

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 identified 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.

RFP Advertisements: 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 (10-2 YR Awards) 500K	10x50K (10-2 YR Awards) 500K 1M 10x50K \$500K	10x50K (10-2 YR Awards) 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.

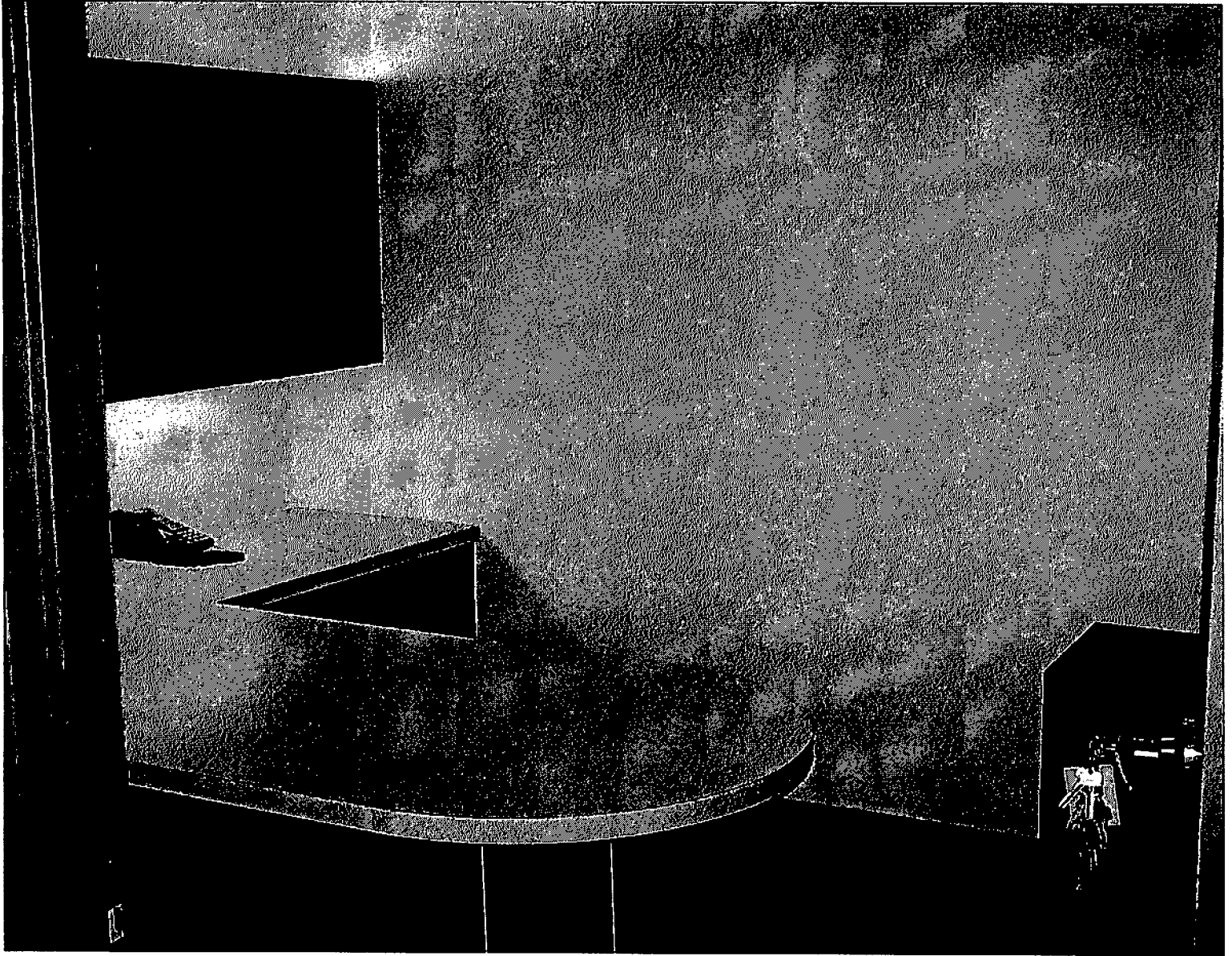
Rent is \$750.00/month.

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