May 26, 2009

U.S. District Court Honorable Judge Richard Stearns 1 Court House Way Suite 2300 Boston, MA. 02210

Re: Cy Pres Distribution Requests Concerning Lupron's Price-Inflation Settlement

## Dear Judge Stearns:

This letter was prompted by the May 20<sup>th</sup> Bloomberg news citing your inclination to give the 'leftover' \$11.4 million from Lupron's inflated price litigation to Brigham & Women's for purposes of prostate cancer research. I am writing with several proposals that I ask you take under consideration.

Bloomberg news also reported that you have declined consideration of allocating these surplus funds back to the original claimants, to which I was a party. I would ask that you reconsider this decision. Since the settlement was decided in favor of the claimants, it would seem only fitting that the claimants should benefit from any surplus.

I had also planned to propose that you consider giving some of these funds to a recently formed 'Consortium' (comprised of the 'Center for Medical Consumers', 'National Women's Health Network', 'Our Bodies Ourselves'. and the 'Endometriosis Association') to fund the much needed education of the risks to Lupron - but I have since learned that you have already received a request by the 'Consortium', and that you have rejected it. I would ask that you reconsider the Consortium's proposal.

And lastly, I ask that you also consider allocating some of these funds to any entity that would initiate investigation and medicolegal assistance for the Lupron's victims.

Further prostate cancer research, while a worthy goal, would build upon an already strong foundation of prior research -- the Lupron victims have no such prior research or study or

recognition. The federal government has allocated some \$335 million to prostate cancer research, and the prostate cancer community has a history of multiple champions (National Prostate Cancer Coalition. CapCure. Tony's Prostate Cancer Research, Prostate Cancer Foundation, and individual institutional prostate cancer centers, to name a few). Lupron victims have had no such formal champions or advocates.

A search of "prostate cancer" and "research" on Google today yields 13,000,000 hits. A search of "Lupron victims" and "research" today yields 624 hits - and my website, www.LupronVictimsHub.com, is the # 1 hit.

The 2001 US government's suit vs. TAP ignored the adverse health effects of Lupron - in fact, statements were made in the press at the time that "the safety of Lupron is not in question". The numerous civil tort litigations involving Lupron's adverse health effects have *all* been met with settlement agreements and gag orders, therefore the risks of Lupron have not been made public (please see lawsuits' page at my website). In the matter at bar, the financial risks to Lupron's inflated price have been acknowledged, publicized and meagerly compensated, yet Lupron's dangers and Lupron's victims remain virtually unknown and in the shadows.

If you so desire, you alone could change this.

My understanding of the manner involved with distribution of Cy Pres funds is that money can be given to 3<sup>rd</sup> parties with only a tangential relation to the litigation, the plan should be flexible, patient-centered, and that funds should be distributed in line with the intent of the settlement. Although I have minimal understanding of Cy Pres distribution, I have to assume that providing funds for the purposes of educating the public about the risks of Lupron or establishing medicolegal advocacy for Lupron's victims would not be outside the intent of the settlement. However, exposure of Lupron's dangers and victims would not be in the best interest of AbbottTAP. Therefore, is it the interest of AbbottTAP, or the claimant's interest, that is to be served here?

Please tell me what purpose did the \$100 remuneration awarded to claimants in this case serve, since the Lupron victim is overwhelmed with acute and chronic symptoms, illnesses and diseases, and has perpetual doctor, dentist, pharmacy. and hospital bills ... and this status quo will exist for the rest of their ruined lives? When one overpays for a poison, the law and the justice system should be concerned not just with investigation and prosecution for the 'overpayment' — but exposure and resolution of the poisoning MUST take place, or our justice system is a farce, and is as harmful as a vial of Lupron has been to its victims.

As of February 11, 2009, the total tally of *reported* adverse events to Lupron/leuprolide since November 1, 1997, according to the FDA. are as follows: total reported reactions 22,667: total reported individual safety reports — 5,069, and total reported deaths — 651.

Given that it is acknowledged that the FDA figures of *reported* adverse events actually represent just 1% of total adverse events experienced, it is easy to calculate that the extent of adverse events to Lupron are not being reported to the FDA. Further study and investigation is indeed warranted, necessary, and long overdue.

By 2000, the founders of the National Lupron Victims Network (NLVN), Drs. Linda and Rita Abend, were involved in a 6 year study of 10,000 + Lupron victims - however the NLVN (with whom I had worked closely) disappeared in 2001. TAP had previously and unsuccessfully attempted to "invest" in the NLVN, according to Linda Abend (and my written notes from our conversations), and so there is reason to believe that it is likely the NLVN subsequently 'agreed to disband'- and in so doing, to take their study/findings, their website, their pending book, and their 'expose Lupron' plans and 'shelve them' permanently. When in the history of this country has "a victims' group", comprised of 10,000+ injured souls, just suddenly disappear without a trace'?

For more than a decade I have been contacted by Lupron victims looking for medical care, legal assistance, and wanting their former life back, but there has been nowhere substantive to send them. Below please find 4 recent emails to my website mailbox, reflecting the harm that men, women, and children have experienced post-Lupron:

- (#1): "My Dad was given Lupron for early onset of prostate cancer. He drove to the Doctor's office to get the Lupron shot & never drove again. He went into Dementia immediately after the shot & progressively got worse. He passed away about 3 years after getting the Lupron shot. He did not even have late stage prostate cancer. We know that Dad lost his life as a result of Lupron. We do not want anyone else to go through what my dad & my family went through as a result of Lupron. If our experience could help this cause, please advise."
- (#2): Dear Ms. Millican, I've visited your website in desperation and felt at times I wasn't going to make it. In February 2009, I was given a 3-4 months injection (course) of Lupron by my urologist. He told me the drug is safe and effective, and little or no side effects maybe a little sweating. At age 58 my life has been destroyed and never the same. ... A few months prior to Lupron, I had a complete physical work-up and was found to be in excellent health with abundance of energy! ... Now I'm lucky if I can walk to the toilet without falling. Without any prior warning, I also went into a diabetic coma ... Each day is another challenge with life or deadly event!"
- (#3): "Lynne, I don't know where else to turn. I have been suffering from passing out, heart palpitations, tremors (head and hand), joint pain, back surgery secondary to stenosis and degenerative disc disease, short term memory issues ... I had taken Lupron for close to 5 years off and on for a total of 11 IVF cycles. Where do I go from here? No one can diagnose my symptoms. I have been in and out of the hospital and have had the so called "million dollar" work up but no one can come up with a diagnosis. Any direction would be greatly appreciated."

(#4): "I found your web site about Lupron while searching for some hopeful answers to help a 12 year old who was treated with Lupron for 3 years and now has debilitating consequences from the medication. I would really like to talk with you if possible. Maybe you can point me in the direction I need to go? If you think you could help or would like some info for your web site, please call me collect at ..." In speaking with this woman, the 12 year old has lost all feeling in the legs, is in extreme pain, now has osteopenia and cannot stand, and has deterioration of the femur bone.

Recently I received the autopsy report of a 27 year old woman (mother to a 7 year old) who was given one shot of Lupron for 'diagnostic purposes for suspected endometriosis' (which she, in fact, did not have). The otherwise healthy woman died in her sleep 3 weeks later, dead from "undetermined cause" - presumed to be a lethal arrhythmia, which would not show on autopsy.

The statistics from my website show daily searches in various terms from apparent Lupron victims searching for information. There are hundreds of variables, and while this is obviously anecdotal, these search terms scream volumes to me, and I want to provide a small sampling here fyi:

"Does Lupron cause MS", "IVF Lupron leiomyosarcoma", "Lupron and dementia", "Lupron side effects central nervous system". "Lupron and ECG changes", "Lupron heart failure", "does Lupron cause seizures". "Lupron and memory loss", "Lupron and neurological side effects", "Lupron lupus", "eye damage after Lupron", "does Lupron cause deafness". "death from Lupron", "Lupron and aphasia", "Lupron stroke", "leuprolide cerebral infarction", "autoimmune disease Lupron". "Lupron thyroid malfunction", "Lupron and gastroparesis", "Lupron bone pain", "sterility after Lupron", "Lupron paresthesias", "Lupron thrombocytopenia", "Lupron sudden death", "side effects of Lupron and brain atrophy", "Lupron and brain damage". "Lupron and neurologic weakness", "Lupron psychosis", "conceived while on Lupron depot", "Lupron and hydrocephalus", "is Lupron associated with breast cancer", "Lupron liver damage", "Lupron myocardial infarction", "pulmonary hypertension and Lupron", "permanent Lupron insomnia", "Lupron and leukemia", "Lupron bone marrow depression", "what are specific birth defects caused by Lupron depot", "Lupron birth defects", "Lupron and Williams Syndrome [rare neurodevelopmental disorder]", "Lupron side effects that are permanent". There are also numerous searches for the terms "Lupron class action", "Lupron lawsuit(s)" and "Lupron attorney(s)", and there are those searching for "Lupron expert witness" and "justice for Lupron victims".

There needs to be attention, study, and answers to these people and their questions! There has not been post-marketing surveillance to ascertain extent of adverse events nor the exact numbers of victims. There needs to be evaluation of the alleged 'safety' and efficacy of Lupron, and there needs to be study of the victims to determine why so many are so sick. But there has been virtually no one (excepting the now-defunct NLVN. and

myself) who has evidenced any real interest in the victims of Lupron, until the advent of the 'Consortium'.

The "National Women's Health Network has initiated a public education and policy campaign to get the word out about the misuse and dangers of Lupron and other drugs" (1). While education about Lupron (and other drug's) risks is the focus of the 'Consortium', if 'leftover millions' were made available, it would be my hope that substantive epidemiologically sound study of the Lupron victims could be undertaken by the Consortium or by some other appropriate entity. Funding is crucial to founding a coalition to study the adverse health effects afflicting the Lupron victims - and presently I know of no other group to refer you to except the Consortium. (And I have no personal connection to this Consortium, although I would certainly hope to be able to provide input into its' future direction.)

But what really is required is a well organized and funded national foundation, dedicated to aggressive medical investigation of and intervention for the Lupron victims. I do not mean to waste your time with a proposal that is in essence a joke, but in desperation (knowing there is no well organized national foundation out there to help Lupron victims) I am compelled to say that if you were to provide to me a substantial portion of the Cy Pres funds - despite my health limitations - I'll somehow find a way to form that foundation. With these funds I would found the organization, locate the lawyers and the epidemiologists, retain the multi-specialty physicians required, rent the mobile PET scans and testing equipment, hire the staff, and organize a nation-wide retrospective study of the men, women, and children suffering post-Lupron. Over the years I have come to know several distinguished individuals in medicine and law that would be agreeable to come on board - so my 'proposal' is not entirely a fantasy. But while someone needs to pick up this ball and run hard and far with it, I am certainly not the appropriate person to do this.

Since testifying in Congress on the risks of Lupron on March 27, 2003 (please see my testimony on my website), I have been hospitalized 38 times for severe gastroparesis - Lupron has (among other things) destroyed the neurological impulses in my gut, and my stomach and intestines are now paralyzed. The neurological impulses to my heart have been impaired as well, and past EKG readings record a heart rate of 38 and 44 beats per minute. I have been very sick, overwhelmed in fact, and am now disabled from my nursing career, and can barely keep up with normal activities of daily living. Someone needs to be fighting on my behalf.

Instead, my website speaks to the amount of 'fight' I have expended since 1992 to expose the dangers of Lupron. I've put on my website some of my numerous correspondences from over the years, but of all the people I've written to - you alone hold the greatest power and ability to inject justice into this equation. Were you to grant

the small proposal by the Consortium, and/or grant other funds to some other organization dedicated to help the Lupron victims - you would be opening The Door.

If you close this door by refusing to allocate any funds to assist those physically harmed by Lupron, could you please advise me as to where the Lupron victims can go for medicolegal assistance? The effects of Lupron has had such far reaching consequences upon the health, well-being, careers, and financial stability of a large group of people. The Lupron victims are a group rendered sick with little ability or energy to fight, and are without advocates. It is nothing short of a travesty of justice that the Lupron victims, amidst all this pricing litigation, have been effectively and silently swept under the rug.

Please see my website for further information on the risks and victims of Lupron. Some of the FDA's Adverse Event Reporting System Reports (AERS) and Deaths from Lupron have been reproduced on my site. Please see LupronSUQS (Serious Unanswered QuestionS), and the 'Risks" and NLVN page for further details. And should you have any questions, please do not hesitate to contact me.

Given the amount of \$11.4 million involved, it is my hope that you will consider a fair and reasonable distribution of these funds. It would seem that some funds to prostate cancer research, some funds returned to claimants, some funds to the 'Consortium', and some funds to an as-yet-known entity able to investigate Lupron's victims, would be a fair and reasonable approach.

On behalf of all the Lupron victims, I especially urge you to please consider granting some or all of the Cy Pres funds from the Lupron pricing litigation to benefit the Lupron victims in a substantive way through the establishment of an entity to educate, investigate, and provide medicolegal assistance — none of which exist at this moment, but could become a reality by your decisions.

Respectfully submitted.

Lynne Millican

(1):

http://www.womenshealthnetwork.org/newsletter/article1.cfm?newsletterarticles id=304