May 12, 1999

National Women's Health Network
Cynthia Pearson
514 10th Street, N.W.
Suite 400
Washington, D.C. 20004

Dear Ms. Pearson:

Although I believe I wrote to the National Women's Health Network in the past concerning this issue, after just reading your April 28, 1989 testimony to the FDA's Fertility and Maternal Health Drugs Advisory Committee Hearing regarding GnRH analogs - I wish to bring this serious matter to your attention once again.

Over ten years ago, you stated: "The controlled clinical trials on nafarelin acetate that have been submitted to the committee today are poorly designed and incomplete and in some cases the data have been presented in a manner which could be described as deceptive. Controlled studies of better design and longer duration are needed. Further animal testing is also needed. The Food and Drug Administration should deny the application at this time on those grounds."

As you envisioned at the time, approval of nafarelin would result in widespread, off-label use and other premature approvals. In 1994, there were calls by the FDA for adequate toxicological, carcinigicity, mutagenicity, etc. studies of GnRH analogs since no adequate such testing was done prior to approval. Following the approval of lupron, there were 40 deaths following lupron's use reported to the FDA as of 1994, and it is my understanding that the number of deaths following lupron now approaches 80. There are thousands of lupron victims, there is a National Lupron Victims Network (http://www.voicenet.com/~nlvn) - many women are sick, and all are unable to access proper medical treatment and legal advocacy. The fact that there are so many who are so sick, and not one of these victims is able to find a lawyer and/or medical expert witness is telling in and of itself. Out of necessity, in 1992, I attempted to bring a medical malpractice action pro se, which is now at the appellate level: my Appendices accompanying the brief are in 3 volumes, and entail nearly 900 pages (including FDA and government documents, and pharmaceutical, medical and scientific literature). In relevant part, my case involves lack of consent (a battery) and human experimentation with lupron. The 'need' to do this pro se is representative of the void in medicolegal advocacy in areas of reprotech -I had no legal experience whatsoever and have had to nearly scale law libraries while experiencing multiple post-lupron health problems (including a tumor)... where are the legal experts to bring these matters forward? Where are the scholars and activists and women's health care advocates?

In 1990, I was one of two women who prompted MA. House 3477 - a first in the nation bill to regulate fertility clinics, which would, among other things, mandate informed consent regarding the risks of fertility drugs. This bill was first presented in 1992, and each year since this bill has either died or been passed over, and so there remains no mechanism in place to ensure informed consent regarding the risks of fertility drugs/treatment. There are few advocating for informed consent of the risks of these drugs (especially the use of lupron in fertility treatment) and technologies, and there are many who lobby against regulation.

With published medical literature documenting serious problems with lupron (but silence from those who write the information), the lack of data tracking, the known problems with lupron's clinical trials, underreporting of side effects, rampant conflicts of interest, endless complaints of side effects from lupron users, overt neglect of the National Lupron Victims Network victims, widespread use of lupron ... why is there no open debate on this issue?

There are serious problems with this agent and with the alleged science involved. The FDA's Summary Basis of Approvals for lupron contain a frightening and unacceptable level of redacted information (words, sentences, paragraphs, and pages - 19 pages in just one instance alone). Information within these documents that has not been redacted clearly identifies serious questions, contradictions, and issues which should have prevented approval of this 'drug' - and, in fact, FDA Medical Officers' themselves attempted, without success, to deny approval of lupron.

It is only through the National Lupron Victims Network that people are informed that lupron is a "Hazardous Drug" according to the National Institutes of Health and the Occupational Safety and Health Administration. And since lupron is a "Pregnancy Category X" drug and a known teratogen, yet is routinely injected 'off-label' into healthy young women attempting to conceive children (as well as those 'donating' eggs) - the issue of human experimentation becomes readily apparent. Collectively these few facts (and there are volumes more) point to a significant health hazard and a national situation that should no longer be ignored.

Given your stated position in 1989, I'm wondering if the National Women's Health Network has a more current position on the ab/use and sequelae of GnRH analogs and womens' right to know this information in order to provide informed consent? In light of the National Lupron Victims Network, and all the women who are sick and unable to access medical or legal advocacy - is there anything that the National Women's Health Network can do to appeal for medico-legal advocacy for lupron victims, or assist in any other manner?

If you could let me know your thoughts on these issues, I would be greatly appreciative. And should you have any questions, please do not hesitate to contact me.

Sincerely,

Lynne Millican, R.N., B.S.N., Paralegal