective research capabilities, and a track record of successful past grant distribution and grantees (i.e., which have advanced the state of knowledge in the grants' or grantees' stated areas of research).
- To increase the power and breadth of prostate cancer and other Lupron® -related disease research, by (i) the strategic administration of new and existing funding mechanisms; (ii) expanding current avenues of investigation; (iii) recruiting new talent into the field; and (iv) ensuring research relevance to the primary goals advancing diagnostic, treatment, and quality of life options for patients with prostate cancer and other Lupron® treatable diseases.

Information of Interest to the Court

The protocol under which grant requests would be solicited and structured:

Grant applications will be solicited by two separate organizations, DF/HCC, and PCF. DF/HCC will solicit certain categories of grant applications from the faculty of Harvard University and its affiliated hospitals, and will solicit certain additional categories of grant applications from faculty and students at colleges, universities and hospitals throughout Massachusetts. PCF will solicit grant applications from interested applicants on a national basis.

Specifically, for prostate cancer researchers within Harvard University and its affiliated hospitals, DF/HCC will create a "High Impact" research grant, and will add to the number of "Career Development" grants and "Development Project" grants that it presently awards on an annual basis. For prostate cancer researchers and researchers-in-training throughout Massachusetts, DF/HCC will create "Lupron®-treatable Disease" research grants, "Community Outreach" grants, and "Student Education" grants, and will add to the number of "Disparity Research" grants that it awards on an annual basis. For prostate cancer researchers throughout the nation, PCF will add to the number of "Challenge" grants that it awards on an annual basis. See **Appendix D** for a description of each category of award that will be made possible through Settlement Pool funds.

To solicit applications from the Harvard University-wide applicant pool, DF/HCC will use the existing infrastructure of the Prostate Cancer Program and SPORE. Specifically, request for proposals (RFPs) will be issued on a yearly basis, by the DF/HCC Prostate Cancer Program and SPORE utilizing existing administrators through a number of established and new channels. To solicit applications from a national applicant pool, RFPs will be issued by PCF through established channels.

Average amount and duration of the awards contemplated:

	<u>Amount</u>	<u>Duration</u>	<u>#</u>
DF/HCC High Impact Award:	\$500K	2 years	5
DF/HCC Career Development Award:	\$100K	2 years	6
DF/HCC Project Development Award:	\$100K	2 years	9
DF/HCC Lupron Treatable Disease Award:	\$100K	2 years	3
DF/HCC Student Training Award:	\$20K	2 years	8
DF/HCC Disparity Research Award:	\$100K	2 years	5
DF/HCC Community Outreach Award:	\$100K	2 years	4
PCF Challenge Grants:	\$1,000K	1 year	5

Please refer to **Appendix E** for a complete budget of grant expenditures.

Eligibility requirements for potential recipients:

DF/HCC High Impact Collaboration Award: Applicants must be on the faculty at Harvard University at the level of Assistant Professor or higher. Applications should include collaborators from at least 2 different DF/HCC member institutions and are encouraged to have collaborators at other institutions

DF/HCC Project Development Award: Applicants must be on the faculty at Harvard University at the level of Instructor or higher.

DF/HCC Career Development Award: Applicants must be in their final year of clinical or postdoctoral fellowship or hold an academic appointment not higher than Assistant Professor at Harvard University.

DF/HCC Lupron® Treatable Disease Award: Applicants must be on the faculty at Harvard University, or any other accredited Massachusetts university, at the level of Instructor or higher.

DF/HCC Student Training Award: Applicants must be students in nursing, medical, or Ph.D. programs at any accredited university within Massachusetts.

DF/HCC Disparity Research Award: Applicants must be on the faculty of at Harvard University at the level of Instructor or higher. Applications that include a partnership with UMB faculty, in support of the DF/HCC's U56 cancer center-minority serving institution partnership grant are encouraged.

DF/HCC Community Outreach Award: Applicants must be on the faculty of at Harvard University at the level of Instructor or higher. Applications that include a partnership with UMASS Boston faculty, in support of the DF/HCC's U56 cancer center-minority serving institution partnership grant are encouraged.

PCF Challenge Award: Teams of at least three highly experienced investigators capable of providing unique scientific expertise to the solution of a significant problem in prostate cancer research. A team may be assembled from one institution, or from several institutions. Investigators representing non-profit academic research centers worldwide are eligible to apply. Investigators from for-profit companies and government-sponsored institutions, i.e., NIH, are ineligible.

Anticipated administrative expenses involved in selecting and monitoring the grant awards:

The anticipated administrative expenses involved in selecting and monitoring grants will be incremental as they would leverage existing infrastructure within the DF/HCC Central Administration, the Prostate Cancer Program and SPORE and within established PCF operations. Grant applications that are solicited by DF/HCC are and will be reviewed, selected and monitored by the Prostate Cancer SPORE governance committee. Grants that are solicited through PCF are managed by Howard Soule PhD EVP and Chief Science Officer at PCF, reviewed and selected by review teams and grantee progress is monitored by Dr. Howard Soule and PCF.

To offset expenses associated with the management of scientific advisory boards and committees, and with reviewing, selecting and monitoring additional grants, we anticipate allocating 10% of Settlement Pool funds toward indirect institutional costs at DF/HCC.

The means by which the grant opportunities would be advertised:

To solicit grant applications from the Harvard-wide applicant pool, DF/HCC will advertise RFPs through the DF/HCC website, the Harvard University and Harvard Medical School website, the Harvard Request for Application process, standardized communication to grant administration offices and email distribution lists.

To solicit grant applications from the Massachusetts-wide applicant pool, DF/HCC will advertise RFPs through the channels mentioned above, and will communicate directly with grants administration offices at major hospitals and universities in Massachusetts about these grant opportunities.

To solicit grant applications from the national applicant pool, PCF will advertise RFPs through its website, email distribution lists, marketing activities and public relations efforts.

The anticipated division of research grants between the investigation of prostate cancer and other Lupron®, treated conditions (such as precocious puberty):

In addition to its use as a prostate cancer treatment, Lupron® may be used in the treatment of endometriosis, uterine fibroids, or a condition known as central precocious puberty. Endometriosis and uterine fibroids are unusually common in women – although estimates vary, certain reports place the prevalence of endometriosis at 5%, and estimate that fibroids may be found in as many as 20% of women of reproductive age. Lupron® is also commonly used to manage ovulation levels during in vitro fertilization treatments. The suitability of Lupron® as a treatment for additional diseases, in particular estrogen-dependent diseases may also be the subject of academic investigations.

\$300,000 has been designated for awards for research involving diseases that are or may be treatable by Lupron®, representing approximately 3% of total direct award costs.

Measures that would be taken to avoid any real or perceived conflict of interest in the awarding of grants:

The DF/HCC SPORE governance committee is comprised of 12 faculty members from within the Harvard University community, which reviews and selects submitted grant applications. Each application slated for review must have at least two assigned reviewers with expertise in the relevant application area. At grant review meetings, each application is presented briefly and then scored using standard NIH scoring system. Scores are presented to the SPORE administrator for tally and applications are prioritized and selected based on these scores. In the event that an application is submitted by a governance committee member, an individual in his or her group, or anyone who may confer a real or perceived bias to a member's judgment abilities, the committee member in question will abstain from voting.

Grant applications solicited by PCF are reviewed by a qualified review team comprised of distinguished members of the scientific community who have specific expertise in the area pertaining to that specific RFP. To avoid real or perceived bias in the selection of such grant applications, scientific reviewers do not be allowed to review or vote on proposals that are submitted by applicants at their employing institution.

Additionally, DF/HCC and PCF will convene a high-level scientific advisory board specifically to ensure that Settlement Funds are distributed fairly, and conforming to the RFP guidelines and/or any other guidelines or principles that are associated with such funds. The board will be comprised of the following individuals:

Howard Soule PhD, EVP and Chief Science Officer at PCF
Philip Kantoff MD, Director of the Lank Center for Genitourinary Oncology at DF/CI, Director of the Prostate Program and SPORE at DF/HCC
William Nelson MD PhD, Director of the John Hopkins University Cancer Center
Director of the Prostate SPORE at Johns Hopkins University

Peter Nelson MD, Director of the Prostate SPORE at the University of Washington

Peter Scardino MD, Chairman of Surgery and Chief of Urology at Memorial Sloan Kettering Cancer Center, Director of the Prostate SPORE at Memorial Sloan Kettering Cancer Center

Jonathan Simons MD, President and Chief Executive Officer at PCF

Ken Pienta MD, Director of the Prostate SPORE at the University of Michigan

Donald Tindall PhD, Director of the Prostate SPORE at Mayo Clinic

Peter Carroll MD, Chief of Urology at University of California at San Francisco, Director of the Prostate SPORE at University of California at San Francisco

Court appointed board member

Restrictions that would be placed on overhead expenses paid to institutions with whom grantees are affiliated:

While we are requesting that 10% of overall funds be allocated to DF/HCC to support the effective distribution of grants, both DF/HCC and PCF will require that no award money be directed to overhead expenses at grantee institutions.

The appointment by the court of a member of the grant-awarding body to serve as the court's monitor:

The court appointed scientific advisory board member(s) will be included in all governance committee and scientific advisory board communiqués from both DF/HCC and PCF, concerning the review, selection and monitoring of the subject awards, and will be invited to any physical meetings or conferences that involve the review selection and/or monitoring of awards.

Mechanism by which grant funds would be paid out and accounted for:

All grant funds will be paid to grantees in yearly installments. Annual progress reports will be required from grantees, and such reports will call for detailed narrative updates and detailed expenditure reports. The issuance of each year's funding installment will be contingent upon satisfactory progress by grantees.

Procedures that would be followed in evaluating the progress of the funded research:

Progress will be measured through the submission of annual reports to DF/HCC or PCF, by the publication of research in academic journals, and if relevant, by progress in clinical trial activity. Generally, progress that approximately meets benchmarks, timelines, or specific aims that are set forth within corresponding proposals will be funded on a per year basis to the completion of the grant term. Unanticipated scientific findings that delay research timelines will not exclude grantee from continued funding so long as grantee research is of a high caliber and is within the scope of the original research proposal.

Provisions for the disposition of any possible intellectual property issues arising from the funded research:

Inventions and other intellectual works that arise from research funded by the Settlement Pool will be managed according to the policies and practices of the grantee's employing institution. In accordance with federal guidelines and regulations, it is expected that most if not all grantee institutions have an affirmative obligation to develop and commercialize inventions toward the public benefit (see http://www.cogr.edu/docs/bayh_dole.pdf). DF/HCC and PCF will not expect any remuneration from royalty streams associated with income from patents, copyrights or other intellectual property.

The time-frame in which the court could expect all funds to be expended and a final accounting made:

The maximum grant period will be two years, however, grant-making will be staggered over five years. A final accounting will thus be achievable within seven years from the start of the distribution of Settlement Pool funds.

Appendix A Description of DF/HCC and PCF

Dana-Farber/ Harvard Cancer Center

Dana-Farber Cancer Institute is the lead institution of Dana-Farber/Harvard Cancer Center (DF/HCC), whose member institutions include: Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Children's Hospital Boston, Harvard Medical School, Harvard School of Public Health, and Massachusetts General Hospital. Affiliate members hail from The Broad Institute at MIT. DF/HCC is the largest National Cancer Institute (NCI) designated Comprehensive Cancer Center in the country, consisting of over 1,100 Harvard faculty members. Founded in 1998, DF/HCC is a multi-institutional research enterprise that unites all of the cancer research efforts of the Harvard-affiliated community. The primary goal of DF/HCC is to encourage and promote collaborative interactions and translational research that will lead to new approaches to cancer prevention, diagnosis, and treatment.

DF/HCC Prostate SPORE

In 1992, the National Cancer Institute (NCI) inaugurated a funding mechanism called the Specialized Programs of Research Excellence (SPORE) to promote translational research by embracing the collaboration of basic and clinical sciences with a goal of moving basic research discoveries from the laboratory to the clinical setting. By providing this research funding, the SPORE will focus on bringing novel ideas that have the potential to reduce cancer incidence and mortality, to increase survival, and to improve quality of life. The hallmark of the SPORE is in the collaboration between laboratory and clinical scientists in planning, designing, and implementing research projects that impact cancer prevention, detection, diagnosis, treatment, and control. The SPORE's program funds scientists from both within and outside of DF/HCC member institutions to increase the translational research base. SPOREs meet annually to share data, assess research progress, identify new research opportunities, and establish priorities for research most likely to reduce incidence and mortality and to increase cancer survival.

The DF/HCC SPORE in prostate cancer (Prostate SPORE) is focused on a wide range of initiatives. The Prostate SPORE has acted as a focal point for translational activities among prostate cancer researchers. Since its inception in 1999, the Prostate SPORE has achieved numerous accomplishments that are reflective of its goals: to understand genetic factors involved in risk in order to construct rational prevention strategies; to assign treatment in a more rational fashion, by the stratification of patients using molecular means; to reduce treatment-related side effects; and to improve therapy for patients with advanced disease. Among the numerous research projects funded are studies to improve clinical decision-making about initiating hormone therapy for prostate cancer and preventing adverse effects in survivors, the use of gene expression patterns to discover genes and gene products linked to tumor development and progression, and the identification of molecular markers that can serve as prognostic indicators of prostate cancer.

DF/HCC Community Outreach and Disparities Initiatives

A key center initiative is the Initiative to Eliminate Health Disparities (IECD) with one primary goal— to eliminate racial, ethnic, and socioeconomic disparities in cancer care

and prevention. DF/HCC faculty conducts original research to understand the causes of cancer disparities and to devise solutions. DF/HCC also facilitates the access of underserved populations to state-of-the-art clinical trials and the delivery of culturally competent care in an effort to reduce disparities in cancer care.

Started in 2003, the mission of the UMass Boston-DF/HCC Comprehensive Cancer Partnership Program is to address health disparities in minority populations, and to improve research, training, and outreach initiatives for minority students, fellows, nurses, and scientists. The Program focuses on accomplishing this by focusing on three areas: collaborative cancer research, shared cancer training efforts, and cancer outreach. Goals include: Develop interdisciplinary programs of collaborative research that stimulate basic cancer research at UMB and health disparities research at both UMB and DF/HCC, Increase and enhanced cancer-focused training opportunities for minority students, postdoctoral fellows and nursing PhD students, Increase community outreach, cancer education, and dissemination of evidenced-based programs, Develop shared mechanisms for minority faculty recruitment and career development. The Program offers developmental funding for collaborative projects between UMB and DF/HCC that focus on any aspect of cancer, including cancer disparities. The Program also funds the development of collaborative projects in community outreach, cancer education, and dissemination of evidenced-based programs.

DFCI's Prostate Cancer Outreach Program is part of a collaborative effort to provide the Greater Boston community with prostate cancer information, education and screening. Collaborations with the Prostate Health Education Network (PHEN), community health centers and other community based organizations make it possible for DFCI's Prostate Cancer Education and Screening Program to educate and offer screening, patient navigation and support group resources to men at risk for prostate cancer with and without the Blum Van. Of the 35 prostate cancer education and/or screening events held this past year, 19 were held at various community locations. This year over 550 people were educated about prostate cancer without the van. DFCI's prostate cancer outreach program also collaborated with the Boston Public Health Commission's Pink and Black Ambassadors to provide prostate cancer education at barber shops and hair salons, partnered with the MDPH at the 11th Annual Massachusetts Prostate Cancer Symposium, participated in the Massachusetts Comprehensive Cancer Control Coalition Survivorship Summit and presented at the State House on Mobile Health and Health Disparities. The Prostate Cancer Outreach Program also received national exposure after being featured in the PBS film, "The Truth About Cancer."

The Blum Family Resource Center Van provides cancer education and screening throughout the region, including local Boston neighborhoods. The Blum Van is equipped with state-of-the-art technology and was designed to accommodate space for individual or small group needs. The following is a selected list of initiatives that took place on the Blum Van in 2008: Prostate Cancer Education and Screening Program: Prostate cancer is the second leading cause of cancer deaths in African American men and is the most frequently diagnosed cancer in the US. The death rate from prostate cancer remains approximately 2.4 times higher in African American men than in white men here in the

US. A total of 35 prostate cancer education and/or screening events were held this past year (with half taking place on the van) where 240 men were educated; 211 were screened; and 9 required follow-up for prostate cancer.

The Continuing Umbrella of Research Experiences (CURE) program is a DF/HCC endeavor that seeks to prepare high school and college students from underrepresented populations across the country to enter the world of cancer research, by placing them in real research settings throughout the Harvard-affiliated cancer research community. Now in its eighth year of operation, the CURE program's overarching goal is to encourage minority students to pursue future careers in the biosciences — particularly cancer research — giving practical meaning to academic course work. By participating in this program at DF/HCC, students learn from experts who are devoted to preventing, treating and curing cancer. Each year, a number of promising students are selected for this unique opportunity to expand and extend their interest in basic, clinical and/or population science cancer research. The CURE program has a proven track record of success in striving to achieve these goals in that over 80% of students that have completed the program are currently employed in the biomedical field and/or are interested in pursuing these careers; and; over 88% of graduating CURE students are enrolled in or plan to pursue graduate degrees (including M.D. and Ph.D.) in biomedical and/or cancer-related fields.

Prostate Cancer Foundation

The Prostate Cancer Foundation (PCF) was founded in 1993 to find better treatments and a cure for prostate cancer. Through its unique model for soliciting and selecting promising research programs and rapid deployment of resources, the PCF has funded more than 1,500 programs at nearly 200 research centers in 20 countries around the world. As the world's leading philanthropic organization for funding prostate-cancer research, the PCF is now a foundation without borders. Its advocacy for increased government and private support of prostate cancer programs has helped build a global research enterprise of nearly \$10 billion. The Prostate Cancer Foundation's primary mission is to fund promising research into better treatments and a cure for prostate cancer. The PCF has provided funding for more than 1,500 research projects at nearly 200 institutions worldwide. The Prostate Cancer Foundation is now the world's largest source of philanthropic support for prostate cancer research, including the discovery and early development of promising new treatments now in clinical trials, the development of gene therapy approaches to combat prostate cancer, and the development of vaccines that work with the body's immune system to kill prostate cancer cells. Each year, the PCF reviews hundreds of applications from cancer researchers around the world and provides funding to those researchers working on the most promising projects. In addition, the PCF hosts an annual scientific retreat that brings together the brightest minds in prostate cancer research in an effort to break down the traditional barriers that impede progress toward better treatments and a cure for prostate cancer.

By initiating new research projects under one coordinated program, we would avoid duplication and encourage complementary research efforts, while leaving intact the

applicant investigators' freedom of academic inquiry, which is so fundamental to innovation and discovery in medical science.

Appendix B DF/HCC SPORE in Prostate Cancer Award History**Career Development Program**

2002				
PI	Institution	Project Title	Mentor	Total Direct
Levi Garraway, MD, PhD	DFCI/MGH	A "Functional Proteomics" Study of Hormone Independence in Prostate Cancer	Ed Harlow, PhD William Sellers, MD	\$40,000
2003				
PI	Institution	Project Title	Mentor	Total Direct
Pradip Majumder, PhD	DFCI	Discovery of Molecular Markers for Prostate Cancer	William Sellers, MD	\$40,000
Matthew Freedman, MD	MGH	A Genomic Approach to Identifying Inherited Variation of the HPC1 Locus in Sporadic Prostate Cancer	David Altschuler, MD	\$40,000
Vijay Yajnik, MD	MGH	DOCK4 in Prostate Cancer Progression	Daniel Haber, MD	\$40,000
Timothy Gilligan MD	DFCI	Prostate Cancer Screening in Decision Aid for African-American Men in Boston	Philip Kantoff, MD	\$30,000
Jean Zhao, PhD	DFCI	Identification of Anti-Tumor Agents that Target the P13K Pathway in Genetically Engineered Human Prostate Tumor Cells	Thomas Roberts, PhD	\$40,000
Dror Michelson, MD, PhD	MGH	Bone Metabolism in Men with Advanced Prostate Cancer: Effects of Disease and Treatment	Matthew Smith, MD, PhD	\$30,000
Jacqueline Banyard, PhD	Children's	Analysis of Collagen XXIII Expression in Human Prostate Cancer	Bruce Zetter, PhD	\$40,000
2004				
PI	Institution	Project Title	Mentor	Total Direct
Lorelei Mucci, PhD	BWH	Developing a Composite Biomarker for Aggressive and Indolent Prostate Cancer	Meir Stampfer, MD	\$40,000

2005					
PI	Institution	Project Title	Mentor	Total Direct	
Larisa Litovchick, MD, PhD	DFCI	The Role of Glycogen Synthase Kinase-3 in Cell Cycle Progression and Survival of Prostate Cancer Cells	James DeCaprio, MD	\$40,000	
Rameen Beroukhim, MD, PhD	DFCI	High-Resolution Genome-wide Mapping of Structural Mutations in Prostate Cancer	William Sellers, MD Matthew Meyerson, MD, PhD	\$40,000	
Shao-Yong Chen, Ph.D	BIDMC	Peptide-Prolyl Isomerase Pin1 In Prostate Cancer Development	Stephen P. Balk, MD, PhD	\$40,000	
Sang Hyun Lee, Ph.D.	DFCI	The Significance of the Phosphoinositide 3-Kinase (PI3Ks) in Prostate Cancer	Thomas M. Roberts, PhD	\$40,000	
2006					
PI	Inst.	Project Title	DIR Award	IDC Award	Total Award
Hu, James	BWH	Not Available	\$60,000	\$10,500	\$70,500
Wang, Qianben	DFCI	Not Available	\$60,000	\$42,000 (NIH)	\$102,000
2007					
PI	Institution	Project Title	DIR Award	IDC Award	Total Award
Zhe Li, Ph.D.	Children's Hospital / Boston	Probing the mechanism of pathogenesis in prostate cancer with TMPRSS2-ERG gene rearrangement using preclinical mouse models	\$40,000	\$25,600	\$65,600
Simo Arredouani, Ph.D. M.Sc.	BIDMC	Targeting novel prostate tumor antigens for cancer immunotherapy	\$38,000	\$11,900	\$49,900
Mark Pomerantz, M.D.	DFCI	Functional analysis of the 8q24 prostate cancer risk locus	\$40,000	\$28,400	\$68,400
Xin Yuan, M.D., D.Sc.	BIDMC	SOX9 regulated tumor angiogenesis in prostate cancer	\$40,000	\$28,000	\$68,000

Michael Rothenberg, M.D., Ph.D	MGH	Defining the function of TMPRSS2-ERG in prostate cancer cell growth and survival	\$40,000	\$7,000	\$47,000
2008					
PI	Inst.	Project Title	DIR Award	IDC Award	Total Award
Jennifer R. Stark, Sc.D.	BWH	The patho-epidemiology of proliferative inflammatory atrophy lesions	\$40,000	\$7,000	\$47,000
Akash Patnaik, M.D., Ph.D	BIDMC	Obesity and prostate cancer	\$40,000	\$28,000	\$68,000

Developmental Projects Program

2002 & 2003			
PI(s)	Institution	Project Title	Total Direct
William C. Hahn, MD, PhD	DFCI	Discovery of Novel Prostate Cancer Therapeutics Using Reverse and Chemical Genetics	\$50,000
Patrick Hu, MD, PhD Muneesh Tewari, MD, PhD	MGH DFCI	Identification and Validation of Novel Drug Targets in the Insulin-Like Growth Factor-1 Signaling Pathway Using <i>C. Elegans</i>	\$50,000
Anders M. Naar, PhD	MGH	The Role of the Androgen Receptor in the Development and Progression of Prostate Cancer	\$50,000
Aria F. Olumi, MD	BIDMC	The Role of Anti-Apoptotic Factors in Evasion of Prostate Tumors from TRAIL-Induced Apoptosis	\$50,000
Matthew R. Smith, MD, PhD David M. Nathan, MD	MGH	Insulin Resistance and Cardiovascular Disease Risk Associated with Androgen Deprivation Therapy for Prostate Cancer	\$50,000
Towia Libermann, PhD	BIDMC	Deregulated IL-6 Gene Expression in Prostate Cancer: A Target for Therapeutic Intervention	\$50,000
2004			
PI(s)	Institution	Project Title	Total Direct
Christopher Carpenter MD	BIDMC	The Role of Bmx in Prostate Cancer	\$40,000
Matthias Hofer MD	BWH	Developing a Molecular Signature of Aggressive Prostate Cancer Based on Genomic Aberration and Expression Array Analysis in a Large Patient Cohort	\$40,000
Jon C. Aster MD	BWH	JAGGED1 in Human Prostate Cancer	\$40,000

2005					
PI(s)	Institution	Project Title	Total Direct		
Jennifer Allen RN, MPH, ScD	DFCI	A Computer-Based Intervention to Promote Informed Decision Making about Prostate Cancer Screening among African American Men	\$20,000		
Michael R. Freeman, Ph.D	Children's	Akt Modifiers from Cholesterol-rich Membrane Rafts	\$40,000		
David A. Frank, M.D., Ph.D.	DFCI	STAT3 in Pathogenesis and Treatment of Prostate Cancer	\$40,000		
Omid C. Farokhzad, MD	BWH	Development of a Microreactor for Engineering of Targeted Nanoparticles for Prostate Cancer Therapy	\$40,000		
Meredith Regan, ScD	DFCI	PSADT as an Endpoint in Clinical Trials for Men with Biochemical Recurrence of Prostate Cancer Following Local Therapy	\$20,000		
Matthew Freedman, M.D.	MGH	A Targeted Genomic Approach to Identifying Genetic Determinants of Prostate Cancer Aggressiveness	\$40,000		
2006					
PI	Institution	Project Title	DIR Award	IDC Award	Total Award
Mucci, Lorelei	BWH	Not available	\$60,000	\$42,000 (NIH)	\$102,000
Balk, Steven	BIDMC	Not available	\$60,000	\$42,000 (NIH)	\$102,000
Libermann, Towia	BIDMC	Not available	\$60,000	\$28,400	\$88,400
DePinho Ronald	DFCI	Not available	\$60,000	\$42,000 (NIH)	\$102,000
2007					
PI	Institution	Project Title	DIR Award	IDC Award	Total Award
William Hahn, M.D., Ph.D.	DFCI	Credentialing kinases that drive hormone manipulation-refractory prostate cancer	\$40,000	\$28,400	\$68,400
Lorelei A. Mucci, ScD	BWH	Genetic variation and the TMPRSS2:ERG fusion in prostate pathogenesis and progression	\$40,000	\$30,000	\$70,000

Steven P. Balk, M.D., Ph.D.	BIDMC	Targeting non-receptor tyrosine kinase Bmx/Etk in prostate cancer	\$40000	\$7000	\$47000
2008					
PI	Inst.	Project Title	DIR Award	IDC Award	Total Award
X. Shirley Liu, Ph.D.	DFCI	Epigenetic signature of hormone independent prostate cancer	\$40,000	\$28,400	\$68,400
Meir Stampfer, M.D, Dr Ph	BWH	Dietary phytoestrogens in relation to prostate cancer risk and survival	\$40,000	\$7,000	\$47,000

Appendix C Prostate Cancer Foundation Award History

Research Awards by the Prostate Cancer Foundation		
1993-2009		
Albert Einstein College of Medicine		\$75,000
Ardono Research		\$125,000
Assaf Harofeh Medical Center		\$200,000
Bar-Ilan University		\$225,000
Baylor College of Medicine		\$2,200,000
Baylor Institute for Immunology Research		\$300,000
Ben-Gurion University of the Negev		\$300,000
Ben May Institute		\$125,000
Boston University		\$25,000
Brandies University		\$250,000
Broad Institute of Harvard and MIT		\$2,994,000
British Columbia Cancer Agency		\$300,000
California Institute of Technology		\$450,000
Cancer Institute of New Jersey		\$75,000
Cantonal Hospital St. Gall		\$75,000
Carmel Medical Center		\$75,000
Case Western Reserve University		\$425,000
Cedars-Sinai Medical Center		\$2,648,000
Center for Prostate Cancer Disease Research		\$200,000
Cleveland Clinic		\$717,000
Cold Spring Harbor		\$100,000
Columbia University		\$2,507,000
Cornell University		\$3,191,000
Weill Medical College	\$3,091,000	
Duke University		\$2,225,000
Eastern Virginia Medical School		\$150,000
Emory University		\$2,125,000
Erasmus University		\$250,000
Fox Chase Cancer Center		\$150,000
Fred C. Hutchinson Cancer Research Center		\$5,257,000
Garvan Institute of Medical Research		\$50,000
Gerogetown University		\$100,000
GMP Genetics		\$100,000
Hadassah University Hospital		\$535,000
Harvard University		\$31,126,000
School of Public Health	\$465,000	
Beth Israel Deaconess Medical Center	\$4,639,000	
Brigham & Women's Hospital	\$8,065,000	
Children's Hospital Boston	\$1,125,000	
Dana-Farber Cancer Institute	\$8,790,000	
Massachusetts General Hospital	\$8,042,000	

Hebrew University		\$1,267,000
Henry Ford Health System		\$100,000
Indiana University		\$375,000
Innsbruck Medical University		\$175,000
Institute for Systems Biology		\$2,023,000
John Wayne Cancer Institute		\$200,000
Johns Hopkins University		\$22,753,000
Justus Liebig University		\$1,175,000
Karolinska Institute		\$10,000
La Jolla Institute for Allergy and Immunology		\$25,000
Lankenau Institute for Medical Research		\$50,000
Long Island College Hospital		\$25,000
Louisiana State University, Shreveport		\$50,000
Massachusetts Institute of Technology		\$1,460,000
Mayo Clinic		\$400,000
McGill University		\$551,000
Medical University of South Carolina		\$263,000
Memorial Sloan Kettering Cancer Center		\$21,693,000
Menzies Centre for Population Health Research		\$1,000,000
Mount Sinai School of Medicine		\$250,000
National Cancer Institute		\$425,000
New England Medical Center		\$230,000
New York Medical College		\$250,000
New York University		\$505,000
Northern California Institute of Research and Education		\$100,000
Northwestern University		\$1,328,000
Ohio State University		\$922,000
Oregon Health & Science University		\$300,000
Pacific Northwest Cancer Foundation		\$475,000
Prostate Centre in Vancouver		\$4,025,912
Providence Portland Medical Center		\$425,000
Rockefeller University		\$300,000
Roger Williams Medical Center		\$300,000
Roswell Park Cancer Institute		\$1,475,000
The Royal Marsden		\$225,000
St. Louis University		\$150,000
Salk Institute for Biological Studies		\$986,000
San Diego Cancer Research Institute		\$150,000
Scripps Clinic		\$175,000
Scripps Research Institute		\$975,000
Sheba Medical Center		\$200,000
Sidney Kimmel Cancer Center (San Diego)		\$150,000
Stanford University		\$1,615,000
State University of New York		\$250,000
Stony Brook	\$150,000	
Upstate Medical University	\$100,000	
Strang Cancer Prevention Center		\$250,000
Technion		\$675,000

Tel Aviv University		\$598,000
Temple University		\$33,000
TGen		\$1,000,000
The Burnham Institute		\$1,506,000
The Ordway Research Institute		\$175,000
Thomas Jefferson University		\$125,000
Translational Genomics Research Institute		\$400,000
Tulane University		\$500,000
University Hospital, Nijmegen		\$275,000
University of Alabama at Birmingham		\$200,000
University of Arizona		\$150,000
Unveristy of Basel		\$75,000
University of Bern		\$100,000
University of British Columbia		\$375,000
University of Calgary		\$225,000
University of California		\$33,866,000
University of California, Berkeley	\$400,000	
Lawrence Livermore National Laboratory	\$175,000	
University of California, Davis	\$589,000	
University of California, Irvine	\$150,000	
University of California, Los Angeles	\$14,345,000	
University of California, Riverside	\$100,000	
University of California, San Diego	\$7,475,000	
University of California, San Francisco	\$10,632,000	
University of Chicago		\$625,000
University of Colorado		\$527,000
University of Connecticut		\$195,000
University of Edinburgh		\$75,000
University of Fukui		\$100,000
University of Helsinki		\$200,000
University of Illinois		\$250,000
University of Iowa		\$575,000
University of Kentucky		\$200,000
University of Louisville		\$200,000
University of Maryland		\$200,000
University of Massachusetts		\$350,000
University of Michigan		\$7,278,000
University of Minnesota		\$325,000
University of Missouri		\$75,000
University of Munich		\$300,000
University of Nebraska		\$100,000
University of North Carolina, Chapel Hill		\$100,000
University of Pennsylvania		\$462,000
University of Pittsburg		\$1,528,000
University of Regensburg		\$200,000
University of Rochester		\$600,000
University of Southern California		\$779,000
University of Tampere		\$300,000

University of Texas		\$19,309,000
M. D. Anderson Cancer Center	\$18,234,000	
University of Texas, San Antonio	\$150,000	
University of Texas, Southwestern	\$925,000	
University of Toronto		\$275,000
University of Utah		\$100,000
University of Virginia		\$3,075,000
University of Washington		\$7,651,000
University of Wisconsin		\$4,631,000
Urological Sciences Research Foundation		\$100,000
Vancouver General Hospital		\$216,000
Vanderbilt University Medical Center		\$740,000
Veterans Administration, San Francisco		\$50,000
Volcani Center		\$180,000
VU Medisch Centru		\$100,000
Wake Forest University		\$215,000
Walter Reed Army Medical Center		\$50,000
Washington University in St. Louis		\$1,975,000
Wayne State University		\$250,000
Weizmann Institute of Science		\$1,850,000
Whitehead Institute for Biomedical Research		\$600,000
Yale University		\$400,000
	Total	\$227,270,912
	Number of Institutions	158

Appendix D

Award Descriptions

DF/HCC High Impact Collaboration Awards (\$500,000 over 2 yrs.)

The High Impact Collaboration Awards are for multi-year, large-scale research projects for teams of at least two highly experienced investigators capable of providing unique scientific expertise to the solution of a significant problem in prostate cancer research. Applications must include collaborators from at least 2 different DF/HCC member institutions or affiliate member institutions.

DF/HCC Career Development Awards (\$100,000 over 2 yrs.)

The Career Development Awards support promising young investigators to promote prostate cancer translational research. A track record of interest and productivity in prostate cancer research is required. Awardees would become a member of the DF/HCC Prostate Cancer Program and the DF/HCC Prostate Cancer SPORE and would be expected to attend SPORE activities (meetings, retreats, research presentations).

DF/HCC Project Development Awards (\$100,000 over 2 yrs.)

The Developmental Project Awards support faculty conducting cutting-edge prostate cancer translational research. Research may span the disciplines of basic biology, population studies, outcomes, or social science. However, all basic research must have a plan for translation into application or studies in humans. Awardees would become a member of the DF/HCC Prostate Cancer Program and the DF/HCC Prostate Cancer SPORE and would be expected to attend SPORE activities (meetings, retreats, research presentations).

DF/HCC Lupron® Treatable Disease Awards (\$100,000 over 2 yrs.)

The Lupron Treatable Disease Awards support physicians and researchers who are faculty at university and major hospitals across Massachusetts focused on diseases and conditions that are Lupron Treatable including but not limited to endometriosis, uterine fibroids, and precocious puberty.

DF/HCC Student Training Awards (\$20,000 over 2 yrs.)

The Student Training Awards support students in nursing, medical, PhD programs and minority students eligible for participation in the CURE Program as well as UMass Boston-DF/HCC Comprehensive Cancer Partnership Program.

DF/HCC Disparity Research Awards (\$100,000 over 2 yrs.) The Disparity Research Awards are multi-year awards to support research efforts to understand and eliminate racial, ethnic, and socioeconomic disparities in cancer care and prevention.

DF/HCC Community Outreach Awards (\$100,000 over 2 yrs.)

The Community Outreach Awards are multi-year awards to support research and increase access of minority and underserved populations to culturally competent care,

screening, diagnostics, state of the art clinical trials as well as to provide education and awareness, early detection screening and prevention strategies.

PCF Challenge Awards (\$1,000,000 for 1 yr.)

The Challenge Awards support large-scale research projects. The proposal must be from teams of at least three highly experienced investigators capable of providing unique scientific expertise to the solution of a significant problem in prostate cancer research. A team may be assembled from one institution, or from several institutions.

Appendix E Budget

		Amount	Number		
DF/HCC Awards	High Impact Grants	\$ 500,000	5		\$ 2,500,000.00
	Career Development Awards	\$ 100,000	6		\$ 600,000.00
	Project Development Awards	\$ 100,000	9		\$ 900,000.00
	Lupron Treatable Disease Awards	\$ 100,000	3		\$ 300,000.00
	Student Awards	\$ 20,000	8		\$ 160,000.00
	Community Outreach Awards	\$ 100,000	5		\$ 500,000.00
	Disparity Grants Awards	\$ 100,000	4		\$ 400,000.00
PCF Awards	Challenge Awards	\$ 1,000,000	5		\$ 5,000,000.00
				Subtotal	\$ 10,360,000.00
				IDC	\$ 1,036,000.00
				Total	\$ 11,396,000.00

DF/HCC

DANA-FARBER HARVARD CANCER CENTER

October 8, 2009

Marsha K. Zierk
Law Clerk to the Honorable Richard G. Stearns
United States District Court
Suite 7130, One Courthouse Way
Boston, MA 02210

Dear Judge Stearns:

It is with great pleasure that I provide this letter of institutional support for the enclosed "Proposal for Disposition of Money Remaining in the Consumer Settlement Pool from Lupron Marketing and Sales Practices Litigation," an initiative that has been developed under the direction of Philip W. Kantoff, M.D. at the Dana-Farber/Harvard Cancer Center (DF/HCC) in collaboration with the Prostate Cancer Foundation (PCF).

The enclosed proposal highlights the importance of funding to address the very significant problem of treating and managing men living with prostate cancer. DF/HCC in conjunction with PCF are ideally poised to address this problem as well as the other Lupron treatable conditions and diseases, by leveraging proven funding mechanisms to distribute and monitor the settlement pool funds to the high impact research projects and talented investigators throughout Massachusetts and the nation.

Since its inception in 1998, DF/HCC seamlessly integrates the cancer research efforts of seven Harvard-affiliated medical institutions and supports the collective efforts of over 1,000 faculty members including basic scientists, translational researchers, clinical researchers and clinicians. DF/HCC's construct encourages powerful research collaborations, shared resource utilization and access new technologies on a scale that is unmatched by any other cancer center in the Nation. Central to DF/HCC's mission is to eliminate cancer disparities in cancer care for underrepresented populations throughout Massachusetts. DF/HCC's effective local and national community outreach programs, including the Blum Family Resource Van, provide access to these patients for who care and services would not otherwise be possible. In fact, the National Cancer Institute regards DF/HCC as "the model" toward which other cancer centers should aspire. For these reasons, I am confident that DF/HCC is outstandingly qualified to fulfill the task of distributing the Lupron settlement funds for maximum impact on research and care benefitting patients throughout the Commonwealth.

I can think of no person more suited to lead this program than Philip W. Kantoff, M.D. He has been the driving force in establishing and leading the nationally recognized Prostate Cancer Program and National Cancer Institute sponsored SPORE in Prostate Cancer at the

Edward J. Benz Jr., M.D.

President
Dana-Farber Cancer Institute

Director
Dana-Farber/Harvard Cancer Center

Richard and Susan Smith
Professor of Medicine
Harvard Medical School

Professor of Pediatrics
Harvard Medical School

Professor of Pathology
Harvard Medical School

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October 8, 2009

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Dana-Farber/Harvard Cancer Center. He is Chief Clinical Research Officer, Director of the Lank Center for Genitourinary Oncology, and Chief of the Division of Solid Tumor Oncology at Dana-Farber Cancer Institute, Brigham and Women's Hospital. He also serves as Professor of Medicine at Harvard Medical School. As both an institutional leader and a physician-researcher, Dr. Kantoff has earned the esteem of his colleagues at Dana-Farber and within the broader prostate research community for over 20 years - he is well known for his collaborative nature and he is a model mentor to numerous young investigators across Harvard and its affiliated hospitals. I have no doubt that Dr. Kantoff will apply these same traits to the program proposed herein.

Please do not hesitate to contact my office for any additional information that you may require. Thank you for your consideration of this request.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward J. Benz, Jr., M.D.", written in a cursive style.

Edward J. Benz, Jr., M.D.



FILED
IN CLERKS OFFICE

2009 OCT - 9

Richard S. Boskey
Senior Vice President and
General Counsel
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Boston, Massachusetts 02115-6084
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richard_boskey@dfci.harvard.edu
www.dana-farber.org

October 9, 2009

Ms. Marsha Zierk
Law Clerk for Hon. Richard G. Stearns
United State District Court
District of Massachusetts
1 Courthouse Way, Suite 2300
Boston, Massachusetts 02210

Re: TAP PHARACEUTICALS/LUPRON CY PRES DISTRIBUTION
CASE NO: 04-10175

Dear Ms. Zierk:

Enclosed for filing in the above captioned case, on behalf of Dana-Farber/Harvard Cancer Center, are the following:

- 1) Motion to consider Dana-Farber/Harvard Cancer Center research proposal re: TAP Pharmaceuticals/LUPRON cy pres distribution
- 2) Proposal from Dana-Farber/Harvard Cancer Center
- 3) Letter of support from Edward J. Benz, Jr., M.D.

Dana-Farber/Harvard Cancer Center is available at the Court's request to answer any questions or provide additional information regarding our submission.

Thank you.

Sincerely,

Richard S. Boskey
Senior Vice President & General Counsel