

February 16, 1994

Attorney'General's Office  
Public Protection Bureau

Debra Ecker

One Ashburton Place Boston,  
MA. 02108

Dear Ms. Ecker:

Enclosed please find some additional information relating to the deceptive and misleading practices by the Infertility Industry, forwarded for your review. From our conversations, it is my understanding that the Attorney General's Office needs concrete evidence that misleading and deceptive practices are taking place before the Attorney General's Office will become involved.

In addition to information I have forwarded since May 1993, I am enclosing copies of brochures from multiple local Infertility Clinics. A woman is told by clinic staff "Lupron results in better quality and better quantity of eggs", and "Pergonal and Clomid have been used for over a quarter of a century and are safe, proven, and effective". These brochures state "Hormonal drug therapies are safe and effective", "There is no clinical evidence of increased incidence of birth defects, congenital abnormalities or spontaneous miscarriage", "None of these medications have been shown to be harmful", "Lupron has been successfully used in IVF programs throughout the world to improve the development of the follicles", "Lupron may have a beneficial effect on the quality of the eggs".

Medical journal articles which I have previously submitted contradict these statements. "Risks for Ovulation Induction" by Patricia St. Clair Stephenson addresses that the presumption of safety (for Pergonal and Clomid) must be regarded with measured skepticism, and details voluminous evidence (including bibliography) of adverse health effects on the woman and child.

"The Routine Use of GnRHa agonists for all patients undergoing in vitro fertilization. Is there any medical advantage? A prospective randomized study" by Kingsland, et al. states that studies comparing the use of GnRHa (Lupron) with regimes not using Lupron have been "very few in number, and their results have been contradictory". This study concludes that (page 808) "it would appear that the medical advantages of using GnRHa routinely for all IVF patients remains unproven by prospective randomized studies", and that since the timing of egg retrieval can be regulated by using Lupron "the major advantage of using Lupron for all patients undergoing IVF is for practical considerations rather than because of any significant medical advantage produced".

In the enclosed 'Reproductive Genetics'<sup>1</sup> article "Hormonal Stimulation for in Vitro Fertilization: A Comparison of Fertilization Rates and Cytogenetic Findings in Unfertilized Oocytes" by DeSutter, et al, multiple statements point to causes for alarm. "More abnormal oocytes are harvested with (Lupron/Pergonal) protocols than with (Clomid/Pergonal), (page 254); "Since oocytes used in IVF are harvested after hormonal stimulation, it is not unlogical to assume an effect of this stimulation on the oocyte quality ... The chromosomal status of preovulatory oocytes is known to be influenced by the use of hormonal stimulation ... Whether different types of hormonal stimulation have different effects on the nuclear oocyte quality is not yet clear", (page 256) "In the literature so far there is no unanimity as to the net advantage of GnRH $\alpha$  for hormonal stimulation for IVF" (page 257).

The literature abounds with further examples of the many unknowns. The literature also holds voluminous examples of birth defects on the offspring, and evidence of cancer in the woman - examples extending back into the 1970's. This information has been suppressed by the Industry for decades, the public has been denied this information, and instead has been told these drugs are safe.

You are correct when you state that the reproductive technologies do not guarantee success, but you are semantically incorrect when you state that these technologies are experimental. While I agree that they are experimental, the technologies have been deemed "non-experimental" by the American Fertility Society and American College of Obstetrics and Gynecologists ... therefore there is no further discussion on the issue. Where I take issue, and implore the Attorney General's Office to do the same, is the methods by which the Industry states a woman will achieve optimum success.

It is a given when a woman enters fertility treatment, that there are no absolute guarantees. However, the clinic will then dictate to the woman the manner in which she must subscribe in order to -'beat the odds'. This information invariable pertains to the drug protocol ... and despite the concrete evidence that these methods have not been properly tested, have not been proven safe, have not been proven effective, and have been shown to have adverse effects (as in Clomid and Pergonal - Lupron is still in it's infancy to have accumulated specific data) ... these clinics will proclaim these drugs as "safe, proven, and effective". This is deception about the safety and efficacy of the treatment, it is misleading, and it is a serious public health issue.

To the question of 'why' this is taking place, I have enclosed a few of RESOLVES newsletters. RESOLVE alleges itself to be a national, non-profit charitable institution with its goal as "support, advocacy, and education for the infertile". As the enclosed information identifies, RESOLVE obtains much financial support from the pharmaceutical giants who make the drugs, as well as obtaining financial support from the clinics and doctors who make use of these drugs. RESOLVE has not educated its members about the known and suspected adverse effects of the fertility drugs, nor of their experimental nature ... and one must wonder why.

RESOLVE filed opposition to the 'Fertility Clinic Regulation Bill', House #2019, on March 30, 1993; one aspect of this legislation would have mandated informed consent about risks of the drug protocol as well as the availability of utilizing a 'natural' or drug-free cycle. Please

note RESOLVE's June 1993 Newsletter in which it informs its members for the first time about the existence of this piece of legislation. RESOLVE filed formal opposition to this fertility bill without ever having informed or polled its members. Clearly, that is not an action done by a 'consumer' organization.

This 'Fertility Industry' is a very well orchestrated organization that is not held to any standards, regulations, or laws. No agency appears to have jurisdiction over its activities, and it functions without culpability. Yet, the FTC has stated, in February 1992: "Promoters of infertility services who deceive consumers as to the safety and efficacy of the treatments they provide put themselves at risk for challenge." This same FTC hearing stated that jurisdiction must lie at the local level, with state attorney general offices.

I have provided to you concrete examples of local IVF clinics utilizing consumer deception as to the alleged "safety and efficacy" of the drug protocols used. There have been evidence in the literature about the risks and dangers of these drugs and procedures for several decades, yet the power of the Industry has prevented any public disclosure. I sincerely believe this to be a national public health issue that must be addressed, and there are reputable professionals who are echoing this very sentiment. Recall that there were known dangers to the radiation experiments and breast implants - yet it took decades for public exposure to occur.

If you could please review the information I've provided to the Attorney General's Office and inform me in writing as to your intentions about this matter, I would be greatly appreciative. Please let me know what actions your agency will be able to undertake regarding this situation. And if it is felt that no action is possible, please provide me written rationale as to why no action is warranted.

If you should have any questions or comments, please do not hesitate to contact me. In addition, there is much more literature, and many professionals, who could be contacted to further validate and/or illuminate the serious public health implications regarding this issue.

Thank you for your time and attention to this matter, and I look forward to your response.

Sincerely,

Lynne Millican