September 17, 2009

Commissioner, F.D.A.
Margaret A. Hamburg, M.D.
10903 New Hampshire Avenue
Building 1, Room 2217
Silver Springs, MD. 20993-0002

Re: Investigation of Lupron & Removal From Market

Dear Commissioner Hamburg:

I am writing this letter with an admitted sense of futility, as this seems to be my millionth letter about Lupron to date, but I am hopeful that with your appointment as Commissioner of the FDA, a full examination of Lupron's approval process and its adverse event profile can finally occur, leading to its removal from the market.

I have been trying since the early 1990's to bring attention to the risks and problems with Lupron's approval and adverse event profile, and I would direct you to my website www.LupronVictimsHub.com for further information.

At my website you will find many documents detailing my research into Lupron (i.e. my 03-27-03 testimony to Congress about the risks of Lupron, 'LupronSUQS' [Serious Unanswered QuestionS], and 'USA[ttorney] Draft Document') as well as letters to Senators and FDA, media stories, and other Lupron links, among many others.

Since taking Lupron in 1989, I have suffered numerous health problems and have undergone much testing and treatment, and will mention only 3 of my diagnoses here: I've been disabled from my nursing career for 6 years due to severe gastroparesis, necessitating 39 hospitalizations since 3/03: Lupron has paralyzed the neurological impulses in my gut. Lupron has also impaired the neurological impulses in my heart - I have frequent bradycardia with several EKG readings of 38 beats per minute (though I also experience atrial fibrillation). And I have severe osteoporosis, which is causing serious dental problems, and I face the heightened risk of fracture. And the list doesn't end there. In the past I have reported adverse events to TAP, however I do not believe these reports were ever filed with the FDA, since I declined to disclose my physician's name to TAP. (Of note, the death of a 27 year old woman, 3 weeks after receiving her first Lupron injection, was never recorded in the FDA's AERS for that time period.). I am enclosing a copy of my MedWatch form fyi.

It is well known that only approximately 1% of all adverse events are reported to the FDA, with Lupron/leuprolide registering 22,667 total reactions (and 651 deaths) reported

to FDA AERS as of February 2009. On March 24, 1999, an FDA epidemiologist reviewing Lupron concluded there were “high prevalence rates” for serious side effects, yet a further review determined no action need be taken. The internet volume of complaints lodged against Lupron in multiple web forums and various petitions has only increased, and certainly speaks to the Lupron problem - while simultaneously the FDA has done nothing and idles silently as more and more victims become permanently injured by Lupron.

Moreover, I believe that the number of adverse events is/has been distorted by TAP's business model, which focused on generating revenue for physicians' practices – creating de facto partnerships with prescribers. Over a decade ago, TAP Pharmaceuticals devised a marketing strategy (1) which permitted physicians to sell Lupron at a profit of up to $284 per injection (2). This, in my opinion, explains why so many woman complained that Lupron was “being shoved down their throat” and why so many woman were “mandated” to take Lupron.

For more than a decade I have been contacted by men, women, and the parents and grandparents of children who have been harmed by Lupron, and their stories are heart wrenching, and their pleas for help leave me feeling helpless, frustrated, and angry. These Lupron victims share common themes; they were not provided informed consent of the risks of Lupron, they have become sick during and/or post-Lupron, and they have great difficulty accessing medicolegal advocacy, and they have virtually nowhere to turn. I’ve had nowhere to turn all these years, and all the while these Lupron victims have turned to me for assistance. I can’t really help them, but you certainly could. Many of these Lupron victims ask me ‘Why doesn’t the FDA do something?” – and I’m never sure what to reply. Please tell me, so I can tell them – ‘Why hasn't the FDA done something substantive’?

A close examination of Lupron’s NDAs will reveal that Lupron should never have been approved to begin with. (3) All Lupron approvals relied in part on the FDA's initial 1985 approval of Lupron daily injections for the limited indication of palliative treatment of prostate cancer. The FDA's Acting Group Leader of Oncology Drugs, commenting on Lupron's NDA for palliative therapy for advanced prostate cancer, observed that “review of the case report forms often shows the reported results are incorrect or not reliable ... Recommendations: 1) This NDA is not approvable because it lacks well controlled studies demonstrating substantial evidence of efficacy.” (4)

The Lupron NDAs I received under FOIA were extensively redacted (i.e., words, sentences, paragraphs in Toxicology, Discussions, Medical Officer Reviews, and dozens of entire pages completely redacted). Can you please have your staff reevaluate whether it was necessary to so extensively redact these NDAs?

For some time attorneys have been phoning or writing me for information and direction, and I have been referring them to several former FDA Medical Officers with knowledge of Lupron. One of the Medical Officers, who was involved in Lupron's NDA approval, is

now serving as plaintiffs' expert witness in Lupron product liability litigation against TAP/Abbott; this is telling in and of itself.

The approval and marketing of Lupron has translated into an overutilization of a dangerous, substandard and/or ineffective, and sometimes deadly 'drug', which has a multitude of risks, known irreversible adverse events, and tens of thousands (if not more) victims. TAP's business model, which permits physicians to sell Lupron at a substantial profit has translated into a plethora of off-label uses, many implicating potentially huge populations which are uniquely unable to complain about the effects of this drug, (i.e. Alzheimers and Autism). Based upon available data, it appears that Medicare has already spent ~ $8 – 12 billion on Lupron since 1990. (5) A drug which FDA's Acting Group Leader of Oncology Drugs concluded was not approvable has cost taxpayers and those who have received this drug a great deal.

I pray the time is ripe to stop this madness, before it harms more men, women, children and babies. Medicare has spent ~ 10 billion on Lupron, yet results of large scale prostate cancer studies in 2008 showed that the use of Lupron resulted in *increased mortality* in a substantial portion of the prostate cancer population. No such large scale, long-term studies have been done tracking Lupron's effects on women or children to allow conclusions about these categories of recipients. And so, I would please ask that you undertake an investigation into Lupron to assess the level of chronic injury and to determine whether this risk of chronic injury is acceptable.

I have enclosed my letter to Deputy Commissioner Sharfstein; it further addresses the plight of a few of the Lupron victims who have contacted me recently.

There is so much more that I could say, but I trust that your staff will consult my website for addition information about this drug. Please do not hesitate to contact me if I can help in any way, shape or form.

Sincerely,

Lynne Millican

(1): "Pietraszek is the first high-ranking current or former TAP official to coment publicly bout the company's sale strategy. ... Pietraszek was named president of TAP in 1986, an assignment he likened to taking the helm of the Titanic. The company lost $25 million that year and Lupron, then the venture's only product, was a close-to-impossible

sell. ... Pietraszek had a brainstorm, born of his service in Japan as an executive for Abbott. In Japan, he recalled, drugs were sold out of doctors' offices. ... TAP sold Lupron to doctors at steeply discounted prices, guaranteeing them fat profits on the prescriptions. ... The TAP president outfitted his sales force with laptop computers to help illustrate Lupron's profit making potential. ... The calculation was dubbed “return to practice” because “profit” was deemed too crass, Pietraszek said. ... As Lupron sales soared, some doctors reaped as much as $400,000 a year on the drug, Pietraszek said. ... The move made the drug, Lupron, a blockbuster seller”. Bruce Jaspen, Andrew Zajac and Laurie Cohen, 'The Lupron loophole: Cancer drug strikes it rich', Chicago Tribune, April 29, 2001.

(2): Bruce Jaspen, Andrew Zajac and Laurie Cohen, 'The Lupron loophole: Cancer drug strikes it rich', Chicago Tribune, April 29, 2001.

(3): Please see ‘Was Lupron’s Initial [Male & Female] Approval Based Upon Safety and Efficacy?’ in my 2001 ‘USA[ttorney] Draft Document’ at www.LupronVictimsHub.com, under ‘History' and 'Documents’.

(4): FDA Acting Group Leader, Oncology Drugs: Review of NDA 19-010, John R. Johnson M.D., July 6, 1984, p.4. (Note: pages 1, 2, and 3 not provided within NDA)

(5): Lupron sales were $734 million in 1997, according to IMS Health, an industry information service. “The lion's share was paid for by Medicare. Of the $3.1 billion the federal insurer spent on outpatient drugs in 1999, about $500 million was spent on Luprn. Medicare has paid more than $4 billion for Lupron in the last decade.” Bruce Jaspen, Andrew Zajac and Laurie Cohen, 'The Lupron loophole: Cancer drug strikes it rich', Chicago Tribune, April 29, 2001. Medicare and its beneficiaries paid $677 million for Lupron in calender year (CY) 2002, accounting for 8 percent of all Medicare drug reimbursements that year. http://oig.hhs.gov/oei/reports/oei-03-03-00250.pdf. Total allowed charges by Medicare for medical castration peaked in 2003 at $1.23 billion. Cancer, 2008:112:2195-201.