October 1, 1994

Public Citizen's Health
Research Group
Dr . Sidney M. Wolfe
Director
2000 P Street NW
Washington D.C. 20036

Dear Dr. Wolfe:

I am writing to ask whether Public Citizen's Health Research Group would be willing to conduct an investigation into fertility drugs, and in particular Lupron (leuprolide acetate). I am very concerned about the health risks to women and children exposed to these drugs; there are a lot of consumers who are ill from using the drugs, and there are a lot of people who've gotten rich from prescribing and selling the drugs ... and there have been virtually no studies designed to gather any data base on the effects of these drugs.

It is my understanding that Public Citizen's Health Research Group is interested in issues such as this, and if so, I would very much appreciate your involvement with this issue. Through my own endeavors as well as through communication with the National Lupron Victims Network and the New England Patient's Rights Group, it is my understanding that little is being done regarding these drugs.

Locally, I have been involved with a piece of legislation which would require Massachusetts fertility clinics, among other things, to provide informed consent of the drug risks. Recently there has been some exposure of the cancer risks of Pergonal and Clomid - but there is silence about Lupron. (Enclosed please find my 1992 & 1994 testimonies to the MA. Health Care Committee in support of House #5050, the latter testimony references multiple sources of documentation of the carcinogenic and teratogenic effect of fertility drugs.)

The 1994 PDR states Lupron causes fetal abnormalities in lab animals at 1/600th the human dose, the drug is considered teratogenic, it is labeled as a Category X drug, and is not approved by the FDA for use in ovulation induction. Is there an explanation as to how such a chemical can be used to assist in conception?"

By using Lupron as an ovulatory adjunct, the woman's ability to respond to ovarian stimulation is impaired, so she is then required to take (buy) three times as much Pergonal as she would have needed if she were not taking Lupron. The woman is often mandated to take Lupron, without informed consent in many cases ... yet published studies have shown "Lupron has practical but no medical advantage" and Lupron is used by a fertility clinic because it is "convienent for the ... staff". By using Lupron, egg retrival can be controlled to occur at 7:00 A.M., verses a 2:30 A.M. wake-up without Lupron.

There appears to be a serious lack of attention to this drug and its effects. My letters to the FDA have brought no answers. National Network Media journalists, in their cursery look at infertility treatment, "will not ask any questions about Lupron".

The National Lupron Victims Network has been conducting a survey of Lurpon patients, and there are numbers of very sick people out there. Cases of autonomic nervous system dysfunction symptomatology, seizure disorders, multiple myelomas, debilitating bone pain, GI problems, etc., etc.. But the most serious sequelae of this drug is the fact that it appears to be only the victims and their network that are alarmed and concerned about this situation.

I would implore you to investigate this matter. There is much more information I could provide should you have questions. If you have a few moments and if you could answer any of these questions and/or provide some insight into this issue, or any information on Lupron - I would appreciate hearing from you.

Thank you for your time and consideration.

Sincerely,

Lynne Millican