UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

IN RE: LUPRON® MARKETING AND
SALES PRACTICES LITIGATION

THIRD REQUEST FOR PUBLIC COMMENT ON THE PROPOSED CY PRES DISTRIBUTION OF THE UNDISTRIBUTED PORTION OF THE LUPRON® SETTLEMENT FUND

May 25, 2010

STEARNS, D.J.

The court, for the reasons explained in its previous orders, has narrowed its choice for the *cy pres* distribution of the approximately $11,400,000 surplus in the Class Settlement Fund to one of two proposals related to the research of cures for prostate cancer and other diseases and conditions treated by Lupron®. See Dkt # 537; # 542; # 549; and # 559. The court directs the Clerk to post on the District Court's web site[1] this Order together with the proposals submitted by the Dana-Farber/Harvard Cancer Center and Prostate Cancer Center (Dkt # 562), and the Loughlin, Garnick, Zietman, and Barry Proposal (Dkt # 541; # 554; and # 561). The court invites any comments from class members and the public on the merits of the two proposals. Comments should be directed to the attention of:

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

[1] www.mad.uscourts.gov

All comments must be received by the court on or before Friday, June 25, 2010.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

IN RE: LUPRON® MARKETING AND
SALES PRACTICES LITIGATION

MEMORANDUM AND ORDER REGARDING DISPOSITION
OF MONEY REMAINING IN THE CONSUMER SETTLEMENT POOL

May 19, 2009

STEARNS, D.J.

This class action involved a scheme in which TAP Pharmaceutical Products, Inc. (TAP), and two affiliated[1] co-defendants were alleged to have artificially inflated the price of the prostate cancer drug Lupron®.[2] Because of the number and similarity of the cases filed against defendants in various state and federal courts by patients, health care plans, and medical insurers, the Multi-District Litigation Panel consolidated the action in the District of Massachusetts for pretrial proceedings. After an extended period of litigation,[3] this court approved the certification of a national class consisting of

[a]ll persons or entities who paid for Lupron® at a price in whole or in part

[1]The co-defendants were Abbot Laboratories and Takeda Pharmaceutical Company Limited (f/k/a Takeda Chemical Industries, Ltd.).

[2]Lupron®, the trade name for leuprolide acetate, is also effective in the treatment of endometriosis, central precocious puberty, and uterine fibroid preoperative anemia.

[3]Decisions published by this court describe in detail the underlying litigation. See, e.g., In re Lupron Marketing and Sales Practices Litig., 345 F. Supp. 2d 135 (D. Mass. 2004) and In re Lupron Marketing and Sales Practices Litig., 245 F. Supp. 2d 280, 295-297 (D. Mass. 2003).

> calculated by reference to the AWP [average wholesale price] as published in national pharmaceutical publications such as the *Red Book* and First Data Bank . . . during the period from January 1, 1991, through September 30, 2001 . . . .

In re Lupron® Marketing and Sales Practices Litig., 228 F.R.D. 75, 81 (D. Mass. 2005). The Settlement Agreement approved by the court divided a $150 million Class Settlement Fund between a Third Party Payor (TPP) Settlement Pool and a Consumer Settlement Pool. The Agreement allocated $110 million to the TPPs, and $40 million to consumer claimants. A nationwide notice campaign was then conducted. By the end of the campaign, the TPP Pool was fully subscribed. Nearly 11,000 consumers also filed claims. The consumers were paid an average of 167 percent of their listed out-of-pocket expenses or insurance co-payments. After the payment of claims, fees, and expenses, an unexpended surplus of $11,400,000 remains in the Consumer Settlement Pool.

The Settlement Agreement included a provision addressing the possibility of a surplus. Under the terms of paragraph 17(b)(6)(ii) of the Agreement, "[a]ll unclaimed funds remaining in the Net Consumer Settlement Pool shall be distributed in the discretion of the Settlement Court as it deems appropriate." The *cy pres* ("near as possible") distribution of unclaimed funds in a common pool is well within the authority of a settlement court. See Six (6) Mexican Workers v. Arizona Citrus Growers, 904 F.2d 1301, 1306 (9th Cir. 1990); Masters v. Wilhelmina Model Agency, Inc., 473 F.3d 423, 436 (2d Cir. 2007). See also In re Folding Carton Antitrust Litig., 557 F. Supp. 1091, 1105 (N.D. Ill. 1983) ("[C]ourts have the power and the responsibility to exercise equitable discretion to achieve substantial justice in the distribution of the [residual] funds."). Cf. Zients v. LaMorte, 459 F.2d 628,

630 (2d Cir. 1972) ("Until the fund created by the settlement is actually distributed, the court retains its traditional equity powers."). As the Second Circuit has explained,

> [c]ourts have utilized Cy Pres distributions where class members are difficult to identify, or where they change constantly, or where there are unclaimed funds." Id. at § 10:16 n.1. In this connection, we take note of the recent Draft of the Principles of the Law of Aggregate Litigation by the American Law Institute. With respect to the approval of settlements providing for a Cy Pres remedy, the Draft proposes a rule limiting Cy Pres "to circumstances in which direct distribution to individual class members is not economically feasible, or where funds remain after class members are given a full opportunity to make a claim." Draft § 3.08, entitled "Cy Pres Settlements." This proposed rule is consonant with the observation of our sister circuit that "[f]ederal courts have frequently approved [the Cy Pres] remedy in the settlement of class actions where the proof of individual claims would be burdensome or distribution of damages costly."

Masters, 473 F.3d at 436, citing Six (6) Mexican Workers, 904 F.2d at 1305.

While affirming the court's discretion in the matter, case law provides little by way of practical guidance when it comes to a *cy pres* distribution. See e.g., In re Airline Ticket Comm'n Antitrust Litig., 307 F.3d 679, 684 (8th Cir. 2002) (the court is to distribute surplus funds to "recipient[s] [who] relate, as nearly as possible, to the original purposes of the class action and its settlement."). Consequently, the court invited suggestions from the parties before deciding how to proceed. The invitation generated a number of proposals including: (a) a renewed notice campaign using previously unavailable patient data from the Centers for Medicare and Medicaid Services in an effort to identify and locate additional potential consumer claimants; (b) the award of funds to nonprofit groups "advocating" on behalf of patients and consumer causes; (c) "brick and mortar" grants to hospitals and medical centers treating prostate cancer; (d) awards to "outreach" groups seeking to "educate" and "screen" prostate cancer patients; (e) the distribution of a

"dividend" to the 11,000 existing claimants (or their heirs); and (f) grants to researchers investigating the causes and cures of diseases or ailments treated by Lupron®. The court convened a hearing on January 13, 2009, to permit the parties to elaborate further upon the suggestions.[4]

After careful reflection and analysis, the court is inclined to adopt the research funding proposal presented by Dr. Kevin Loughlin, the Director of Urologic Research at Brigham and Women's Hospital.[5] In brief, Dr. Loughlin proposes that the money be used to fund cutting-edge research into the causes and cures of prostate cancer and other Lupron®-treated conditions.

The court will invite Dr. Loughlin to submit a formal proposal along the lines of his January 13, 2009 presentation. Of particular interest to the court are the following: (1) the protocol under which grant requests would be solicited and structured; (2) the average amount and duration of the awards contemplated; (3) the eligibility requirements for potential recipients; (4) the anticipated administrative expenses involved in selecting and monitoring the grant awards; (5) the means by which the grant opportunities would be

[4]There was very little dissent among the parties over the appropriateness of any one or all of the *cy pres* proposals submitted. The TAP interests opposed any distribution of funds to so-called "advocacy" groups, while the Intervenors strongly preferred that the money be divided among the existing consumer class members. All parties agreed that any further expenditure of settlement funds on attorneys' fees was neither necessary nor appropriate.

[5]Dr. Loughlin's participation came at the invitation of the Plaintiffs' Counsel Steering Committee. Three other physicians worked with Dr. Loughlin in developing the research proposal. They are Dr. Marc Garnick, an oncologist and prostate cancer researcher at Beth Israel-Deaconess Medical Center; Dr. Anthony Zietman, a radiation oncologist at Massachusetts General Hospital; and Dr. Michael Barry, the Chief of the General Medicine Unit at Massachusetts General Hospital.

advertised; (6) the anticipated division of research grants between the investigation of prostate cancer and other Lupron®-treated conditions (such as precocious puberty); (6) the measures that would be taken to avoid any real or perceived conflict of interest in the awarding of grants; (7) the restrictions that would be placed on overhead expenses paid to institutions with whom grantees are affiliated; (8) the appointment by the court of a member of the grant-awarding body to serve as the court's monitor; (9) the mechanism by which grant funds would be paid out and accounted for; (10) the procedures that would be followed in evaluating the progress of the funded research; (11) provisions for the disposition of any possible intellectual property issues arising from the funded research; and (12) the time-frame in which the court could expect all funds to be expended and a final accounting made.

ORDER

The court invites Dr. Loughlin to submit a formal proposal for the *cy pres* distribution of the excess settlement funds within sixty (60) days of today's date (if feasible), consistent with the preliminary proposal that he outlined at the hearing, and addressing the issues (among others), raised by the court in this Memorandum and Order.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: LUPRON® MARKETING AND SALES PRACTICES LITIGATION	MDL NO. 1430
	MASTER FILE NO. 01-CV-10861
THIS DOCUMENT RELATES TO ALL ACTIONS	Judge Richard Stearns

NOTICE OF FILING

Pursuant to the Court's May 19, 2009 "Memorandum and Order Regarding Disposition of Money Remaining in the Consumer Settlement Pool", Co-Lead Plaintiffs hereby submit (attached as an Exhibit here) the response to the Court's questions set forth in the Memorandum and Order, and additional information, supplied by Kevin R. Loughlin, MD, MBA (Chairperson), Marc B. Garnick, MD, Anthony L. Zietman, MD, and Michael J. Barry, MD. Of course, these doctors remain available for any additional questions the Court may have or to provide any additional information the Court may desire, or to appear at a Hearing if requested.

Plaintiffs' Counsel note that an appeal has been filed on the May 19 Order. Without commenting on the merits or validity of the appeal at this time, and of course without responding to it here, Plaintiffs' Counsel note that no stay has been requested on the Memorandum and Order and they therefore are filing the requested answers to questions within the time period set by the Court.

Dated: July 17, 2009

Respectfully submitted,

/s/ Thomas M. Sobol
Thomas M. Sobol (BBO#471770)
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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that a true and correct copy of the foregoing Notice of Filing, was served on all counsel of record electronically on July 17, 2009, pursuant to Section III of Case Management Order No. 2.

By: /s/ Thomas M. Sobol

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RESPONSE TO THE COURT'S
MAY 19, 2009 MEMORANDUM AND ORDER

Kevin R. Loughlin, MD, MBA (Chairperson), Marc B. Garnick, MD, Anthony L. Zietman, MD, and Michael J. Barry, MD hereby respectfully submit their responses to the Court's questions set forth in its "Memorandum and Order Regarding Disposition of Money Remaining in the Consumer Settlement Pool" dated May 19, 2009. We have also set forth here additional information on the budget for the grant protocol (Exhibit B), and on the expected administration of the proposed program for research into the causes and cures of prostate cancer and other Lupron-treated diseases/conditions. See Exhibit A ("Overview of the Lupron Fund Settlement Foundation Program") Of course, we remain available for any additional questions the Court may have or to provide any additional information the Court may desire.

ANSWERS TO THE QUESTIONS OF THE COURT

1. What will be the protocol under which grant requests would be solicited and structured?

   We will place advertisements in major medical journals and newspapers to publicize the grant announcements. The names of the presently-anticipated journals and newspapers are set forth below in Exhibit B, Attachment 3. One press release for national exposure will be created that outlines the availability of the grants. We will establish a website that will contain all the specifics of the available grant awards and the process for applying. All grant applications will be submitted electronically.

2. What will be the average amount and duration of the awards contemplated?

   See attached detailed budget, Exhibit B. We have created a spectrum of grant application formats suitable to the differing potential applicant pool. Our aim is to award as many applicants as possible with a monetary award that will enable meaningful contributions to maximize the care of prostate cancer patients and others with Lupron-treated diseases through education, diagnosis, research and treatment. (as stated in our Goal Statement, set forth below at Exhibit A)

3. What will be the eligibility requirements for potential recipients?

   We will have different grant categories. These will include medical students, nurses, young investigators, basic science researchers and clinicians. Applicable

education and work experience will be required for each category and evaluated for each grant applicant.

4. What are the anticipated administrative expenses involved in selecting and monitoring the grant awards?

   We are planning on limiting the administrative and governance charges for the overall grant program to 15 percent of the total budget. In addition, as in the Milken Foundation, the grant awards will not permit institutional overhead so that all of the awarded grant monies are used for the stated goal to maximize the care of prostate cancer patients and others with Lupron-treated disease through education, diagnosis, research and treatment. Thus, the awardees will not be permitted to use the monies for institutional or administrative expenses.

5. What are the means by which the grant opportunities would be advertised?

   As mentioned above, the grant announcements will be made in medical journals, newspapers and on the website. The list of the presently- anticipated journals and newspapers is set forth below in Exhibit B, Attachment 3. One nationally syndicated press release outlining the existence of the grant program and its goals will be created and provided at the commencement of each of the two separate granting periods. (Cycle 1 starting on Day 1; Cycle 2 starting on Day 366)

6. What is the anticipated division of research grants between the investigation of prostate cancer and other Lupron-treated conditions (such as precocious puberty)?

   Given the relative incidences of the diseases, we presently anticipate that about 90 percent of the awards will go to prostate cancer topics and about 10 percent to endometriosis, uterine fibroids, precocious puberty and other Lupron- treated disorders. However the awards will be made on scientific merit rather than strict quotas. Please see Exhibit A for more detail on the categories of research anticipated to be awarded under this program.

7. What measures would be taken to avoid any real or perceived conflict of interest in the awarding of grants?

   We four will constitute the Reviewing and Governance Committee. Any grants that emanate from applicants that are associated with one of the three hospitals that are represented by us (or with which any of the four of us have a relationship)

will require that member to recuse himself, both from review of the application and any decision (positive or negative) on whether to award funds to the applicant. We anticipate temporarily replacing that member with an independent ad hoc member if the necessary expertise to carry out peer review is deficient as a result of the recused member. In addition, we anticipate that an integral member of the Review and Governance Committee will include a Court -appointed member who will serve as an ex-officio participant in all of the Committees deliberations. Where necessary, additional ad hoc support and input will be sought on grant applications that are related to "non-prostate cancer Lupron-treated disease." Full financial disclosures of applicants will be an integral portion of the application and will considered for each application to avoid any real or perceived conflicts of interest in awarding of the grant monies.

8. What restrictions would be placed on overhead expenses paid to institutions with whom grantees are affiliated?

   As has been the case with the Milken Foundation grants, no institutional overhead will be awarded or allowed.

9. The Committee's response to the appointment by the Court of a member of the grant-awarding body to serve as the Court's monitor?

   We would welcome the appointment by the Court of an individual who would serve as the Court's monitor of the grant-awarding body. This could be the same person as would serve as the ex-officio participant in the Reviewing and Governance Committee's deliberations, or (as the Court chooses) an additional and separate monitor.

10. What would be the mechanism by which grant funds would be paid out and accounted for during the process?

    Half of the award would be given to the grantee at the time of the award. Midway through the grant cycle a status report would be required from the awardee. Grant cycles could run one, two or more years. Upon review and approval of the status report by the Reviewing and Governance Committee, the remainder of the grant money would be awarded. Submission of a final report outlining the accomplishments, publications and planned future research will be a requirement of the granting process. Two separate scientific research symposia that will embrace investigators and awardees will be planned at Year 3 and Year 5. All awardees will be required to participate in these symposia, which are intended to

allow the broadest dissemination of ongoing and contemplated research and results, and interactions among awardees to result in the best possible and broadest results.

11. What procedures would be followed in evaluating the progress of the funded research?

Each grant award will require submission of a status report at the mid-point of the grant award period. Grantees that are either experiencing delays in their work, or having performance issues in terms of meeting the grant's expectations will be handled and reviewed on an individual basis. One member of the Reviewing and Governance Committee will be assigned to the grantee and provide counseling related to the performance of the grantee. The Review and Governance Committee will reserve the right to prematurely terminate the second portion of the grant award if there is significant delinquency in the required submissions of the original application progress reports and/or if the deficiencies indentified at the mid- time in the cycle cannot be adequately addressed to the satisfaction of the Review and Governance Committee. We anticipate this to be a rare occurrence but will act on any such circumstance.

12. What are the provisions for the disposition of any possible intellectual property issues arising from the funded research?

All research would be considered in the public domain. If the Court approved, we will require all manuscripts and presentations to note acceptance and acknowledgement of following statement: " A portion or the whole of the work presented was supported by an award provided by the "Lupron Consumer Litigation Settlement Fund Foundation."

13. What is the time-frame in which the Court could expect all funds to be expended and a final accounting made?

We are anticipate that all the funds would be expended during a five year period that encompasses Cycle 1 and Cycle 2, as set forth above and further detailed in Exhibit A.

Respectfully submitted,
Kevin R. Loughlin, MD, MBA (Chairperson)
Marc B. Garnick, MD
Anthony L. Zietman, MD
Michael J. Barry, MD

EXHIBIT A

OVERVIEW OF AND ADDITIONAL INFORMATION ON THE LUPRON SETTLEMENT FUND FOUNDATION PROGRAM

Goals and Objectives

The goal of the Review and Governance Committee would be to provide overall governance of the program including the responsibility to review all grant applications and distribute the funds provided by the Court to maximize the care of prostate cancer patients and others with Lupron-treated diseases through education, diagnosis, research and treatment.

Review and Governance Committee

The Review and Governance Committee (hence the administrative board for the program) would be composed of four Harvard Medical School professors each with a separate Harvard affiliated-hospital affiliation with extensive experience in aspects related to research, diagnosis and treatment of prostate cancer, the principal disease managed by Lupron. The four major medical disciplines that diagnose and treat patients with prostate cancer are represented and include urologic surgery, medical oncology, radiation oncology and primary care medicine.

The members of the Committee will be the following:

Kevin R. Loughlin, MD, MBA, Chairperson
Professor of Surgery, Harvard Medical School
Director of Urologic Research, Brigham and Women's Hospital

Marc B. Garnick, MD
Clinical Professor of Medicine, Harvard Medical School
Medical Oncology and Founder, Hershey Foundation for Basic and Clinical Research in Prostate Cancer, Beth Israel-Deaconess Medical Center

Anthony L. Zietman, MD
Professor of Radiation Oncology, Harvard Medical School
Radiation Oncology, Massachusetts General Hospital

Michael J. Barry, MD
Professor of Medicine, Harvard Medical School
General Medicine Unit, Massachusetts General Hospital

Funding Process

We would announce the RFP in major medical journals and, a widely distributed press release, as well as lay publications (newspapers). We would employ a fast-track review process whereby each proposal would be limited to ten typewritten pages and investigators would be asked to include a NIH format biosketch. Much like the Milken CaPCure and Hershey Foundation grants, no institutional overhead would be allowed under a grant (no funds will be spent on institutional overhead).

Grant Descriptions

We expect that the vast majority of the grant applications will focus on prostate cancer including clinical and basic research and treatment related to this disease. A smaller number of grants are expected to relate to other diseases treated with Lupron, including uterine fibroids, endometriosis, and precocious puberty. These would include the following categories:

Clinical and Basic Research:

- Clinical research related to prostate cancer and Lupron treated diseases.
- Basic science research related to prostate cancer and Lupron treated diseases.
- Within each of these categories, investigator proposals for establishing or enhancing the development and inter-institutional use and access to tissue banks, when appropriate, will be encouraged.

Patient Education and Decision Making Research

- Community outreach and patient programs related to increased awareness and access to educational materials for prostate cancer, including populations where English is a second language.
- Similar outreach and patient education program concerning other Lupron-treated diseases.

Recruitment of Health Care Professionals to Careers Related to Prostate Cancer and Other Lupron -treated Diseases

- Recruitment of Young Investigators (at junior faculty level) for providing support to allow qualified individuals to enter research careers focusing on prostate cancer and other Lupron-treated diseases.

- Recruitment of medical students for summer internships in prostate cancer and other Lupron-treated diseases.

- Recruitment of nurses, via educational grants, to enhance skills in developing excellence in specific areas of clinical care for prostate cancer and other Lupron-treated diseases.

Continuing Educational Initiatives for the Entire Grant Recipient Group and Expanded Audiences

We would also propose an integrated scientific symposium in years three and five for the purpose of presenting the research and promoting further collaboration among the investigators. Periodic research updates of awardees progress would be compiled on a periodic basis and shared with the entire group of Grantees.

Proposed Time(starting from the day of notification of being the recipient of the monies for the program).

0 to 6 months (post- receipt of the administrative and governance responsibility) Development and dissemination of the RPF advertisements on the existence of the program and grants in lay media, a specific press release and appropriately- selected professional journals. This will be printed and publicized as soon as possible, but we need to deal with publication scheduled of the journals. As noted, a second cycle would start with Year 2.

7 -9 months Grant proposals would be required to be electronically submitted three months after the RFP announcements.

10-12 months Systematic peer review of grants and notification of awards to the successful applicants. Distribution of award monies to successful applicants to occur no later that at the completion of Year 1.

48 months The maximum duration of awards would be thirty- six months, so all the projects would be completed by four years after the initial RFP announcement.

Grant Descriptions

General Proposals: These proposals can be on any topic related to prostate cancer and Lupron- treated diseases including clinical and basic science research, community outreach, with particular emphasis to minorities, patient education programs and establishment of tissue banks. The duration of these proposals should be one to three years, and depending upon the actual type of grant solicited, would have certain dollar limit restrictions.

Young Investigator Awards: These awards will be made to residents, fellows or junior faculty members who have completed their training within the last three years. There will be twenty, two year awards with a stipend of $50,000 per year and twenty, one year awards with a stipend of $50,000 per year.

Medical Student Awards: These will be made to medical students with a faculty sponsor to perform a summer project related to prostate cancer and other Lupron-treated disease. There will be forty awards with a $2,500 stipend for each.

Nursing Award: These awards will be made to nurses to promote patient care, education and clinical research related to prostate cancer and other Lupron-treated disease. Five awards per year will be made. Each will be for $10,000.

Administration: Our aim is to maximize the amount of money devoted to improving the care of prostate cancer patients and patients with other with Lupron-treated diseases through education,diagnosis, research and treatment. Toward that end, we will establish the Lupron Settlement Fund Foundation. We presently intend to keep the administrative overhead of the foundation at 15% (approximately $1.71M) of the total corpus over the five year period of the awards.

EXHIBIT B

Budget Assumptions and Justifications:

Governance Committee: Our judgment is that we will need a full-time administrator and an office physically separate from any of our Harvard Medical School and affiliated Hospital institutions. In addition, we anticipate it will require approximately four hours per week for each of us to direct the activities of the program and provide its overall governance. During the course of the program and in consideration of the professional services provided by the Review and Governance Committee, we propose compensation to each of us at a rate of $250/hr. This represents a standard fee (indeed for us a reduced rate) for provision of these types of services.

Program Support Administrator: The administrator would be paid a salary of $85,000/year without benefits. We would anticipate a 3-4 percent salary increase per year.

Office Space: We have indentified a small office space on Stuart Street, centrally located in downtown Boston renting at $800/month. This includes 4 hours of free conference room time per month and a rate of $35/hour for any conference room time over the 4 allotted hours. (Attachments 1 and 2)

Website: The cost of designing and establishing a web page is approximately $4,000 and maintenance fees will vary depending on the amount of activity involved.

RFPAdvertisements: Attachment 3 summarizes the ad rates for the major professional journals, a syndicated press release and advertisements in lay newspapers. We would anticipate running ads over a 3-month period in the major publications- every year of a new funding cycle. We would estimate this will cost approximately $35,000-40,000 the first year with the possibility of decreasing the advertisement costs somewhat in subsequent years.

Phone/Fax/Copying/Stationery/Computer: An appropriate computer would cost approximately $3500 and we anticipate office supplies would require $2500/year.

Incorporation: Utilizing Legal zoom.com would cost approximately $1087 which would include incorporation, state fees, preparation of the 501c3 papers, registered agent fee and Tax ID number. We are currently researching the cost of liability insurance and would appreciate the Court's direction on this issue.

Grant Awards:

Young Investigator Awards: This would be limited to individuals who are three years or less from completing their training. The awards would be for $50,000/year. We propose a total of 40 awards to young investigators, twenty with one-year durations and twenty with two-year durations.
(Budget $3,000.000)

Medical Student Awards: We propose 40 awards (10 per summer) to medical students to enable them to work with established investigators and to introduce them to the research fields directed at prostate cancer and other Lupron-treated diseases.
(Budget $1,000,000)

Nursing: We propose 20 awards to nurses to encourage research relevant to patient care involving Lupron-treated diseases.
(Budget $200,000)

General Awards: These would be awards to established investigators. We would not propose a specific number or duration of awards, but would aim to fund the best scientific research proposals. We would plan on allocating up to $1,500,000/year- for these awards which could last one to three years.
(Budget $5,890,000)

Research Symposia: We propose holding two research symposia at the end of Year Three and Year Five. These research symposia would allow funded investigators to present their work and would foster future collaboration between investigators who might otherwise not meet each other. We would anticipate inviting guest speakers to present relevant research topics as well.

Apropos of a recent New York Times article (Grant System Leads Cancer Researchers to Play It Safe, NYT 6/28/09), we would encourage innovative proposals and new investigators to this area of cancer research.
(Budget $500,000)

Administration: As mentioned above, we would aim for 15 percent administrative overhead over the five year cycle of the research foundation.
(Budget $1,710,000)

Total Budget:
$11,400,000

Year	1	2	3	4	5	Total
Young Investigator		10x50K (10-2 YR Awards) 500K 1M 10x50K $500 K	10x50K 500K	10x50K (10-2 YR Awards) 500K 1M 10x50K $500K	10x50K 500K	3M
Medical Student		10x2.5K 25K	10x2.5K 25K	10x2.5K 25K	10x2.5K 25K	100K
Nursing		5x10K 50K	5x10K 50 K	5x10K 50K	5x10K 50K	200 K
Research Symposium			250 K		250K	500K
General Awards		1.4725M	1.4725M	1.4725M	1.4725M	5.89M

Attachment 1

312 Stuart Street, Boston MA

Rental Specifications
Turn-key furnished office solution.
Small interior office has common kitchenette, mail services and conference room for rent. Included in the rent are 4 hours per month of conference room time, mail sorting, electric, and HVAC. Over 4 hours per month the conference room is available to rent for $35/hr or $200/day.

There is a one-time set-up fee for telephone services of $100.00, after that unlimited local phone service and voice mail are $25/month. The second line devoted to a fax is an additional $25/month. Long distance telephone charges are billed directly to the user on a per minute basis by the management company. High volume copy and fax machines are available on a usage charge basis if needed.
Rent is $750.00/month.

To start an agreement with this location the following would be necessary:

First Month's Rent:	$750
Last Month's Rent:	$750
Refundable Retainer:	$750
Setup Fee (phone/fax/internet)	$100
First Month Phone & Fax	$50

TOTAL: $2,400.00

Attachment 2

Attachment 3

Journal	Cost 1X	Cost 3X	Total in dollars
New England Journal of Medicine (50 words)	302.50	277.50	832.50
The Journal of the American Medical Association (1/6 page)	3261	n/a	9783.00
Journal of Urology (1/4 page)	1020	1385	4155.00
Journal of Clinical Oncology (1/4 page)	1300	n/a	3900.00
Red Journal – International Journal of Radiation Oncology Biology Physics (1/4 page)	1280	1105	3315.00
American Journal of Obstetrics and Gynecology (1/4 page)	2170	2140	6420.00
L.A. Times (3-line ad, 4days max reach, 7 days online)	96.00	n/a	288.00
N.Y. Times (1/4 page; nationwide Sunday)	1406	n/a	4218.00
Chicago Tribune (5-line ad, 7days max reach, 7 days online)	299	n/a	897.00
Wall Street Journal (<1/6 page = per column inch)	1639/inch	n/a	4917.00
Syndicated Press Release (to go out on PR News wireservice)	$1100 in year 1 and 2		2200.00 **40,925.50**

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

IN RE: LUPRON® MARKETING AND
SALES PRACTICES LITIGATION

REQUEST FOR PUBLIC COMMENT ON THE PROPOSED
CY PRES DISTRIBUTION OF THE UNDISTRIBUTED PORTION
OF THE LUPRON® SETTLEMENT FUND

July 22, 2009

STEARNS, D.J.

The Court will direct the Clerk to post on the District Court web site[1] this Order, the Court's May 19, 2009 Memorandum and Order Regarding Disposition of Money Remaining in the Consumer Settlement Pool, and the submission received on July 17, 2009, in response to the Court's May 19 request, from Kevin R. Loughlin, MD, MBA (Chairperson), Marc B. Garnick, MD, Anthony L. Zietman, MD, and Michael J. Barry, MD. Before entering a final order on the *cy pres* distribution of the remaining funds, the Court invites public comment on the Loughlin proposal. These should be directed to the attention of:

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

All comments must be received by the Court on or before Thursday, August 27, 2009.

SO ORDERED.

/s/ Richard G. Stearns

[1] www.mad.uscourts.gov

UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

IN RE: LUPRON® MARKETING AND
SALES PRACTICES LITIGATION

SECOND REQUEST FOR PUBLIC COMMENT ON THE PROPOSED CY PRES DISTRIBUTION OF THE UNDISTRIBUTED PORTION OF THE LUPRON® SETTLEMENT FUND

October 14, 2009

STEARNS, D.J.

The court directs the clerk to post on the District Court web site[1] this Order and the research proposal received on October 9, 2009, from the Dana-Farber/Harvard Cancer Center. Before making a decision on the cy pres distribution of the remaining funds, the court invites public comment on the Dana-Farber proposal. These should be directed to the attention of:

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

All comments must be received by the court on or before Friday, November 13, 2009.

SO ORDERED.

/s/ Richard G. Stearns
_____
UNITED STATES DISTRICT JUDGE

[1] www.mad.uscourts.gov

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

In re: LUPRON MARKETING AND SALES PRACTICES LITIGATION

To: The Honorable Richard G. Stearns
United States District Court
District of Massachusetts

From: Kevin R. Loughlin, MD, MBA (Chairperson)
Marc B. Garnick, MD
Anthony L. Zietman, MD
Michael J. Barry, MD

Re: Proposal from Dana-Farber/Harvard Cancer Center (DF/HCC) regarding Lupron Class Action Settlement cy pres distribution

Date: 11 November 2009

The four authors were pleased to receive the approval given in the Court's stated initial decision to award and allow use of the Lupron Class Action Settlement funds in a program for research into the causes and cures of prostate cancer and other Lupron-treated diseases/conditions. Our original proposal was submitted in August 2008 and we responded to the Court's May 19 Order asking for additional information and details in our July 17 submission. We set forth here additional information on our qualifications and our demonstrated ability to work collaboratively and cohesively to execute the stated goals and objectives of the program. We also set forth the strengths of our proposal, and – as requested by the Court's October 14, 2009 Second Request – review questions or issues raised by the Dana-Farber/Harvard Cancer Center's proposal that was submitted well after the advertised deadline.

We stand ready to meet with the Court again (Dr. Loughlin appeared before the Court on January 13) or to make another filing to answer any questions of the Court.

We Have a Long History of Collaboration, Teamwork and Leadership in the Specific Areas Addressed by Court's Apparent Goals for the Use of the Lupron Settlement Fund.

We wish to note that all of us are members of the DF/HCC by virtue of our respective academic (Harvard Medical School) and hospital (Massachusetts General Hospital,

Brigham and Women's Hospital and Beth Israel Deaconess Medical Center) affiliations. However, as the Court is aware, we have joined together on a voluntary basis to run the proposed program.

Over the years, we have collaboratively worked together on topics and work relating to research on prostate cancer and other Lupron-treated disorders. Most notably, the four of us were selected from the entire Harvard Medical School faculty by the Risk Management Foundation (RMF) of the Harvard Medical Institutions to produce PSA guidelines for prostate cancer screening (Appendix 1). This topic is one of the most controversial topics not only in cancer medicine, but medicine as a whole. RMF recognized our expertise and our ability to collaborate and solicited us to draft a consensus statement that would serve as a blueprint for primary care physicians and specialist physicians nationwide. The guidelines led to the publication of a "Decision Support Tool", which has been widely circulated to all primary care physicians at each of the Harvard teaching hospitals and other physicians nationwide. All deadlines were met during the production of this document which was accepted, without revision, by a wide representation of the Harvard faculty with an expertise in PSA screening and prostate cancer management, who critically reviewed the document.

In submitting our Lupron Settlement proposal to the Court, we came together -- each of us representing a different specialty – and made our proposal independent of any institutional influence or bias, which we felt was crucial to ensure that research funds from the settlement could be made available to investigators from any institution without prejudice or favor, and to new as well as established investigators, based solely on the quality of the research proposals submitted to us. The four of us, as individuals, have a record throughout our careers of leadership roles in prostate cancer management in particular, as well as other areas of medicine. (Appendix 2)

Considerations Related to the Submission of the DF/HCC

1. Grant procedures -- deadlines and confidentiality

On January 13, 2009 the Court heard and considered the proposals of many parties interested in receiving monies from the Lupron Class Action Settlement cy pres fund. All of these proposals had been publicly filed with the Court in August 2008. The Court made a preliminary determination to award the cy pres funds to our group, and made this public announcement by posting it on the Court's website on May 19, 2009; this Order was also widely and publicly reported by Bloomberg news. In that Order, the Court asked us to submit more information about our proposal and we did so on July 17. The Court then posted that response and issued a July 22 Order that required that any comments on or objections to the preliminary determination and proposal be filed with the Court by August 27, 2009. Indeed, within that timeframe, one objection/appeal was filed, by Donald E. Haviland, Esq.. The DF/HCC filed their proposal on October 9, 2009 – nearly 9 months since the original Court hearing attended by Dr Loughlin.

- The Court can address the legal issues regarding the above deadlines far better than we can. However, we can provide our perspective on the timing of the DF/HCC proposal based on our collective long experience with medical research grants (which represents both local, national and international standards). We have never witnessed a situation where a grant proposal would be filed with total disregard for deadlines and for the confidentiality of competing proposals.

- Our collective experience with federal and private granting agencies has been that deadlines for submission of research proposals are firm. Applications are not accepted or considered if they are a day late, let alone months late.

- In addition, all grant applications to federal and private agencies are made without the applicants having the ability to read and review competing applications prior to writing their own submission. If any applicant is found to have read a submission, they are dismissed from consideration in that grant cycle or program. This allows for the integrity of research proposals.

2. Overhead charges.

One of the unique features of our proposal was that it was independent of the "bricks and mortar" of any large institutions and, as such, we were able to include an expected overhead charge of only 15%, which is substantially less than the overhead charged by academic facilities or hospitals and related entities. The DF/HCC standard overhead, according to their grants office, is 25% (we have checked this with the office in the last two weeks). However, perhaps after reading our proposal, the DF/HCC group included an overhead of only 10% in its proposal to the Court. Nowhere in their proposal does DF/HCC provide a justification for that number or an explanation of how they will now lower their long-established overhead costs. In addition, unlike our proposal, DF/HCC does not provide a detailed budget of what specifically the institutional overhead will cover (personnel, offices, supplies etc.). It should be emphasized that each of us, by being members of our own hospitals' administration and members of the DF/HCC organization, knew what existing and typical overheads were. In selecting a 15% overhead, we acted personally to avoid the "to-be-expected overhead" charge that would be levied by any academic institution or hospital, and also dramatically lowered our hourly rates and fees that might have been paid to us as the leaders of the program.

3. Restricted eligibility

Our proposal makes the cy pres monies available to the community of prostate cancer researchers nationally and internationally, junior and senior, based on the quality of the research proposals. There are no constraints due to or advantages given to specific institutions or geographic regions. However the DF/HCC proposal (pg. 3 of their document) would direct nearly half of the award ($5.36M) exclusively to Harvard faculty

or Massachusetts residents. This is inconsistent with the spirit of the settlement or the subject matter of the litigation. The Lupron class action addressed a national issue, and our proposal recognized that it would be inappropriate to award any major part of the cy pres monies to one university and/or one state. We continue to believe that this is true. Harvard and other Massachusetts investigators should compete for these funds on an equal footing, and the best research proposals should be funded, regardless of origin.

4. Advertisements/Announcements

We believe that an important part of our proposal was the designation of an appropriate amount of our proposed overhead to advertisements in a broad spectrum of medical journals with a diverse readership, as well as lay publications. Our purpose was to successfully publicize the availability of the research funds as widely as possible in both a spirit of fairness, but also with the goal of attracting a diverse applicant pool to obtain the very best research proposals.

In contrast, the DFCI/HCC proposal (pg. 4 of their document) would announce the availability of the research funds only through the DF/HCC, Harvard University and Harvard Medical School websites. Once again, this plan seems to us designed to give an unfair advantage to Harvard and local applicants and undermines the goal of establishing a truly national program. There is no provision whatsoever in their proposal to announce the availability of the funds in widely-read medical journals, which would thereby clearly exclude many potential applicants who would be unaware of these research funds.

5. DF/HCC's Awarding of Lupron Settlement Funds Via a Mechanism that Includes the Prostate Cancer Foundation And to a Limited Number of Senior Applicants (described on pg. 3 and 4 of their document)

A major component of the DF/HCC proposal is to establish five awards of $1M each for a period of one year, and to find those researchers through the Prostate Cancer Foundation. Such an arrangement is slanted to find and fund a very few investigators who are very likely to be very senior with very well-established ongoing projects and likely well-established funding already in place. We question the desirability of allocating almost half of the settlement funds to only five investigators. Such an arrangement is very unlikely to attract new investigators with innovative proposals; we believe this is an important goal that should be part of any program to use the Lupron Class Action Settlement Fund – it should be innovative and inclusive, looking to sponsor young, less well-established researchers who will be the future of prostate cancer and other research.

6. Duration of Project

We believe that the Court's intention is to bring closure to the Lupron matter and have the research program completed in a reasonable time period, and in fact as quickly as possible. Our proposal provided for distribution of the funds and completion of the

program within five years, whereas the DF/HCC proposal will not complete distribution and expenditure of the funds for seven years (pg. 7 of their document).

Conclusion

For these reasons, we respectfully ask the Court to uphold its preliminary determination to award the Lupron Class Action Settlement cy pres funds to us for our proposed program.

Respectfully submitted,

Kevin R. Loughlin, MD, MBA (Chairperson)
Marc B. Garnick, MD
Anthony L. Zietman, MD
Michael J. Barry, MD

PSA TESTING FOR PROSTATE CANCER

A CRICO/RMF DECISION SUPPORT TOOL

Created: 2008

CRICO RMF
Protecting providers.
Promoting safety.

PROSTATE-SPECIFIC ANTIGEN TESTING FOR PROSTATE CANCER

A DECISION SUPPORT TOOL

Prostate cancer is the most common cancer diagnosed among American men and is frequently cited in medical malpractice cases naming CRICO-insured physicians alleging a failure to diagnose, or a delay in diagnosis. General medicine physicians are named most frequently in such cases. The most common factors leading to such claims are:

- patient assessment, i.e. poor history (including family history) or a physical examination that does not include a digital rectal exam;
- test-related missteps: PSA testing is not discussed, or if discussed and ordered, testing is not properly tracked or followed up upon;
- inadequate communication about testing, result reporting, and follow-up (among providers and between providers and patients); and
- inadequate documentation of test discussion, results, or follow-up plan.

CRICO/RMF is the patient safety and medical malpractice company owned by and serving the Harvard medical community since 1976. The CRICO/RMF *PSA Testing for Prostate Cancer* is based on a review of national prostate cancer testing guidelines and related evidence. This is a decision-support tool which should not be construed as a standard of care.

Prostate Cancer and Medical Malpractice

Case examples

Case 1

From age 71–75, the patient presented with signs and symptoms of BPH. He underwent DREs but not PSA testing. At age 75, the patient presented with leg edema, worsening renal function, retroperitoneal adenopathy, supraclavicular lymphadenopathy. He was referred to Urology for a stent placement; a simultaneous biopsy revealed prostate cancer. His post-biopsy PSA was 135ng/ml; he died at age 76. His estate's suit against the PCP for failure to diagnose prostate cancer was settled with payment.

Case 2

Without any prior discussion, the PCP for a 52-year-old male with a negative DRE ordered a PSA test. The result (9.5 ng/ml) was not acknowledged by the PCP nor communicated to the patient. Two years later (after his initial PCP had left the practice) the patient saw a second PCP who inquired about why there had been no follow up of the prior PSA results. A repeat PSA was 11.8 ng/ml; on exam the prostate was asymmetrical. A biopsy indicated prostate cancer; post-op the patient had a penile prosthesis which had to be removed due to complications. He is otherwise well. A malpractice suit against the patient's original PCP, for failing to communicate and follow up on his initial PSA test results, was settled with payment.

Case 3

A 62-year-old male received annual physical exams by a number of internists from 1998–2004. At one point, the patient had symptoms of blood in his urine. Throughout this period, rectal exams were done. The patient was offered PSA testing and the discussion was documented. In 2004, the patient was admitted to the ED with flank pain radiating to his lower right abdomen. His PSA was found to be 477ng/ml and he was diagnosed with metastatic prostate cancer. The defendant physicians successfully argued that offering (not simply doing) PSA testing was the standard of care, and that earlier detection would not have changed his outcome.

Cases filed from 2002–2007 involving the diagnosis of prostate cancer (N=23*)

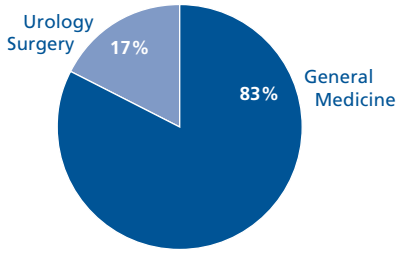
Process of care breakdowns

Malpractice cases stemming from missed or delayed diagnosis of prostate cancer frequently allege one or more missteps along the process of care path, as illustrated below based on the most recently analyzed CRICO claims and suits.

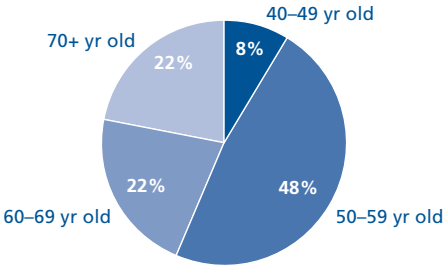
Process of Care Step	Cases	Total Incurred†	% of $
Patient notes problem and seeks care	1	$1,540,000	9%
Physician performs history/physical	7	$6,320,000	39%
Order of diagnostic labs/tests	14	$10,465,586	64%
Performance of tests	1	$1,040,000	6%
Interpretation of tests	3	$1,620,000	10%
Receipt/transmittal of test results	8	$6,730,000	41%
Follow-up plan and referral (if indicated)	14	$11,465,586	70%
Patient adherence with plan	2	$1,620,000	10%

†Total Incurred: aggregate of expenses, reserves, and payments on open and closed cases.

Responsible Service



Claimant Age



*N=23 cases asserted 1/1/03–12/31/07 with a final diagnosis of prostate cancer and a diagnosis-related major allegation.

"Information should be provided to all men about what is known and what is uncertain about the benefits, limitations, and harms of early detection and treatment of prostate cancer so they can make an informed decision about testing."

—American Cancer Society Guidelines for the Early Detection of Cancer

Clinical Approach

For male patients age 50 and over, it is advisable to initiate a discussion regarding testing for prostate cancer, and to revisit the topic with the patient periodically. During the initial conversation, the patient should be advised that the prostate is assessed by digital rectal exam (DRE); prostate specific antigen (PSA) testing (if appropriate); and biopsy, if necessary. PSA testing—especially over time—may help identify some prostate cancers that are not detectable by DRE, and may, in some cases, lead to detecting some prostate cancers earlier.

However, reduced morbidity and mortality from prostate cancer have not been documented in randomized trials of PSA screening. At the same time, such benefits have not, to date, been refuted. Results of ongoing prostate cancer screening trials will probably not be available for several more years.

Once PSA testing has been initiated, physicians are obligated to continue to test periodically (until the patient reaches an age at which he is unlikely to benefit from testing) and to track the results. A suspicious test, or significant velocity, can raise anxiety, and that, too, needs to be followed. If prostate cancer is indeed found, that diagnosis can lead to treatments with considerable morbidity and a small but finite mortality, all for an uncertain gain.

By reason of these various uncertainties and risks, professional groups have not reached consensus on the value of PSA testing. However, all agree that testing should be discussed with men age 50 and over, and revisited periodically. Primary care physicians may harbor uncertainty about clinical efficacy of PSA testing, but the greatest risk of being named in a malpractice lawsuit alleging failure to diagnose prostate cancer stems from either failing to have the initial physician-patient discussion or system breakdowns that occur after the decision to begin PSA testing has been made. The recommendations that follow address those high-risk processes.

General and prostate-specific cancer testing risk management

- Discuss with the patient the risks and benefits of testing options (including no testing) and document the discussion (including materials used) and the patient's preference, in the medical record.
- Track and document tests ordered and performed, and their results.
- Follow up on all test results, including consideration of referral.
- Transmit test results to the patient with an explanation appropriate for the patient's level of understanding.
- If you refer the patient to a specialist, you have an obligation to track the referral and coordinate future (related) care and follow-up with the specialist.
- Document recommendations to the patient for further testing and evaluation; if appropriate, add reminders to your tickler system.

Important risk factors for prostate cancer

- African American
- Family history: 1st degree relative(s)
- Prior prostate biopsy showing high grade prostatic intraepithelial neoplasia (refer to Urology)

Non-contributory factors

- Lower urinary tract symptoms (LUTS) suggesting benign prostatic hyperplasia (BPH) or prostatitis

Key points in the physican-patient discussion about PSA testing

The physician and patient should engage in an informed consent/refusal discussion with a goal of conveying what the patient needs to know in order to make an informed decision. The discussion and any information materials provided should cover the following:

- Prevalence of prostate cancer
- Important risk factors
- Nature and risk of the test itself
- Normal PSA range and what is learned from subsequent testing
- False positives/negatives
- Advantages/disadvantages to testing
- Reasons for referral/biopsy
- Brief description of treatment options

See *Information for Patients Regarding Prostate Cancer and PSA Testing*

Recommendations

- Prostate cancer testing should be discussed beginning at age 50, and up to age 74, for men without important risk factors (see sidebar).
- For men with important risk factors, consider discussing prostate cancer testing beginning at age 45.
- For patients age 75 or older, or for younger men with significant co-morbidities, prostate cancer testing is not recommended.
- DRE should be part of prostate testing.
- In general, a DRE should be documented as normal (including symetrically enlarged) or abnormal.
- Refer patients with abnormal results to Urology.
- PSA test can be drawn before or after the DRE.
- Frequency of repeat PSA discussion/testing
  1. For patients who decline PSA testing, the discussion should be revisited periodically (not necessarily annually)
  2. Patients who undergo PSA testing, and who have normal results, should be instructed that optimal retesting frequency has not been established, but that one reasonable strategy is:
     - for patients with an initial value <1.0, retest every five years;
     - for patients with an initial value 1.0–2.0, retest every two years; and
     - for patients with an initial value >2.0–<4.0, retest every year.
- Special factors to consider before beginning PSA testing
  1. Bacterial infection (UTI) or clinical prostatitis can raise PSA and render evaluation more difficult. Both conditions need to be treated and symptoms resolved 2–3 months (ideally) before PSA testing. No evidence supports the use of antibiotics in a non-infected asymptomatic patient to reduce PSA levels.
  2. For patients on finasteride (Proscar) or dutasteride (Avodart), the PSA will likely be up to 50 percent lower than normal. Therefore, double the values and interpret as usual. Rising PSA levels in patients compliant with these medications are worrisome and merit referral to Urology.

- Interpreting PSA test results
  1. The optimal PSA threshold for biopsy has not been established. A reasonable threshold for referral to Urology for further management (biopsy may not always be indicated) is a PSA >4.0 ng/ml for patients age 50 and older. For men younger than 50 with a PSA >2.5 ng/ml, refer to Urology.
  2. If an initial PSA is slightly above the referral threshold, consider repeat testing with the patient having abstained from sex and bicycling for at least 48 hours. If the repeat value is below the referral threshold, then a referral is not necessary, but the schedule for retesting (as specified in the guideline above) should be followed.
  3. Transrectal ultrasound is not sufficiently sensitive, by itself, to be used in the decision to order a biopsy and should not be ordered in primary care to evaluate an elevated PSA.
  4. Percent free PSA determinations, as part of total PSA, are generally not helpful in making a decision to refer to Urology. They may occasionally be ordered by a urologist as part of risk stratification for biopsy.
  5. Patients with PSA velocities greater than 0.75 ng/ml/year (based on three values over at least two years) should be referred to Urology regardless of the total PSA value.
  6. For an increase in PSA value greater than 2 ng/ml over 12 months, repeat within three months and, if confirmed, refer to Urology.
- After a negative biopsy, establish a repeat PSA testing plan and threshold for re-referral in collaboration with Urology. In general, consider repeat referral to Urology for patients who exceed the velocity threshold (more than 0.75 ng/ml/year, or velocity greater than 2 ng/ml over 12 months) or who exhibit changes in the DRE.
- Testosterone Replacement: prior to prescribing testosterone replacement for patient of any age, acquire a baseline PSA, conduct a DRE, and follow annually.

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Prostate Cancer Task Force

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For more information contact the CRICO/RMF Loss Prevention/Patient Safety Department at 617.679.1552.

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Information for Patients Regarding Prostate Cancer and PSA Testing

Professional medical organizations have not reached consensus on the value of testing for prostate cancer or treating detected cancers. However, all agree that testing should be discussed with men over age 50 and revisited periodically. The following information is intended as a reference for patients who have recently had that discussion. If you have any questions about prostate cancer testing, call your doctor.

How common is prostate cancer?

- One-third of men over 80 years old will have prostate cancer. Because these cancers grow slowly, they rarely cause problems for older men.
- Prostate cancer is less common for younger men, but more likely to impact their quality of life.
- African-Americans and men with a close relative who had prostate cancer are at higher risk than other men.
- About 1 in 30 men will die from prostate cancer.

Should I be tested for prostate cancer?

Men over age 50 should discuss prostate cancer with their physicians. For some men, depending on their age and overall health, testing is not necessary. Because most prostate cancers grow slowly, testing is not considered useful after age 75.

Your decision to undergo or decline prostate cancer testing should be based on: a thorough understanding of what the tests can and cannot determine, and the risk and benefits of testing.

What does prostate cancer testing involve?

1. *Personal and family history*
   The doctor will ask about your medical history and whether or not any close relatives were diagnosed with prostate cancer. He or she may also ask about certain symptoms that might indicate prostate disease (including cancer). Waking during the night to urinate, frequent need to urinate, or difficulty starting or stopping while urinating may indicate that your prostate is enlarged. This is can be due to infections, BPH (benign prostatic hyperplasia), or prostate cancer.
2. *Digital rectal exam*
   The doctor will exam your prostate gland with his or her finger to detect any abnormalities, such as enlargement or nodules (lumps).
3. *Prostate Specific Antigen (PSA) Test*
   By testing your blood, the doctor can determine if your prostate is producing an excessive amount of PSA. If your PSA is above average—or if it increases significantly over the course of several annual blood tests—your doctor may recommend that you have a biopsy. Unfortunately, current PSA testing is not highly accurate or specific: some men with normal PSA test results nevertheless have prostate cancer and some men with abnormal PSA test results do not have prostate cancer.
4. *Biopsy*
   To confirm or rule out prostate cancer, your doctor may order a biopsy, in which a small sample of your prostate is removed (by needle) and examined under a microscope.

Deciding What to Do

Because men diagnosed with prostate cancer often decline or delay treatment, you may decide not to undergo PSA testing. Your age and risk factors can help you and your doctor make the decision. If you decline testing at the time of the initial discussion, your doctor will revisit the subject in a year or two—or if you begin to exhibit concerning symptoms. Once you do begin PSA testing, your doctor will recommend periodic repeat tests to determine if your PSA is increasing at an abnormal rate.

Anthony L. Zietman MD
Jenot and William Shipley Professor of Radiation Oncology
Harvard Medical School
Massachusetts General Hospital
Boston MA

Representative sample of accomplishments related to prostate disorders and Lupron related disorders

Prostate Cancer and Lupron related accomplishments

Lupron and Androgen Deprivation related

- First investigator to demonstrate a synergistic interaction between androgen deprivation and radiation in an experimental model

- First investigator to demonstrate the sequence dependence of androgen deprivation and radiation in an experimental model

- Principal investigator in the national Patterns of Care Study demonstrating the uptake, use, and overuse of Lupron and related agents in prostate cancer treated with radiation

- Co-Investigator on the first studies to demonstrate and quantify the bone and muscle loss associated with Lupron and of maneuvers to mitigate this problem. Published in the New England Journal of Medicine.

Prostate Cancer Related

- Co-Chair of National Cancer Institute's Genito-Urinary Cancer Steering Committee. This is the national body that reviews and then either approves or declines all randomized trials involving any aspect of prostate cancer therapeutics

- President of American Society of Radiation Oncology (ASTRO). This is the largest radiation oncology organization in the world and one that organizes research, educates, and advocates for radiation oncologists. Prostate cancer, along with lung and breast cancer, is the mainstay of its work.

- Trustee of American Board of Radiology. The only certifying body for all Radiation Oncologists and serves to uphold standards of practice in the United States. I am one of the two chairs of the prostate cancer examining committee.

- Member of American Urological Association's Prostate Cancer Guidelines Committee.

Publishing and educational accomplishments

- Author of over 80 original scientific articles on the diagnosis and treatment of prostate cancer.

- Section editor for GU cancers including prostate in Clinical Radiation Oncology (Eds: Gunderson and Tepper) the premier radiation oncology textbook

- Invited or Keynote speaker at over 30 international scientific meetings on prostate cancer generally and Lupron specifically

- Author (along with Drs. Loughlin, Garnick, and Barry) for Harvard Institutions Risk Management Foundation of a widely distributed prostate cancer and PSA decision tool for internists and primary care physicians

- Lead author on multiple editorials and review articles published in major journals such as Nature Urology and the Journal of Clinical Oncology on prostate cancer diagnosis and treatment with a special interest in the overuse of therapy.

Kevin R. Loughlin, MD, MBA
Professor of Surgery (Urology)
Harvard Medical School
Brigham and Women's Hospital
Boston, MA

Representative sample of accomplishments related to prostate cancer and Lupron related disorders

Prostate Cancer and Lupron related

Lupron and Androgen Deprivation related

- Site investigator, a multi-center open label dose escalation study of the safety and therapeutic effects of PPI-149 depot administrated as an intramuscular (IM) or subcutaneous (SC) injection in prostate cancer patients who were candidates for initial hormone therapy. Praecis Pharmaceuticals

- Senior author-Demonstration of protective effect of leuprolide on post chemotherapy fertility in an animal model

Prostate Cancer Related

- Member, NCCN Prostate Cancer Early Detection Panel

- Member (along with Doctors Barry, Garnick and Zietman) for Harvard Institutions Risk Management Foundation of a widely distributed prostate cancer and PSA decision tool for internists and primary care physicians

- Co-Principal Investigator, From gene discovery to bioassay: a collaborative application of the yeast two hybrid genetic screen to prostate cancer progression CaP Cure Award , Milken Foundation

- Investigator, Prostate cancer prevention by n-3 unsaturated fatty acid, NIH funded.

- Investigator, Randomized, double blind placebo-controlled multicenter efficacy and safety study of Toremitene Citrate for the prevention of prostate cancer in men with high grade prostatic intraepithelial neoplasia (PIN), GTX Inc.

- Co-Investigator, Molecular diagnosis of prostate cancer, CIMIT

- Senior author, The use of endorectal coil MRI in surgical planning for radical prostatectomy

- Co-author, utility of matrix metalloproteinases as a urinary biomarker in several cancers, including prostate cancer

Publishing and educational accomplishments

- Served on editorial boards of Journal of Urology and Contemporary Urology
- Currently on editorial board of Urology
- Ad hoc reviewer for New England Journal of Medicine
- Advisory/Editorial Board, Perspectives on Prostate Disease, Harvard Health Publications
- Author of book, Clinical Guide to Prostate Specific Antigen, Bladon Medical Publishing (also published in German)
- Co-author with a patient, 100 Questions and Answers about Prostate Disease, Jones and Bartlett Publishers
- Author of over 180 peer-reviewed articles
- Awarded the Faculty Teaching Award on three occasions by the graduating urology residents
- 3rd Prize Clinical Research Paper, American Urological Association (awarded as a resident)
- 1st Prize Paper, New England Section of the American Urological Association (awarded as a resident)
- Named on numerous "Best Doctor" lists
- Recipient National Kidney Foundation Fellowship

National Leadership

- President, New England Section of the American Urological Association 2008-2009
- Secretary, New England Section of the American Urological Association 2002-2007
- Research Committee, American Urological Association 1994-1996
- Men's Health Committee, American Urological Association 2009
- Curriculum Committee, American Urological Association 2007-2008
- Alumnus Medal of Honor, 2003(Given annually by New York Medical College to an outstanding alumnus)
- Lifetime Achievement Award, 2008. Awarded by the New England Section of the AUA. Only three individuals have ever been given this award.

Marc B. Garnick MD
Clinical Professor of Medicine
Harvard Medical School
Beth Israel Deaconess Medical Center
Boston MA

Representative sample of accomplishments related to prostate disorders and Lupron related disorders

Prostate Cancer and Lupron related accomplishments

Lupron Related and LHRH analogue related

- Academic Principal Investigator and one of three academic presenters (along with Dr. Michael Glode and Dr. Jay Smith) to the FDA advisory committee related to the initial FDA approval of Lupron for prostate cancer

- Lead investigator on multiple phase II and the pivotal Phase III study of Lupron for prostate cancer, published in the New England Journal of Medicine

- Investigator on multiple follow on studies following the approval of Lupron in order to assess its post marketing safety and efficacy

- Lead developer of abarelix, the first approved LHRH antagonist for prostate cancer in US and Germany

- Co-Organizer (with the late William Fair MD) of the annual International Conference on Neoadjuvant Hormonal Therapy for Prostate Cancer

- Inventor of multiple patents related to the use of LHRH analogues for the management of prostate cancer and other Lupron related disorders outside of prostate cancer (adjunct to mammography for dense breast imaging, differential suppression of FSH between Lupron and LHRH antagonists)

Prostate Cancer Related

- Founder of Hershey Foundation for Basic and Clinical Research in Prostate Cancer, housed at the Beth Israel Deaconess Medical Center, that established basic and clinical research programs, young investigator awards, educational colloquia and *de novo* establishment of a prostate cancer tissue bank, available for use by all Massachusetts researchers

- Reviewer for SPORE grant applications in the formative years of the SPORE program

- Panel Reviewer on NIH Consensus Development Conference for management of clinically localized prostate cancer

Publishing and educational accomplishments

- Author, The Patient's Guide to Prostate Cancer, published by Viking/Penguin Imprints (230,000 copies sold) (a lay book based upon several articles initially published in Scientific American on prostate cancer)

- Editor in chief and founder of Perspectives on Prostate Diseases, a quarterly journal published by Harvard Medical School's Harvard Health Publications and founder of a companion website (available to anyone with internet connection) of www.harvardprostateknowledge.org (Dr. Loughlin serves on editorial board)

- Founder and director (until 1992), HMS Continuing Medical Educational program entitled Urologic Cancer, the premier course in Urologic Cancer for physicians

- Author, American College of Physicians policy statement on Screening for Prostate Cancer, published through its PIER (Physician Information Educational Resource) a point of care resource for physicians worldwide

- Author (along with Drs. Loughlin, Zeitman and Barry) for Harvard Institutions Risk Management Foundation of a widely distributed prostate cancer and PSA decision tool for internists and primary care physicians

- Lecturer at multiple national and international colloquia on prostate related disorders and prostate cancer and LHRH analogues, including Lupron

- Founder of Prostate Cancer Educational Breakfast Series, a series of colloquia for general education related to prostate cancer

- Participant in several regional (New England and New York) programs to increase awareness of prostate cancer issues for the African American Communities

- Lead author on two review articles published in Annals of Internal Medicine on prostate cancer screening

Michael J Barry, MD
Professor of Medicine
Harvard Medical School
Medical Director, John D. Stoeckle Center for Primary Care Innovation
Massachusetts General Hospital
Boston MA

Representative sample of accomplishments related to prostate cancer and Lupron related disorders

Lupron and Androgen Deprivation related

- First investigator to describe the patterns of androgen deprivation use, including Lupron, among older men in the united states in the "PSA era".

- Part of the team that described the use of androgen deprivation, including Lupron, over time among men with localized prostate cancer not initially treated with radiation or surgery.

- Senior investigator on the first intensive study of the quality of life of men treated with androgen deprivation, including Lupron, in the setting of treatment failure after radical prostatectomy.

- Senior investigator on a nationwide survey of urologists' practices in prescribing androgen deprivation, including Lupron

- Senior investigator on a 15 year study of the rates of androgen deprivation among men more or less intensively screened for prostate cancer.

- Medical Editor on a nationally distributed patient decision aid designed to help patients to make a decision about androgen deprivation, including Lupron, for evidence of residual or recurrent prostate cancer after surgery or radiation. (Program was the 2007 winner of the top prize in Men's Health from the International Health and Medical Media Awards)

Prostate Cancer Related

- Member of the National Cancer Center Network's Prostate Cancer Early Detection Guideline Panel.

- Co-author on the American College of Physicians prostate cancer screening guideline.

- Member of the Executive Committee and Chair of the Endpoints Committee for the 15-year Prostate Cancer Intervention versus Observation Trial (PIVOT)

- Member of the Prostate Diseases and Urologic Cancers Group of the International Cochrane Collaboration.

- Committee Chairperson for the World Health Organization/International Union Against Cancer International Consultation on Prostate Cancer

- Principal Investigator on the $5 million federal Patient Outcome Research Team for Prostatic Diseases

Publishing and educational accomplishments

- Author of over 100 scientific papers on the diagnosis and treatment of prostate cancer.

- Author of prostate disease chapters for prominent general medical textbooks including Primary Care Medicine and Cecil's Textbook of Medicine

- Invited or Keynote speaker at over 40 national and international scientific meetings on prostate cancer

- Guest on *DiscoveryHealth* national television special on prostate cancer prevention and screening

- Author (along with Drs. Loughlin, Garnick, and Zietman) for Harvard Institutions Risk Management Foundation of a widely distributed prostate cancer and PSA decision tool for internists and primary care physicians

- Lead author on multiple editorials and review articles published in major journals such as the *New England Journal of Medicine* and the *Journal of the National Cancer Institute* on prostate cancer diagnosis and treatment

National/International Primary Care Leadership

- Past President of the Society of General Internal Medicine

- Past President of the Society for Medical Decision Making

- Master of the American College of Physicians

- Elected Member of the National Academies of Practice

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

IN RE: LUPRON® MARKETING AND
SALES PRACTICES LITIGATION

MEMORANDUM AND ORDER REGARDING
CY PRES DISPOSITION OF SURPLUS
CONSUMER SETTLEMENT POOL FUNDS

March 2, 2010

STEARNS, D.J.

On January 7, 2010, the First Circuit Court of Appeals entered judgment on the Motion for Voluntary Dismissal of Appeal filed by counsel for intervenor-appellant Valerie Samsell. Mandate then issued with the effect of restoring the case to the docket of this court. The court has before it two proposals[1] for the distribution of approximately $11,400,000 remaining in the Class Settlement Fund.[2]

In their proposal submitted on November 24, 2009, the Dana-Farber/Harvard Cancer Center (DF/HCC) and the Prostate Cancer Foundation (PCF) addressed most of the relevant questions that the court had earlier propounded to the group led by Dr. Kevin Loughlin, the Director of Urologic Research at Brigham and Women's Hospital. The court

[1]In a Memorandum and Order dated May 19, 2009, the court considered and decided against *cy pres* distribution to six groups – three "standalone" medical institutions treating prostate cancer, and three political advocacy groups. That Order was the subject of the Samsell appeal.

[2]The surplus funds were deposited into an account established in the Court Registry Investment System (CRIS) titled In Re: Lupron® Marketing and Sales Practices Litigation/Consumer Settlement Pool. The balance as of 02/17/10 is $11,421,356.72.

requests that DF/HCC and PCF provide the following supplementary information.

1. A clearer description of the governing body that would decide on the selection of grantees and also oversee the accounting of research awards.

2. A more precise statement of the stipends or any other compensation that would be paid to persons involved in the grant award process.

3. The proposal states that "[t]o offset expenses associated with the management of the scientific advisory boards and committees, and with reviewing selecting and monitoring additional grants, we anticipate allocating 10% of the Settlement Pool funds toward indirect institutional costs at DF/HCC." The court requests a more specific description of the contemplated "indirect institutional costs" and the basis for a 10% administration fee allocation?

4. An explanation of why 50% of the total research awards would be earmarked for grantees with a Harvard Medical School affiliation and a definition of the term "affiliation" as used in the proposed earmarks.

The court would be appreciative if responses could be filed with the court within the next 30 days.

SO ORDERED.

/s/ Richard G. Stearns

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UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

In re: LUPRON MARKETING AND SALES PRACTICES LITIGATION

To: The Honorable Richard G. Stearns
United States District Court
District of Massachusetts

From: Kevin R. Loughlin, MD, MBA (Chairperson)
Marc B. Garnick, MD
Anthony L. Zietman, MD
Michael J. Barry, MD

Re: Response of Dana-Farber/Harvard Cancer Center (DF/HCC) regarding Lupron Class Action Settlement cy pres distribution, pursuant to the Court's Order dated March 2, 2010

Date: April 6, 2010

As noted in our earlier filing, the four authors were pleased to receive the approval given in the Court's stated initial decision to award and allow use of the Lupron Class Action Settlement Funds in a program for research into the causes and cures of prostate cancer and other Lupron-treated diseases/conditions. We appreciate the Court's permission to comment on the proposal belatedly submitted by the Dana-Farber/Harvard Cancer Center, and now to comment briefly on its response to the Court's March 2, 2010 Order. We sincerely hope that this document will set forth the clear and specific differences between our proposal and the Dana-Farber/HarvardCC proposal on the governance and distribution of the Lupron Settlement Funds for furthering research in and related to Lupron-related disorders.

We stand ready to meet with the Court again (Dr. Loughlin appeared before the Court on January 13, 2009) or to make another filing to answer any questions of the Court.

Section I -- Summary:

The differences between the Dana-Farber/HarvardCC proposal and our program can be summarized as follows:

- **Our proposal will encourage and solicit grant proposals from a national base of investigators -- using advertising via national media and nationally-read medical journals to broad audiences -- including young investigators, nurses**

and community organizations as well as established investigators, for the further study and research related to all Lupron-related disorders including prostate cancer, precocious puberty and endometriosis, the specific diseases from which the settlement monies arose.

- *In contrast, the Dana-Farber/HarvardCC proposal is very narrowly focused specifically on a small segment of prostate cancer research, with no identification of monies to be awarded on a national level, with most of the money targeted to established research at large medical or research centers, and specifically targeted to institutions in Massachusetts, and further specifically to institutions already part of Harvard and Dana-Farber. In addition, while Dana-Farber and Harvard Cancer Center list the multitude of their affiliated or member institutions, only a minority of them have a mission that addresses Lupron-related disorders, skewing the balance to favor a majority of grant proposals to emanate from Dana-Farber or Harvard Cancer Center themselves, and thus that majority of the money to go to them.*

- **Our proposal specifically, deliberately and unambiguously sets out the use of the funds to be generated by our proposed 15% overhead. This overhead will go to provide compensation for a grant supervisor, the four of us, and office supplies and rental costs. Our overhead proposal ensures that the governance and operational responsibilities for administering the grant's mission to appropriately distribute the Settlement Funds will be completed by the four physician members. In addition we have specifically noted in our proposal that grantee award recipients will *not* receive institutional overhead, which can range from 20% to 75% as indirect costs.**

- *In contrast, in the Dana-Farber/HarvardCC request, there are significant inconsistencies and ambiguities surrounding the manner in which the 10% overhead will be used. As stated in their proposal, $40,000 will be used to support a half-time grant administrator, and apparently more than $1,100,000 will go to Dana-Farber/Harvard CC institutional overhead. Moreover, the Dana-Farber/HarvardCC proposal does not address whether their grantees who receive awards will receive their own institutional overhead to do the funded research. This situation is the norm unless stated otherwise. Assuming even only the minimal rate of 20%, this adds an additional $2,000,000+ to overhead expenses to their grantee institutions, bringing their total potential overhead expenditures to over $3,000,000.*

- **Our group and proposal, with regard to governance and operational structure, includes medical disciplines from the key and critical disciplines that address Lupron-related disorders:**
  - **for prostate cancer: urology, radiation therapy, medical oncology and internal medicine/primary care;**

- **for precocious puberty: urology and internal medicine/primary care;**
- **for endometriosis: medical oncology with an expertise in endometriosis studies involving Lupron, and internal medicine and primary care.**

One expert from each of these disciplines is represented, each assuming an equal sharing of the review and administrative responsibilities – without the necessity of hiring separate senior administrative personnel.

- *In contrast, the Dana-Farber/HarvardCC proposal is both top-heavy with administrators and multi-duplicative representation of medical oncology, with no representation of either radiation oncology and internal medicine/primary care. This organizational structure is not optimal to address the mission of furthering research in the Lupron-related disorders and appropriate disbursement of the Lupron Settlement Funds.*

Section II:

This section will provide more specific comments to the Dana-Farber/HarvardCC response to the Court's queries and contrast the facts of our proposal with that of Dana-Farber/HarvardCC.

Description of Grantee Selection

- We note that in the Dana-Farber/HarvardCC response, it is unclear who is going to be responsible for generating the Request For Proposals (RFP) – Dana-Farber, Harvard Cancer Center or the Prostate Cancer Foundation (PCF). As described, there is little assurance that the application process will attempt to get involvement and grant applications from the groups that we identified – medical students, nurses, young investigators. The Dana-Farber/HarvardCC proposal is looking for investigators with a "track record". We, too, will be looking for those gifted investigators with a track record; but we also are working under the premise that many of our most talented young applicants will be new to the process and a track record will not yet have been established. We simply want to elicit the strongest, most diverse and creative proposals from a national geographic base that includes a national and non-Harvard base of institutions. The best research proposals should be funded, regardless of state or institution of origin.

- We will use national advertising through syndicated press releases and strategically-placed medical journal advertisements in top quality, widely-read medical journals, to both advertise the unique nature of the RFP and to encourage a wide-range of investigators to seek Lupron Settlement Fund awards. The emphasis will be national, and not local; it will include all institutions, not only

Harvard or Massachusetts affiliations. We feel that this is the most equitable fashion in which to award the grants, since the creation of the Lupron Settlement Funds came from a lawsuit that involved a national class and thus patients should be the beneficiaries of the research emerging from investigators living in these geographic areas.

- The make-up of the grant award selection committees is vastly different between the Dana-Farber/HarvardCC proposal and ours. The Dana-Farber/HarvardCC proposal contains duplicative and a narrow focus of prostate cancer experts in medical oncology and urology and does not include the critical disciplines of radiation oncology and internal medicine/primary care. Nearly all men with prostate cancer are diagnosed, followed, and counseled by their primary care physicians. Further, 60,000 men per year receive radiation therapy.
    - Specifically, the Dana-Farber/HarvardCC composition of its selection committee breaks down to:
        - Duplicative SPORE heads, all with similar backgrounds (7 SPORE heads)(SPORE is the Specialized Program of Research Excellence, which is already sponsored by the National Cancer Institute.)
        - Two high-level Administrators, both from the Prostate Cancer Foundation
    - Our composition, in contrast, includes:
        - Urologist/Urologic Oncologist with prostate cancer clinical and basic science expertise
        - Radiation Oncologist with prostate cancer clinical and basic science expertise
        - Medical Oncologist with experience in both prostate cancer and endometriosis studies
        - Internal Medicine/Primary Care Physician with expertise in prostate cancer and other Lupron-related disorders
        - No appointed high-level Administrator – we will do our own appropriate administrative responsibilities (and the grant supervisor will have different responsibilities)
- This distinction is critically important for several reasons: The scope of the Dana-Farber/HarvardCC proposal and grants, by virtue of its narrow, Harvard-based and Massachusetts-based focus, will be limiting and thus will not address the true spirit of the Settlement Fund: to be efficient, to deal with a national group of

investigators, both established and new, and to work on all Lupron-related disorders. In contrast, our more streamlined and more multi-disciplinary group will address the broadest audience possible across the relevant disciplines that include all of the Lupron-related disorders, for which the Lupron Settlement Funds should be directed.

Research Award Accounting:

- We perceive that the Dana-Farber/HarvardCC proposal with regard to grant administration structure is problematic. We believe that they have grossly underestimated the need for at least a full-time grant supervisor, as we have proposed.

- In our proposal, the use of any monies for overhead is set forth in detail; it specifically and systematically identifies where this portion of the funding is and will be expended, including the (low, but certainly real) compensation for the professionals that will be responsible for doing the work, which shows that we know this will take real time and effort on our part. This contrasts with the Dana-Farber/HarvardCC's expectation that all professionals will be working pro bono on this program, which could cause concern about the amount of time and attention that will be paid to it. In fact, this expectation may be the result of the fact that the Dana-Farber/HarvardCC proposal really only intends to "add-on" or "top-off" its already-in-place and funded programs with the Lupron Settlement Funds.

- We are concerned that the Dana-Farber/HarvardCC proposal does not adequately insure that the research work will be prioritized, especially since the overhead identified will apparently go to non-Lupron funding initiatives and other uses identified in the Dana-Farber/HarvardCC response that outlines the use of funds for indirect costs. The description set forth in Appendix C of the response is far from transparent, but their paragraph on indirect costs mentions that the overhead is going for facilities operations, grants management costs, and maintenance costs. We do not believe the Lupron Settlement Funds should be diverted in that fashion away from the real purpose here: research.

- Our proposal allows Dana-Farber, Harvard and their related institutions to apply for the research funds through our program, avoiding the additional overhead they propose.

The Proposal for 50% of the Awards to go to Harvard Institutions

- The two proposals are very different in terms of recipient institutions that can receive Lupron Settlement Funds.

- Our proposal is inclusive of all institutions throughout the United States and includes research for all Lupron-related disorders.

- The Dana-Farber/HarvardCC focus is predominantly on Harvard institutions, Dana-Farber, the Prostate Cancer Foundation, and institutions in Massachusetts.

- Page 3 of the Dana-Farber/HarvardCC proposal makes clear that the DF/HCC High Impact Awards, DF/HCC Career Development Awards, DF/HCC Project Development Awards, DF/HCC Disparity Research Awards, and even the DF/HCC Community Outreach Awards (totaling $4.9 million) would go to Harvard hospitals or institutions. Only $460,000 could even go to other Massachusetts institutions, and the $5 million in challenge grants would go to only 5 teams around the country, limited to teams with three highly experienced investigators. Even this $5,460,000 can go to Harvard groups and doctors. This means there really is little room for smaller proposals from outside of Harvard, and for proposals from around the country.

- We also respectfully point out that many of the long list of Harvard-affiliated institutions set forth in Appendix D of the Dana-Farber/HarvardCC proposal have little or nothing to do with either prostate cancer or other Lupron-related disorders. Thus, while their proposal states that there will be a diffusion of grant awardees and that funds will be disbursed among the many Harvard institutions, it is more likely that most will be from just a few institutions, and many will be from Dana-Farber /Harvard Cancer Center, placing them in an inappropriately advantageous position. At a minimum, there can be little question that the proposal will give an advantageous position to Massachusetts-based investigators.

Conclusion

Our proposal allows for large institutions and established researchers to request and receive funds alongside new, additional, deserving national talent. Although we work at and in such institutions and respect them, we do not believe that awarding "top-off" money to large, already well-funded institutions is *a priori* the optimal method for advancing prostate cancer research.

We will, of course, answer any questions the Court may have.

For these reasons, we respectfully ask the Court to uphold its preliminary determination to award the Lupron Class Action Settlement cy pres funds to us for our proposed program.

Respectfully submitted,

Kevin R. Loughlin, MD, MBA (Chairperson)
Marc B. Garnick, MD

Anthony L. Zietman, MD
Michael J. Barry, MD

UNITED STATE DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: LUPRON ® MARKETING AND SALES PRACTICES LITIGATION	MDL NO. 1430
	MASTER FILE NO. 01-CV-10861-RGS
THIS DOCUMENT RELATES TO ALL ACTIONS	Hon. Richard G. Stearns

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

Submitted by:
Dana-Farber/Harvard Cancer Center in collaboration with the Prostate Cancer Foundation

Summary

This proposal describes a plan for the distribution of approximately $11.4M that remains in a Lupron litigation-derived consumer settlement pool. Through this plan, Dana-Farber/Harvard Cancer Center (DF/HCC) and the Prostate Cancer Foundation (PCF) will join forces to create a series of research awards that address a range of needs in prostate cancer and Lupron-treatable disease research. Ninety percent of these funds will be apportioned directly for research use, and ten percent of funds will be used to support research infrastructure and administration. DF/HCC and PCF will each administer one half of the research funds through competitive grant programs that are in place at each organization. DF/HCC will oversee the design and implementation of seven DF/HCC award categories, which are in large part intended to catalyze collaborative research at a national level. PCF will oversee the design and implementation of a single category of awards, eligible to teams of researchers on a national and international level, which are intended to address and overcome significant problems in the field of prostate cancer. Applications to each organization will be selected for funding through established review committees and procedures. An additional committee, comprised of national leaders in prostate cancer research, will provide oversight of granting activities and of stewardship of the settlement pool funds, and representative members therein will also participate in the review process itself.

Background

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 resulted from prostate cancer 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, about 20 to 30% of patients who receive treatment will have recurrences wherein the tumor metastasizes. For such patients, no curative therapies are available. Moreover, the side effects of Lupron are substantial and are being increasingly appreciated.

DF/HCC and PCF have each designed and implemented distinct and effective strategies to address the problems posed by prostate cancer. Specifically, at DF/HCC, the mission of the Prostate Cancer Program and National Cancer Institute sponsored "Specialized Program of Research Excellence" (SPORE) 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.

Introduction

Through this proposal, we seek to leverage the existing institutional infrastructure, funding mechanisms and relationships of DF/HCC and PCF to distribute settlement funds annually, on a competitive basis, nationally and locally, 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 the treatment of prostate cancer 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 national and local level, and to spur collaborative prostate cancer and Lupron-treatable disease research.

- To distribute Settlement Pool funds through existing organizational channels that have an established record of successful grant distributions (i.e., which have advanced the state of knowledge in the grants' 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.

Description of Award Program

Grant solicitation protocol and structure of grant program:

Grant applications will be solicited by two separate organizations, DF/HCC, and PCF. DF/HCC will solicit several categories of grant applications from the faculty of Harvard University and its affiliated hospitals; many of these grants will encourage extramural collaborations. Additional categories of grant applications will be solicited from faculty and students at colleges, universities and hospitals throughout Massachusetts. PCF will solicit grant applications from interested applicants on a national basis.

Specifically, DF/HCC will create *High Impact* research grants, *Lupron-Treatable Disease* research grants, *Community Outreach* grants, and *Student Education* grants, and will add to the number of *Career Development* grants, *Project Development* grants and *Disparity Research* grants that it presently awards on an annual basis. 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.

DF/HCC and PCF will solicit applications on a yearly basis leveraging existing infrastructure. DF/HCC will utilize the Prostate Cancer Program and SPORE to solicit applications from the Harvard University-wide applicant pool and PCF will issue request-for-proposals (RFPs) through well established channels to solicit applications from a national applicant pool.

Average amount and duration of program awards:

	Amount	Duration	#
DF/HCC High Impact Award:	$500K	2 years	5
DF/HCC Project Development Award:	$100K	2 years	9
DF/HCC Career Development Award:	$100K	2 years	6
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	2 years	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 including investigators from more than one DF/HCC member institution will be encouraged. Applicants are also encouraged to have collaborators at other institutions throughout the country. Such collaborations will be viewed as important criteria for merit in the review process.

DF/HCC Project Development Award: Applicants must be on the faculty at Harvard University at the level of Instructor or higher. Applicants are encouraged to have collaborators at other institutions throughout the country. Such collaborations will be viewed as important criteria for merit in the review process.

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. Applicants are encouraged to have collaborators at other institutions throughout the country. Such collaborations will be viewed as important criteria for merit in the review process.

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 at Harvard University at the level of Instructor or higher. Applications that include a partnership with University of Massachusetts Boston 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 at Harvard University at the level of Instructor or higher. Applications that include a partnership with University of Massachusetts 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.

Advertisement of grant opportunities:

DF/HCC will advertise RFPs through the DF/HCC website, the Harvard University and Harvard Medical School website, the Harvard Request for Proposal process, standardized communication to grant administration offices, and email distribution lists. To encourage collaborations at a national level, RFPs will also be distributed to the members of an oversight committee who are leaders in prostate cancer research at their respective institutions, which are deemed by the National Cancer Institute to be centers of excellence by their designation as SPORE sites (refer to "Oversight SAB" description below).

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

The division of research grants between the investigation of prostate cancer and other Lupron-treated conditions:

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 funds.

Governance of Award Process

Description of oversight committee:

DF/HCC and PCF will convene a high-level scientific advisory board (the "Oversight SAB") to participate in the application review process, and to ensure that Settlement Funds are distributed fairly, and in accordance with RFP guidelines and any other 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 DFCI, 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 Member	*TBD*

In addition to their leadership roles in prostate cancer research and medicine, these committee members bring with them expertise in fields such as urologic oncology, medical oncology, and basic science.

Oversight SAB members will not be compensated financially for their involvement in the Settlement Pool funds awards program. Please see Appendix F for a full description of the Oversight SAB responsibilities.

Description of governing bodies involved in award review and selection:

At DF/HCC, applications will be reviewed by members of the DF/HCC Prostate Cancer Program and SPORE Governance Committee, and by at least two non-DF/HCC members of the Oversight SAB, who will likely serve in this capacity on a rotating basis. The DF/HCC Prostate Cancer Program and SPORE Governance Committee is comprised of approximately ten Harvard faculty members representing Harvard Medical School and its affiliated institutions, and one to two patient advocates. The faculty members were chosen on the basis of their accomplishments, broad vision, impartiality, and diverse expertise. They have expertise and training in one or more of the following disciplines: medical oncology, urologic oncology, radiation oncology, population science, and basic science. The patient advocate(s) were asked to participate based on their expressed interest in patient advocacy. The prospective members of the 2010 Settlement Pool Review Committee are listed on Appendix G.

At PCF, applications will be reviewed by a subset of an established review committee comprised of seventy nine members with expertise spanning at least ten major disciplines, including medical oncology, surgical urologic oncology, immunotherapy, genomics, basic science, radiation oncology, nutrition research, molecular imaging, molecular pathology and statistics. At least two non-PCF members of the Oversight SAB will also participate in this review process, on a rotating basis. The members of the 2010-2011 review committee are listed on Appendix H.

Neither the DF/HCC review team members nor the PCF review team members will be compensated financially for their involvement in the Settlement Pool funds awards program.

Description of application review and grantee selection:

The process for selection of grantees at DF/HCC and PCF will be substantively similar. At DF/HCC, all applications submitted for each Settlement Pool award opportunity will be sent to each member of the review committee. Each application slated for review must have at least two assigned reviewers with expertise in the relevant application area. In the case of the Lupron-treatable disease awards, prominent researchers from related fields such as reproductive medicine will be recruited to temporarily sit on the review committee. At PCF, each application will be sent to three reviewers, who will be selected from a seventy-nine member board by matching areas of expertise to the scientific content of the proposal. At both organizations, if a reviewer has a real or perceived conflict of interest in the outcome of a particular application, he or she will be required to abstain from reviewing that application. Each reviewer will be asked to provide a brief written evaluation of each application. Evaluations should highlight the application's strengths and weaknesses, the track record of the applicant(s) and the project's potential impact to the field of prostate cancer. Each application will then be discussed, voted on, and ranked. The application(s) with the highest rank per award will be selected. At DF/HCC, the patient advocate(s) may not review applications *per se*, but they attend review meetings, participate in the proposal discussion, and lend perspective to the reviewer evaluations before voting and ranking takes place.

Avoidance of real or perceived conflict of interest in the awarding of grants:

At DF/HCC, in the event that an application is submitted by a governance committee member, an individual under his or her supervision, or anyone who may confer a real or perceived bias to a member's judgment abilities, the committee member in question will recuse himself or herself from the discussions and abstain from voting. At PCF, to avoid real or perceived bias in the selection of grant applications, scientific reviewers will not be allowed to review or vote on proposals that are submitted by applicants at their employing institution.

Court involvement in award process:

The court appointed board member(s) will be included in all governance committee and scientific review 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.

In addition, Judge Stearns, or any judge he so designates, will be subject to the same consideration, or aspects thereof, upon request.

Administrative Expenses Involved in Selecting and Monitoring Grants:

In total, 10% of Settlement Pool funds will be allocated to indirect institutional costs (IDC). All remaining Settlement Pool funds will be used directly by grantees for research purposes.

Description of "indirect institutional costs" and the basis for a 10% administration fee allocation:

To solicit, review, select and monitor grants, we will leverage existing DF/HCC and PCF infrastructure, including facilities, personnel, and equipment. To help support such infrastructure, 10% of Settlement Pool funds will be allocated to a general, institute-wide, "IDC pool" that is administered by DF/HCC. IDC are research related expenses that are incurred to pay for common objectives and infrastructure, and which are difficult to assign to a particular project in a clear and consistent manner. For example, administrative expenses, grants management costs, and facilities operation and maintenance expenses are all cost categories that are attributable to IDC. For a more detailed background and description of IDC, please see Appendix I.

Although it is DF/HCC's policy to apportion 20% of all non-federal programmatic gifts and grants toward IDC, we petitioned DF/HCC executive management to grant an exception to these conventional rate practices for the administration of the Settlement Pool funds. Two major factors were taken into consideration in requesting a new IDC rate:

- It is likely that only one half the total funds, at maximum, will draw upon DF/HCC's research infrastructure, because: (i) 50% of the funds will be directed to PCF; and (ii) several of the DF/HCC research awards emphasize collaboration with outside institutions.

- The program manager position overseeing the administration of the total Settlement Pool funds will sit at DF/HCC.

DF/HCC executive management agreed that it will be acceptable to apportion 10%, or $1,140,000, of the total Settlement Pool funds to IDC, in the event that these funds are made available to DF/HCC and PCF. As PCF does not house research infrastructure it will not collect any IDC from its portion of these funds. Thus, the remainder of the funds, $10,000,000 will be designated in its entirety for research use.

Restrictions placed on overhead expenses paid to grantee institutions:

Both DF/HCC and PCF will require that no award money be directed to overhead expenses at grantee institutions. Therefore, the Settlement Pool funds would be subject to IDC at only one point in the overall award process, i.e., upon receipt of funds by DF/HCC.

Stipends or any other compensation paid to persons involved in the grant award process:

A DF/HCC program manager will be appointed to administer the Settlement Pool program. We envision that the administration of this program will require at least half time job effort, and most likely closer to full time effort. Program manager salaries are commensurate with experience: half time managers are paid approximately $40,000 per year, and full time managers are paid approximately $70,000 per year, not including benefits. Compensation for this position will be

paid for by DF/HCC administration (please see IDC description in Appendix I). As such, this position will not be paid for through the Settlement Pool funds designated for direct research use.

All other people involved in the administration of the Settlement Pool funds will be involved on a *pro bono* basis. For example, no stipends or compensation from this fund will be paid to other members of DF/HCC or the DF/HCC Governance Committee, to members of PCF or the PCF scientific review board, or to the Oversight SAB.

Grant Management Overview:

Lupron Settlement Pool program management:

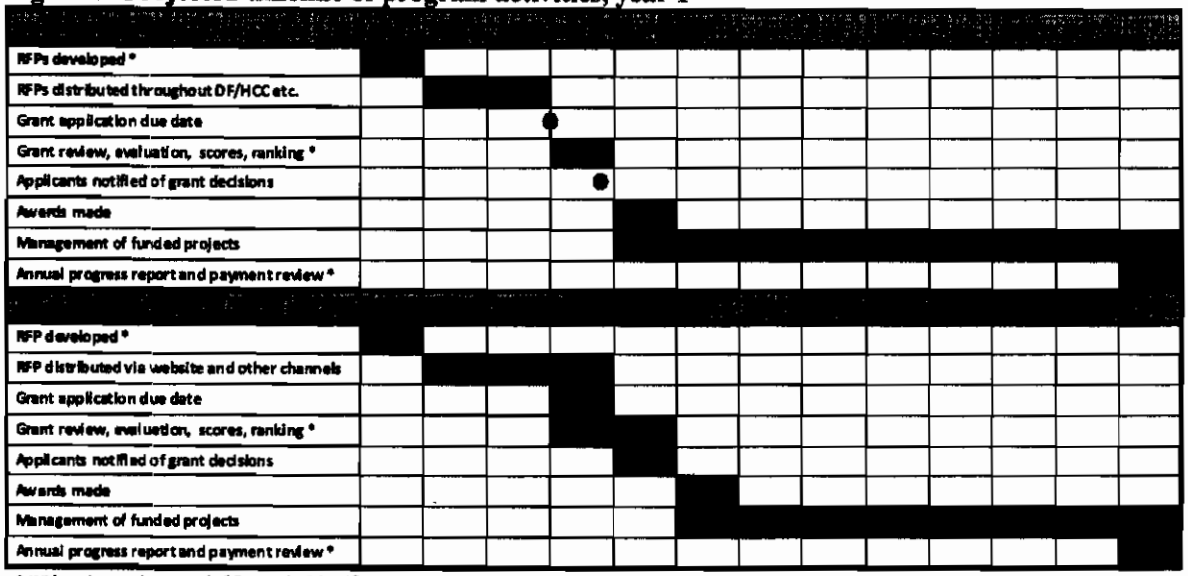
A DF/HCC program manager will manage the Settlement Pool program on a day-to-day basis at DF/HCC, under the direction of Philip Kantoff, MD, Director of the Prostate Cancer Program and SPORE at DF/HCC. The program manager will also coordinate and liaison with the PCF award program. The DF/HCC program manager's responsibilities are described in more detail in Appendix J. Howard Soule, PhD, EVP and Chief Science Officer at PCF, will manage the Settlement Pool program at PCF.

Settlement Pool funds will initially be deposited into an account at DF/HCC established exclusively for the management of the funds ("Settlement Pool Account"). The Settlement Pool Account will be managed under the direction of Dr. Kantoff. No other monies will be deposited in this account. After the funds are subjected to a one-time 10% indirect cost allocation, 50% of the funds will be subcontracted to PCF.

Upon receipt of funds, the Oversight SAB and the two review committees will be notified of the commencement of the award program, and select program RFPs will be drafted, approved and advertised. After grant applications are submitted to each organization, the respective review committees will review, evaluate and score proposals. Proposals will then be ranked and those with the highest ranks will be selected for funding, with approval of the Oversight SAB. The timing of the DF/HCC awards program will be linked to the existing SPORE program, in which RFPs are released annually in July and awards are made in November. At PCF, the first series of grants will be made within six months of the award program launch. Progress and financial reports will be expected from grantees at the end of year one, and second year grant payments will be made with approval of the respective board chairs and the Oversight SAB. Final progress and financial expenditure reports will be expected at the end of the award term. An anticipated timeline of these activities is presented in Figure 1. For a more detailed description of DF/HCC's existing program management infrastructure, see Appendix K. For a more detailed description of PCF's program management activities, see Appendix L.

The court appointed board member(s), and, as requested, Judge Stearns, will be included in all governance committee and scientific review board correspondences, and will be invited to any face to face meetings or conferences that involve award governance and/or grantee presentations. Yearly reports on Settlement Pool Account financial activity will be submitted to the court designee and to Judge Stearns.

Figure 1: Projected timeline of program activities, year 1



** With review and approval of Oversight Scientific Advisory Board*

The time-frame for the expenditure of funds:

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.

Mechanism by which grant funds will 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 will include detailed narrative updates and expenditure reports. The issuance of each year's funding installment will be contingent upon satisfactory progress by grantees.

Procedures 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 grantees from continued funding so long as grantee research is of a high caliber and is within the scope of the original research proposal.

Description of research award accounting:

For each award, to ensure that Settlement Pool funds are used in accordance with award intent, a research budget will be required as a component of the initial proposal and will form part of the

basis of the reviewer evaluations. Financial expenditure reports will be required as part of progress reporting and will be reviewed by the Oversight SAB on a yearly basis. Awardees who do not fully spend funds by the end of the stated award term must receive special permission to extend the award term.

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 Appendix M for information about university obligations under the Bayh-Dole Act). DF/HCC and PCF will not expect any remuneration from royalty streams associated with income from patents, copyrights or other intellectual property.

National Impact of Award Distribution

Rationale for DF/HCC- PCF partnership:

Ultimately, we aim to improve the length and quality of life for patients with cancer and Lupron-treatable diseases, as efficiently as possible, through the allocation of Settlement Pool money. We believe that a research award program administered cooperatively by DF/HCC and PCF is an ideal vehicle to achieve this aim, in part by galvanizing creative, ambitious research plans that would otherwise not be undertaken. In the proposed partnership between DF/HCC and PCF we recommend that the distribution of the total direct research awards be split by DF/HCC and PCF for several key reasons:

1. PCF and DF/HCC have complementary strengths: PCF is primarily an award granting institution, and DF/HCC is first and foremost a research organization, which has a built-in grant-making capability. In granting awards, PCF specializes in a venture capital model of philanthropic investing, by providing initial funding for *high-impact,* and often *early-stage, high-risk* research projects that offer hope for new treatments. Results from these projects can then be leveraged to compete for grants from more traditional funding sources such as the National Cancer Institute or the pharmaceutical industry. DF/HCC specializes in *promoting collaborative interactions and linkages between scientists across disciplines* and in *encouraging translational research* to generate new approaches to cancer diagnosis and care. DF/HCC's focus on translational research, which refers to clinical research that incorporates laboratory generated endpoints, and conversely, laboratory research that incorporates clinical materials, encompasses all stages of research, and uniquely emphasizes research that is *translatable to clinical care in the near term.* Thus, an equal balance of PCF and DF/HCC grants is likely to address a full "bench-to-bedside" spectrum of innovative, high impact research projects.

2. Award funds will reach a large number of researchers: Prostate cancer researchers from across the country and globe will be eligible to apply for the Settlement Pool funds to be administered by PCF, which represents 50% percent, or $5M of the Settlement Pool research

awards. Additionally, applicants to the DF/HCC High Impact, Project Development, and Lupron-Treatable Disease Awards, which represent $3.7M of the Settlement Pool funds, will be expressly encouraged to collaborate with researchers from any institution nation-wide. We believe this emphasis will have the important effect of creating additional potential collaborations where none have previously existed. The opportunity to directly compete for DF/HCC-administered awards extends well beyond the DF/HCC community: Five of the seven proposed DF/HCC grants are open to all Harvard University affiliated faculty (see Appendix N), and the remaining grants are open to eligible applicants from any accredited Massachusetts university. DF/HCC itself is comprised of over 1,100 faculty members. The distribution of all DF/HCC grants will be guided by the core mission of DF/HCC - collaboration.

3. Emphasis on public benefit: Our strong institutional emphasis on conducting research for the public benefit will increase the potential for the Settlement Pool funds to impact prostate cancer and Lupron-treatable disease patients *in a positive and timely manner*. For example, the freedom to publish data is a central tenet of Harvard policy, and as such, ensures that results from DF/HCC-sponsored research are likely to enter the public domain very rapidly, through publication in peer-reviewed journals and conference presentations among other mechanisms. Accordingly, research conducted through the distribution of the proposed DF/HCC Settlement Pool awards will be able to be accessed, reviewed, verified and added to by third party researchers nationally and internationally. In a similar vein, Harvard and its affiliated hospitals are obligated under government and university regulations and guidelines to steward new innovations and inventions toward the public benefit. Notably, a fundamental aspect of DF/HCC's mission is to train the next generation of physician researchers. Training awards are a key means of accomplishing this objective. It is anticipated that many recipients of training awards will move to other institutions, and as such these awards will aid in the development of new investigators nation-wide and at times world wide.

Thus, DF/HCC's expertise in patient-oriented research is complemented by PCF's expertise in early stage seed grants, and these programs together will engender high caliber research, training and outreach projects that address a continuum of prostate cancer and Lupron-treatable disease research needs. A wide variety of laboratory, clinical and translational researchers will be eligible to compete for these funds. Our expectation that innovation and publication will be key aspects of awardee work product ensures that researchers and patients, nationally and internationally, will be beneficiaries of the research made possible through this awards program.

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 1997, 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 developing 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 2001, 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 enhance cancer-focused training opportunities for minority students, postdoctoral fellows and nursing PhD students; Increase community outreach, cancer education, and dissemination of evidenced-based programs; and 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.

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, 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, 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. 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, 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, 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.

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 *C. Elegans*	$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 prostatc 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
Rockfeller 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 Resaerch 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, Southerwestern	$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 that include investigators from at least two DF/HCC member institutions will be encouraged. Collaborators from additional institutions throughout the country will also be encouraged, and such collaborations will be viewed as important criteria for merit in the review process.

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. All basic research must have a plan for translation into application or studies in humans. Collaborations with researchers from additional institutions throughout the country will be encouraged. 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. Collaborations with researchers from additional institutions throughout the country will be encouraged. Such collaborations will be viewed as important criteria for merit in the review process.

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 over 2 yrs.)
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, from across the country or globe.

APPENDIX E
Award Program 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 Training 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

APPENDIX F
Oversight Scientific Advisory Board Responsibilities

Responsibilities of the Oversight SAB will include the following with respect to the Settlement Pool funds:

- Review of request-for-proposals (RFPs) from both DF/HCC and PCF previous to their release, to ensure alignment with the spirit and letter of this program.
- For each award, after reviews are complete and before selections are announced, an audit of the highest ranking application, to ensure conformance with selection criteria and award intent. In the event that the majority (51%) of SAB members agree that the finalist application does not match selection criteria or award intent, the application with the next highest ranking will undergo the same scrutiny.
- For each award granted, the review of progress reports before second year funds are released, to assess conformance, on a general level, to the original proposal. In the event that a majority of SAB members agree that the subject grant recipient has not made satisfactory progress, second year funds will not be released and the grant will be terminated.
- Participation in the application review process, upon request from DF/HCC or PCF.

APPENDIX G
DF/HCC Review Committee 2010

DF/HCC Members

Philip Kantoff, MD (Chair)	*Professor, Department of Medicine, HMS* *Director, Lank Center for Genitourinary Oncology, DFCI* *Chief, Clinical Research Officer, DFCI* *Chief, Division of Solid Tumor Oncology, DFCI*
Matthew Smith, MD, PhD (Co-Chair)	*Associate Professor, Department of Medicine, HMS* *Assistant in Medicine, Hematology/Oncology, MGH*
Martin Sanda, MD (Co-Chair)	*Associate Professor, Department of Urology, HMS* *Director, Prostate Center, Urology, BIDMC*
Glenn Bubley, MD	*Associate Professor, Department of Medicine, HMS* *Director, Genitourinary Medical Oncology, BIDMC*
Steven Balk, MD, PhD	*Associate Professor, Department of Medicine, HMS* *Staff Physician, Hematology/Oncology, BIDMC*
Lewis Cantley, PhD	*William Bosworth Castle Professor of Medicine, HMS* *Professor, Department of Systems Biology, HMS* *Chief, Signal Transduction, BIDMC*
Meir Stampfer, PhD MD	*Professor of Epidemiology and Nutrition, HSPH* *Physician, Channing Laboratory, BWH*
William Hahn, MD PD	*Associate Professor, Department of Medicine, HMS* *Director, Center for Cancer Genome Discovery, DFCI* *Associate Professor of Medicine, Medical Oncology, DFCI*
Meredith M. Regan, ScD	*Assistant Professor, Department of Medicine, HMS* *Senior Research Scientist, Biostatistics and Computational Biology, DFCI*
Anthony D'Amico, MD PhD	*Professor, Department of Radiation Oncology, HMS* *Chief, Genitourinary Radiation Oncology, DFCI* *Chief, Genitourinary Radiation Oncology, BWH*

Patient Advocate(s)
Stanley Klein

Initial Oversight SAB Members (reviewers may rotate over time)

William Nelson, MD, PhD	*Director of the John Hopkins University Cancer Center Director of the Prostate SPORE at Johns Hopkins University*
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*

Court Appointee
Guest Reviewers
Gynecology and Reproductive Medicine experts

APPENDIX H
PCF Review Committee (2010-2011)

From the Prostate Cancer Foundation
Howard Soule, Chairman
Jonathan Simons
Stuart Holden

Surgical Urologic Oncology
Robert Reiter, UCLA
Martin Sanda, Harvard Medical School
Joel Nelson, University of Pittsburgh
Ash Tewari, Weil Cornell Medical College
Bal Carter, Johns Hopkins Medicine
Skip Holden, Cedars-Sinai Medical Center
Peter Carroll, UCSF
Laurence Klotz, University of Toronto
Ian Thompson, UT Health Sciences Center at San Antonio
Martin Gleave, University of British Columbia
Tom Guzzo, University of Pennsylvania

Medical Oncology & Treatment Science
Ken Pienta, University of Michigan
Neal Rosen, Memorial Sloan-Kettering Cancer Center
Peter Nelson, Fred Hutchinson Cancer Research Center
Howard Scher, Memorial Sloan-Kettering Cancer Center
Chris Logothetis, M.D. Anderson Cancer Center
Daniel Haber, Mass General Hospital
George Wilding, University of Wisconsin
Phil Kantoff, Dana-Farber Cancer Institute
Dan George, Duke University
Roberto Pili, Roswell Park Cancer Institute
Walter Stadler, University of Chicago
Elizabeth Heath, Wayne State University
David Solit, Memorial Sloan-Kettering Cancer Center
Matthew Smith, Mass General Hospital
Tia Higano, University of Washington
Tom Beer, Oregon Health & Science University
Bill Dahut, National Cancer Institute
William Oh, Mt. Sinai School of Medicine
Johann DeBono, Royal Marsden Hospital

Immunotherapy
Chuck Drake, Johns Hopkins Medicine
Jim Allison, Memorial Sloan-Kettering Cancer Center

Eric Small, UCSF
James Gulley, National Cancer Institute
Jedd Wolchok, Memorial Sloan-Kettering Cancer Center
Larry Fong, UCSF

Genomics
Levi Garraway, Dana-Farber Cancer Institute
Colin Collins, Univ of British Columbia
Bill Hahn, Dana-Farber Cancer Institute
Lorelei Mucci, Harvard School of Public Health
John Carpten, Translational Genomics Institute
William Isaacs, Johns Hopkins Medicine

Basic Science
Candace Johnson, Roswell Park Cancer Institute
John Isaacs, Johns Hopkins Medicine
Lucia Languino, University of Massachusetts
Rob Getzenberg, Johns Hopkins Medicine
Owen Witte, UCLA
Cory Abate-Shen, Columbia University
Don Coffey, Johns Hopkins Medicine
Tim Thompson, M.D. Anderson Cancer Center
Jack Schalken, University Hospital of Nijmegen
Colleen Nelson, Queensland Univ. of Technology

Radiation Oncology
Howard Sandler, Cedars-Sinai Medical Center
Adam Dicker, Thomas Jefferson University
Ted DeWeese, Johns Hopkins Medicine
Rob Bristow, University of Toronto
Anthony D'Amico, Brigham and Women's Hospital

Nutrition Research
David Heber, UCLA
June Chan, UCSF
Meir Stampfer, Harvard School of Public Health
William Nelson, Johns Hopkins Medicine

Molecular Imaging
Peter Choyke, National Cancer Institute
Steve Larson, Memorial Sloan-Kettering Cancer Center
Lily Wu, UCLA
Sam Gambhir, Stanford University
Martin Pomper, Johns Hopkins Medicine

Molecular Pathology

Angelo DeMarzo, Johns Hopkins Medicine
Michael Ittmann, Baylor College of Medicine
Tim McDonnell, M.D. Anderson Cancer Center
Arul Chinnaiyan, University of Michigan
Scott Tomlins, University of Michigan
Jeffrey Simko, UCSF
Karen Kaul, Northwestern University
Max Loda, Dana-Farber Cancer Institute
Mahul Amin, Cedars-Sinai Medical Center
Mark Rubin, Weil Cornell Medical College

Statistics
Bruce Trock, Johns Hopkins Medicine
Susan Halabi, Duke University
Steve Piantadosi, Cedars-Sinai Medical Center

Initial Oversight SAB Members (reviewers may rotate over time)
Peter Nelson MD, Director of the Prostate SPORE at the University of Washington
Don Tindall PhD, Director of the Prostate SPORE at Mayo Clinic

Court Appointee

APPENDIX I
Indirect Cost Background and Description

Indirect costs (IDC) are those that are incurred for common or joint objectives, and which cannot be easily identified with a particular sponsored project in a straightforward manner. The concept of IDC evolved along with the inception of significant government research funding during and after World War II. It became evident that university-based research programs could only expand to incorporate new projects if infrastructure costs were supported in tandem with "direct" research expenses. Although it was technically possible to parse out each sponsored project's use of facilities and administrative resources per government grant, it proved difficult to establish uniform accounting procedures for this practice, and correspondingly, to audit such practices.

For this reason, government funding agencies and research institutions developed a specific formula to calculate overall IDC rate on all government grants, a practice which continues today. This rate is calculated on a per institution basis. The federal overhead rate for DF/HCC is 75%. Federal regulations spell out explicitly which type of research costs should be attributed to indirect costs and which should be attributed to direct costs.

To maintain consistent accounting procedures, DF/HCC abides by federal IDC guidelines for the identification and assignment of IDC costs, uniformly for all federal and non-federal grants and gifts. DF/HCC applies a 20% IDC rate on non-federal programmatic gifts and grants made to the Institute. Although the actual cost of maintaining research infrastructure is much higher (see federal rate above), DF/HCC is generally able to employ discretionary funds to reimburse these additional infrastructure costs. These costs include but are not limited to: departmental administration costs, general administration costs, research computing costs, grants administration costs, facilities operation and maintenance expenses, and more.

APPENDIX J
Program Manager Responsibilities

The responsibilities of the Settlement Pool Program Manager will include the following:

- Act as program authority and point person for DF/HCC applicant, grantee and administrator questions.
- Act as program liaison with PCF, University of Massachusetts and other Massachusetts universities. Be available to answer applicant, grantee and administrator questions as needed.
- Draft, publish and promote program-related DF/HCC RFPs. Oversight of program-related PCF RFP drafts, publication and promotion.
- Act as liaison to the Oversight SAB. Provide Oversight SAB with pertinent materials and solicit feedback as warranted throughout the life cycle of each grant.
- Manage DF/HCC program funds. Distribute Settlement Funds to PCF, collect relevant account information from PCF for reporting and oversight purposes.
- Provide overall annual reports to the First Circuit Court of Appeals, and/or a court designee.

APPENDIX K
DF/HCC SPORE Program Management Activities 2010-11

The anticipated dates and activities for the DF/HCC SPORE award program, below, will serve as a template for Settlement Pool award program dates and activities:

07/15/10: An invitation is sent out to the SPORE Review Committee asking for their participation in reviewing new applications (due 10/01/10). Responses are tallied and a face-to-face Review Committee Meeting is scheduled for mid-October.

08/15/10: 2010 RFAs are distributed to DF/HCC membership list (maintained by DF/HCC administrator) and DF/HCC SPORE in Prostate Cancer PIs (past and present) and collaborators list (maintained by DF/HCC SPORE in Prostate Cancer administrator) and to DFCI Investigators (maintained by DFCI Grants and Contracts). RFAs and program information is also made available to all DFCI faculty via the DFCI intranet, and all DF/HCC faculty via the DF/HCC internet.

10/01/10: Due date for 2010 SPORE Applications.

10/01/10-10/07/10: All review committee members receive a Reviewer Packet (including reviewer's letter, scoring sheets, copies of the RFAs, and a copy of all applications received), provided in hard copy and by email. Each reviewer is responsible for scoring, ranking, and commenting on all proposals, except those which pose a conflict of interest.

10/1/10-10/15/10: For all applications, reviewers score (NIH scoring) and rank in order of fundability with consideration focused on 1) quality of the science, 2) quality of the investigator, 3) translational potential, 4) potential to help the program and SPORE. The purpose of the ranking is to eliminate the lower approximate 50% which will allow us to review the top 50% in greater detail at our face-to-face review session.

10/15/10: Reviewer scores, ranks and comments are due to the Program Administrator, who will integrate all responses into a combined scoring spreadsheet, which will be provided to all at the face-to-face meeting.

10/17/10: Approximate date for face-to-face 2010 SPORE Review Committee Meeting. The merits of each proposal and investigator are discussed and a final ranking is conducted. The new projects are selected.

10/22/10: All applicants are notified regarding their application funding status, and if awarded, the next steps required for account setup. Next steps may include submission of a revised budget, Statement of Work (for outside institutions), and IRB/IACUC approval information (as applicable, depending whether human or animal protocols are involved).

11/1/10-11/15/10: All requested documentation is received and forwarded on to Grant and Contracts for Account Setup.

11/1/10-11/30/10: All selected projects are funded. Grants and Contracts issues accounts for personnel and executes subcontract agreements for collaborating institutions.

07/01/11: Progress reports and requests for no-cost extensions must be received.

08/15/11: Financial expenditure reports and subcontract agreement invoices due to DF/HCC for preparation of Financial Summary Report.

APPENDIX L
PCF Program Management Activities

The Prostate Cancer Foundation's rigorous grant review process is modeled on the NIH peer-review system. Each application will be sent to three reviewers who are selected by matching areas of expertise to the scientific content of the proposal. Each reviewer is asked to score the application in 5 to 10 relevant areas, using NIH scoring methodology. Review criteria include, as examples: qualification of investigator, quality of scientific environment, level of scientific innovation of the proposal, strength of the collaborative team, and likelihood that the research will benefit patients in the near term. Additionally, a brief written critique concerning the strengths and weaknesses of the proposal and investigator is requested. Grants will be selected and funded within six months of program launch.

For each of five selected $1M Challenge Grant awardees, grantee progress will be reviewed quarterly through verbal communications, and annually via written reports. Grant payments will be made upon grantee achievement of key research milestones. Additionally, the Chief Scientific Officer of PCF will make a site visit to each grantee research team during the term of the award to ensure proper stewardship of these funds.

Grantees will be expected to attend the Annual PCF Scientific Retreat, and to submit all papers published as a result of grants to PCF.

APPENDIX M
Information about the Bayh-Dole Act

The Bayh-Dole Act, passed in 1980, enables universities to retain ownership of federally funded inventions, in accordance with federal regulations (37 CFR part 401) which are designed in part to promote the commercialization and public availability of inventions made in the United States.

Universities are subject to the a number of provisions under Bayh-Dole Act, including the following: they may elect to retain title to innovations developed under federally-funded research programs; they are encouraged to promote the utilization of inventions that arise from federal funding; they are expected to file patent applications on their inventions; and they are expected to prioritize small businesses as potential licensees.

A May 3, 2010 press release issued by the Association of University Technology Managers (www.autm.net) describes the Bayh-Dole Act as "an enduring example of a public-private sector partnership addressing a common problem - turning taxpayer funded research into products the public can use, along with creating jobs and new companies." A website dedicated to providing information about the Bayh-Dole Act can be found at http://www.b-d30.org.

APPENDIX N
Harvard Medical School Affiliates and DF/HCC Member Institutions

Harvard Medical School Affiliates:
Beth Israel Deaconess Medical Center
Brigham and Women's Hospital
Cambridge Health Alliance
Children's Hospital Boston
Dana-Farber Cancer Institute
Forsyth Institute
Harvard Pilgrim Healthcare
Hebrew SeniorLife
Joslin Diabetes Center
Judge Baker Children's Center
Massachusetts Eye and Ear Infirmary
Massachusetts General Hospital
McLean Hospital
Mount Auburn Hospital
Schepens Eye Research Institute
Spaulding Rehabilitation Hospital
Veterans Affairs Boston Healthcare System

DF/HCC Member Institutions:
Dana-Farber Cancer Institute
Beth Israel Deaconness Medical Center
Brigham and Women's Hospital
Children's Hospital Boston
Harvard Medical School
Harvard School of Public Health
Massachusetts General Hospital

SUPPORTING DOCUMENTS

DF/HCC

DANA-FARBER HARVARD CANCER CENTER

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
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44 Binney Street
Boston, Massachusetts 02115-6084
617.632.4266 tel. 617.632.2161 fax
edward_benz@dfci.harvard.edu
www.dfhcc.harvard.edu

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

NCI CCC
A Comprehensive Cancer Center Designated by the National Cancer Institute

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,

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

DANA-FARBER CANCER INSTITUTE | BRIGHAM AND WOMEN'S HOSPITAL

Philip W. Kantoff, M.D.
Chief Clinical Research Officer
Chief, Division of Solid Tumor Oncology
Director, The Lank Center for Genitourinary Oncology
Department of Medical Oncology
Dana-Farber Cancer Institute

Professor of Medicine
Harvard Medical School

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617.632.1914 tel, 617.632.2165 fax
philip_kantoff@dfci.harvard.edu
www.dana-farber.org

March 23, 2010

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

Re: Response to memorandum dated March 2, 2010 regarding the disposition of consumer settlement pool funds

Dear Judge Stearns:

Thank you for your review of our November 24, 2009 proposal for the distribution of funds in the Lupron litigation settlement pool. In formulating our response to your insightful and thought-provoking questions, we closely examined our proposed award mechanism. We remain convinced that a partnership approach between DF/HCC and PCF is a unique way to catalyze diverse and innovative research that has great potential to advance the state of care for prostate cancer and Lupron treatable disease patients.

Please do not hesitate to contact me at 617-632-1914 or philip_kantoff@dfci.harvard.edu should you have any additional questions, or feedback, either about the enclosed response or our original proposal. Thank you again for your consideration.

Sincerely,

Philip Kantoff, M.D.

Prostate
Cancer
Foundation

Jonathan W. Simons, MD
President and Chief Executive Officer
David H. Koch Chair

March 18, 2010

Judge Richard G. Stearns
United States District Court
Suite #7130
1 Courthouse Way
Boston, MA 02210

Dear Judge Stearns:

Prostate cancer is the second leading cause of death from cancer in U.S. men. A man is diagnosed every 4 minutes. Every 19 minutes a man dies from prostate cancer.

On behalf of the Prostate Cancer Foundation, I strongly endorse the plan that Dr. Philip Kantoff and others on his team have developed for your consideration. By way of introduction, 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.

Dr. Kantoff is a world leader in prostate cancer research and is nationally admired for having, in the best sense of the word, a "judicial spirit" of evaluating the merits of other scientists' work and supporting it. I cannot think of a wiser research leader in American to be involved in the implementation and stewardship of this project.

In this severe recession, and with a flat federal budget for cancer research, some of the nation's best prostate cancer research ideas will achieve funding with this proposal. This would not have occurred, in all likelihood, without the judicial system catalyzing a form of justice in supporting transformational research for prostate cancer patients.

1250 Fourth Street, Santa Monica, CA 90401 *Tel* 310.570.4711 *Fax* 310.570.4694
jsimons@pcf.org *www.pcf.org*

Thank you for your thoughtful consideration.

Sincerely yours,

Jonathan W. Simons, MD
President and CEO
Prostate Cancer Foundation
David H. Koch Chair

JWS:mma

Prostate
Cancer
Foundation

Howard R. Soule, PhD

Executive Vice President
Chief Science Officer

April 10, 2010

Philip W. Kantoff, MD
Chief Clinical Research Officer
Chief, Division of Solid Tumor Oncology
Director of the Lank Center for
Genitourinary Oncology
Dana-Farber Cancer Institute
44 Binney Street
Suite D1230
Boston, MA 02115-6013

Dear Dr. Kantoff:

Thank you for your recent request for information concerning the process of awarding research funds by the Prostate Cancer Foundation (PCF). The following should fulfill your request. Please do not hesitate to contact us you need further detail or clarification.

In 2010 PCF formed a Standing Committee for Research Award Application review. As the PCF Chief Science Officer, I chair this committee. Dr. Jonathan Simons, PCF President and CEO, is a member of the committee. The full referee committee is presented on the PCF website (http://www.pcf.org/review). The Standing Committee is composed of international experts in all areas of prostate cancer research from basic science through drug development. Represented disciplines include: surgical urologic oncology, medical oncology and treatment science, immunotherapy, genomics, basic laboratory science, radiation oncology, nutrition research, molecular imaging, molecular pathology, and statistics. The list of 79 experts on this committee is appended to this letter. The PCF Research Awards Standing Review Committee works *pro bono*. There are no stipends. Reviewers are required to recuse themselves if there is an actual or perceived conflict of interest regarding a specific award application.

The grant review process is rigorous and modeled on the NIH peer-review system, but to a shorter timeframe to notification of funding. Each application is sent to three reviewers selected by matching areas of expertise to the scientific content of the proposal. Each is asked to score the application in 5-10 relevant areas using NIH scoring methodology. Review criteria include, as examples: qualification of investigator, quality of scientific environment, level of scientific innovation of the proposal, strength of the collaborative team, likelihood that the research will benefit patients in the near term, etc. A brief

written critique concerning the strengths and weaknesses of the proposal and investigator(s) is also requested.

PCF plans, after an international research proposal competition, to award five interdisciplinary team research awards for $1 million each. This is payable against highly scrutinized budgets submitted from each research team. Payment is made upon achievement of key research milestones. Generally, these awards are made over 24 months. These five awards will fund research with the high likelihood of translation to the clinic in the near term for patients with advanced prostate cancer, and will "fast-forward" improvements in treatment. The number and timing of awards is dependent on the schedule for distribution of the settlement proceeds.

Our financial accountability mechanism is based on achievement of research milestones that are reviewed quarterly by the PCF Chief Science Officer. The Chief Science Officer will site visit each research team to ensure good and timely stewardship of these precious research funds.

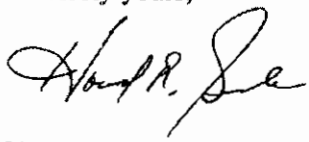
One hundred percent of the funds will be applied to the research awards and their respective teams. PCF will absorb the entire cost of administering the five research awards from beginning to end.

The research award cycle at PCF is highly responsible but swift, based on the urgency of "fast-forwarding" solutions for patients with advanced prostate cancer. Within six months of program launch, applications will be solicited, reviewed, and five interdisciplinary, highly translational research programs focused on improved treatments for advanced prostate cancer will be funded.

Communication of results at the Annual PCF Scientific Retreat, and dissemination of published papers via the office of the Chief Science Officer are a core requisite of our funded research programs.

I hope that this information clarifies any procedures of the PCF grant-making process.

Sincerely yours,



Howard R. Soule, PhD

PCF Research Awards Standing Review Committee Members

2010 - 2011

From the Prostate Cancer Foundation: Howard Soule, Chairman
Jonathan Simons
Stuart Holden

Surgical Urologic Oncology

1.	Robert Reiter	UCLA
2.	Martin Sanda	Harvard Medical School
3.	Joel Nelson	University of Pittsburgh
4.	Ash Tewari	Weil Cornell Medical College
5.	Bal Carter	Johns Hopkins Medicine
6.	Skip Holden	Cedars-Sinai Medical Center
7.	Peter Carroll	UCSF
8.	Laurence Klotz	University of Toronto
9.	Ian Thompson	UT Health Sciences Center at San Antonio
10.	Martin Gleave	University of British Columbia
11.	Tom Guzzo	University of Pennsylvania

Medical Oncology & Treatment Science

12.	Ken Pienta	University of Michigan
13.	Neal Rosen	Memorial Sloan-Kettering Cancer Center
14.	Peter Nelson	Fred Hutchinson Cancer Research Center
15.	Howard Scher	Memorial Sloan-Kettering Cancer Center
16.	Chris Logothetis	M.D. Anderson Cancer Center
17.	Daniel Haber	Mass General Hospital
18.	George Wilding	University of Wisconsin
19.	Phil Kantoff	Dana-Farber Cancer Institute

Medical Oncology & Treatment Science, con't.

20.	Dan George	Duke University
21.	Roberto Pili	Roswell Park Cancer Institute
22.	Walter Stadler	University of Chicago
23.	Elizabeth Heath	Wayne State University
24.	David Solit	Memorial Sloan-Kettering Cancer Center
25.	Matthew Smith	Mass General Hospital
26.	Tia Higano	University of Washington
27.	Tom Beer	Oregon Health & Science University
28.	Bill Dahut	National Cancer Institute
29.	William Oh	Mt. Sinai School of Medicine
30.	Johann DeBono	Royal Marsden Hospital

Immunotherapy

31.	Chuck Drake	Johns Hopkins Medicine
32.	Jim Allison	Memorial Sloan-Kettering Cancer Center
33.	Eric Small	UCSF
34.	James Gulley	National Cancer Institute
35.	Jedd Wolchok	Memorial Sloan-Kettering Cancer Center
36.	Larry Fong	UCSF

Genomics

37.	Levi Garraway	Dana-Farber Cancer Institute
38.	Colin Collins	Univ of British Columbia
39.	Bill Hahn	Dana-Farber Cancer Institute
40.	Lorelei Mucci	Harvard School of Public Health

Genomics, con't.

41.	John Carpten	Translational Genomics Institute
42.	William Isaacs	Johns Hopkins Medicine

Basic Science

43.	Candace Johnson	Roswell Park Cancer Institute
44.	John Isaacs	Johns Hopkins Medicine
45.	Lucia Languino	University of Massachusetts
46.	Rob Getzenberg	Johns Hopkins Medicine
47.	Owen Witte	UCLA
48.	Cory Abate-Shen	Columbia University
49.	Don Coffey	Johns Hopkins Medicine
50.	Tim Thompson	M.D. Anderson Cancer Center
51.	Jack Schalken	University Hospital of Nijmegen
52.	Colleen Nelson	Queensland Univ. of Technology

Radiation Oncology

53.	Howard Sandler	Cedars-Sinai Medical Center
54.	Adam Dicker	Thomas Jefferson University
55.	Ted DeWeese	Johns Hopkins Medicine
56.	Rob Bristow	University of Toronto
57.	Anthony D'Amico	Brigham and Women's Hospital

Nutrition Research

58.	David Heber	UCLA
59.	June Chan	UCSF
60.	Meir Stampfer	Harvard School of Public Health
61.	William Nelson	Johns Hopkins Medicine

Molecular Imaging

62.	Peter Choyke	National Cancer Institute
63.	Steve Larson	Memorial Sloan-Kettering Cancer Center
64.	Lily Wu	UCLA
65.	Sam Gambhir	Stanford University
66.	Martin Pomper	Johns Hopkins Medicine

Molecular Pathology

67.	Angelo DeMarzo	Johns Hopkins Medicine
68.	Michael Ittmann	Baylor College of Medicine
69.	Tim McDonnell	M.D. Anderson Cancer Center
70.	Arul Chinnaiyan	University of Michigan
71.	Scott Tomlins	University of Michigan
72.	Jeffrey Simko	UCSF
73.	Karen Kaul	Northwestern University
74.	Max Loda	Dana-Farber Cancer Institute
75.	Mahul Amin	Cedars-Sinai Medical Center
76.	Mark Rubin	Weil Cornell Medical College

Statistics

77.	Bruce Trock	Johns Hopkins Medicine
78.	Susan Halabi	Duke University
79.	Steve Piantadosi	Cedars-Sinai Medical Center