TO: The Health Care Committee
RE: IVF Regulation
From: Lynne Mi11ican
Date: March 30, 1993

This is the second year that I have appeared before this committee to speak in favor of regulating the Infertility Industry, and since last year's hearing my belief concerning the necessity to establish standards and controls for this burgeoning field has only strengthened. In the past year I have learned a lot more information and misinformation, and I have educated a lot of people regarding both … and the bottom line still remains that there is no protection of and for the consumer.

For those members of the Committee who were not present at last year's hearing, I would like to reiterate that I, as an infertility consumer, spent four years attempting to obtain just one, fair, optimal cycle -and instead had three wasted cycles because of oversights; and in the process experienced frightening carelessness, poor management, negligent, deliberate and malicious mistreatment, misrepresentation of facts, multiple patients' rights violations, alteration of medical records, several breaches of confidentiality, collusion amongst those involved to commit fraud and coverup, and an expressed refusal to provide care on the basis of "hard feelings" and "not having the time to waste to pour over [my] medical records".

Because of these negative experiences, I voiced my concerns and complaints to each and every state agency, and I then learned that because there is no regulation within this relatively new field of medicine, there is no body of jurisdiction, and subsequently no accountabi1ity for any actions or inactions, and therefore no recourse for the consumer when wrongs have been committed.

Without standards, laws, and regulations there are no mandatory sets of protocol to be executed regarding quality of care, quality assurance, quality control, informed consent, patient selection, consumer protection, data collection or record keeping. Until such controls are enacted and made enforceable - the possibility for substandard, unethical, negligent, discriminatory and fraudulent treatment wi11 remain.

Ihere is a certain amount of pride associated with being involved in this first in the nation piece of legislation, however in reality it is unforturate that it is, in fact, a "first".

The U.S. created its first IVF baby in 1982, and in the following 11 years the fertility industry has prospered in a legal and regulatory vacuum. Of note regarding this first U.S. IVF pregnancy is the fact that the woman selected for this trial procedure had had three previous non-assisted ectopic pregnancies, therefore she was not "infertile" in the absolute sense, but in addition neither she nor her husband had been informed or were aware that there had never been any prior U.S. successes with 1VF and that they were in fact the test case.

I believe it is pertinent to quote a 2/18/92 New York Times News Service article in which Ethicist George Annas states "Secrecy orders are a severe problem in the medical profession. There is a systematic cover-up". These statements were made as a general application to the medical profession, but I believe that those facts have specific indications for infertility professionals. It has been my experience as an infertility consumer to not hear all known, suspected, or debated information, but to merely be told what information those professionals desire for me to hear.

Many cases illustrating this fact can be found in a multitude of media exposes on assisted reproductive technologies. Newspaper stories and television shows (Geraldo, Phil Donahue, Qprah, The Today Show) detail happy outcomes of in vitro fertilization and third party surrogates ... details and facts which originate from the infertility clinic and its doctors. But any and all information about the known and suspected risks of fertility drugs is abscent, there is no discussion about the increased numbers of babies who die around the time of birth, no mention of the higher risk of permanent neurological handicaps or spontaneous abortions. And more importantly - this absence of information would not be apparent to a naive infertile consumer absorbing these "facts' with intent to seek treatment.

Several years ago the Federal Trade Commission filed charges against five clinics for misrepresentation of success rates, yet despite this course of action - one of the clinics which was cited was recently filmed by an undercover agent from '2O/20' while verbalizing misrepresentions of the drug risks involved in IVF. It has become well known that there is a built-in arena of competition between clinics which then prevents any open collaboration for the betterment of the technology. Add the fact that there has been a lack of public funding for reproductive research, which has then prompted IVF clinics to maximize the number of patients and monies recruited, and it can easily be seen why this technology has expanded to non-infertile post-menopausal women. David Letterman's "Number One reason you know you've gone to a bad infertility doctor is when the sign out front reads buses welcome" ... my impression is that statement has more basis in reality than humor.

All this and more has and continues to take place without any standards, laws, regulation, accountability or culpability.

Recently, however, some equilibrium has begun to creep into the Media's exposure of the risks with and the lack of regulation in assisted reproductive technologies. This more comprehensive exposure has been prompted in part by the recent Stanford study linking ovarian cancer to the use of fertility drugs, as well as by consumer complaints regarding past biased coverage.

There has been reasonable questions raised regarding the methodology used in the Stanford study, but none the less, these results deserve serious attention. A previous Sweden study also reported on the development of ovarian cancer as a result of fertility drugs. There have been three reported cases of breast cancer, two bilateral, as a result of fertility drug use. Dr. Wagner of the World Health Organization has expressed concern that fertility drugs may lead to cancer in women. Uterine and endometrial cancers have also been noted related to fertility drug use. A June 1992 Glamour article stated that one renowned specialist stated "we expect a cancer epidemic" as a result of fertility drug use. 'Fertility and Sterility' reported in it's February 1993 issue that "two additional U.S.A. cases (of ovarian cancer have been submitted for publication ... five other cases of ovarian epithelial carcinoma plus three nonepithelial ovarian cancers have been reported to the FDA ... and 12 ovarian tumors have been reported to have followed ovulation induction in France". These studies and statements should be cause for immediate alarm and expedient action.

In this state or in this country there is no way of knowing how many women are taking fertility drugs. There is an estimate that, as of 1988, 1.9 million women have taken these drugs - however, that figure cannot be quoted with certainty and, in addition, consumption of these drugs has increased in the interim. There has been no registry established to track

the recipient of these drugs, the offspring born as a result of these drugs, or the subsequent health effects of these drugs on either the woman or her child, and it would appear vitally necessary to do so now.

It has come to my attention that Israel has kept track of the women who have used fertility drugs since 1965, and that the resultant 6000 children have been monitored and show no ill effects. While this positive information is encouraging, caution needs to be exercised in evaluating the meaning of such information: the amount of drugs utilized in assisting conception prior to the 1980's was in much lesser quantities than is utilized since the advent of IVF, and a determination of the effects of massive doses of fertility drugs cannot be determined without data collection followed by analysis. In addition, I am unaware if the drug Lupron has been used in Israel, or if their fertility drugs are made by the same pharmaceutical companies with the same additives, etc. But the very fact that war torn Israel has been able to accomplish what this country has not even considered is remarkable and commendable.

Though I have personally suffered from severe endometriosis, infertility, and a knee problem, I had none the less always considered myself healthy --- until taking these drugs. Shortly after injecting these drugs, which I had been told were safe and proven, I experienced a barrage of medical problems that have yet to cease. I have had gastric problems and intestinal problems resulting in multiple tests, invasive procedures and medications, I developed a breast mass resulting in mammogram, biopsy and excision, and developed a gall bladder mass necessitating multiple tests and eventual gallbladder removal, bad pap smear necessitating culposcopy, increased problems with both my knees, unexplainable chronic aches in my feet and persistant foot swelling. Are these problems related to these drugs? Have other women had similar problems? There is no data being collected, and this is unacceptable.

Without regulations, fertility clinics and doctors will not be required to collect this or any type of relevant data. It must be made mandatory that information regarding the prescription and use of these fertility drugs are kept in a systematic manner so that the resultant data can yield answers to the questions of safety for the millions of women and their offspring who are being exposed. It would seem illogical to do otherwise.

Other countries have surpassed the United States in regulating this Industry. The United Kingdom has exercised the most prudence in regulations, but other countries such as Australia, France, and Germany have established laws as well. In 1984 the U.K. produced the Warnock Report, which resulted in the licensing of IVF centers after inspection and the formulation of a rigid "code of practice". Quoting 'Fertility and Sterility' in February 1993: this licensing body "with its powers to license and to bring the full weight of the criminal law to bear for serious offenses, such as running an IVF center without a license, had the desired result of eliminating poorly run clinics. Therefore, patients are protected from inefficiently run units and confidentiality has been ensured".

There is no good reason why standards encompassing all aspects of infertility treatment are not developed, and there is no good reason why an infertility clinic should not be licensed and there is no good reason why an embryo lab should not be certified. Yes, currently we do have guidelines in place -but these are not mandatory and therefore are not dependable and accountable modes of treatment protocol. The infertile patient deserves to have guaranteed informed consent, standards for quality of care, quality assurance, quality control, accurate record keeping,

and full accountability for any and all procedures performed.

It is well known that women's health issues have largely been ignored and unstudied, and it is also well known that the pharmaceutical industry, insurance companies, and medical society are some of the most powerful forces to be found. It is my hope and conviction that these circumstances undergo substantial revisions, and in its own small way this bill would be a first step.

In the Report which accompanies H.R. 4773, The Fertility Clinic Success Rate and Certification Act of 1992, there exists limitations which, to my understanding, negate the very purpose of this bill. These limitations state that "the Secretary may not, and the State may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs". This is very troublesome.

It is apparent to many that this field of reproductive medicine, without any accountability, standards, or culpability needs to have some supervision and control exercised upon it. Since the Industry has been unable to develop proper standards and controls of its own, legislators have stepped in. Yet, somehow, in the development of this Federal Bill, provisions to protect the Industry from having supervision or control exercised upon it took place nonetheless. It is my sincere hope that similar protective clauses do not find their way into the Massachusetts Bill.

Health Care Committee

Representative Carmen Buell

State House Boston, MA. 02133

May 21, 1993

Dear Representative Buell:

As you are considering House Bill 2019, I would like to offer the following statements as an addendum to the testimony I submitted to the Health Care Committee on March 30, 1993 relating to this issue.

On the day of the hearing for this bill, I verbalized little. In retrospect, I wish I had informed the Committee that I felt constrained due to the fact that I have a current malpractice lawsuit against 7 Boston area defendants relative to my infertility 'treatment'. And I should have made the point that I have had to bring this law suit Pro Se because of the very lack of laws, regulations, and standards that House Bill 2019 attempts to put in place. While many attorneys have given me much advice and guidance, "because of the novel nature and lack of regulation" no one can assist me - so I'm on my own. With regulation and standards, the circumstances involved in this litigation might never have occurred.

Because of the enormous amount of time and energy involved in this Pro Se undertaking, the written testimony I submitted to the Committee was lacking in some information that I wish Committee members to be aware of. Therefore, please consider the following statements and enclosures as additional testimony in support of House Bill 2019.

The enclosed 2/93 'Fertility & Sterility' article entitled "Implications of the

Fertility Clinic Success Rate and Certification Act of 1992" discusses the Federal Bill, and states the "the AFS and SART harbor some concern over the Bill's potential to interfere in the practice of medicine. At our request language was added to the bill's report, a document explaining legislative intent, to specifically bar the federal government from interfering in patient selection or acting as a barrier to physicians in accepting patients as candidates for the ARTs".

From this statement, I believe that the "Limitations" contained on page 4 of the Report to accompany H.R. 4773 are in fact part of the Federal Bill: 'In developing the certification program and in adopting the certification program, the Secretary and the State respectively' "may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs".

The AFS and SART state that the limitations were necessary to "bar the federal government from interfering in patient selection or acting as a barrier to physicians in accepting patients as candidates for the ART's". Since when does an embryologist or embryo laboratory make decisions to select patients or do any accepting of patient candidates? This seems a poor argument.

In my opinion, these "limitations" were included in a bill to certify labs, under the guise of "protecting consumer access", and hence have paved the way for limitations in any regulation of the clinical side.

Presently, Resolve, AFS, and SART's position is that regulation of IVF clinics would result in increased costs, threaten insurance benefits, and restrict access; another poor argument. How can that be said when right now the costs are high and you either have the insurance to cover it or you don't, and THEY are restricting access to patients right now!

There are 42 year old infertile women that are being denied access because of their age, while fertile post-menopausal women are provided the technology to conceive; and there are infertile single women who are denied access because this is not socially acceptable, while fertile single heterosexual and lesbian women are being provided the technology to conceive. (The US made history several years ago by having the first virgin birth!) It has been the Industry who has determined who gains access ... legislation is needed to ensure that that access is uniform.

While I agree the laboratory needs governing, I feel this is putting, the cart before the horse ... if you don't have optimal stimulation and a proper treatment course, you won't have optimal quality of eggs for the laboratory.

The enclosed copy of an April 1990 'IVF-Australia Newsletter' describes a couple's dissatisfaction with another IVF vendor and then finding IVF-Australia, whose vital attraction was "the fact that the program was a 24 hour a day, seven day a week program" and "keep trying ... find a program that is not just 9-5, because your needs to not stop after 5:00 p.m.". Just 3 years ago IVF-Australia had a philosophy to serve 24 hours a day, yet during this year's hearing you did not hear IVF-Australia voice support for that provision within House Bill 2019.

You also didn't hear that IVF-Australia, in the fall of 1990, began widespread

use of Lupron, resulting in a 24 hour service no longer being 'necessary'. But at whose expense and at what cost? Women were put on this experimental drug without informed consent, there were no studies done prior to the blanket institution of this drug, and years later there still is no conclusive data to prove either efficacy or to dispute harm. Yet, women have been told that either they take Lupron, or they will not be allowed to cycle; their reasoning being Lupron "results in better quality and quantity of egg" - yet this is a statement that is not based on fact. In reality, Lupron is utilized for the clinic's desire to control hours of operation to THEIR desires: *i.e.* Lupron eliminates the 3 A.M. trip to the operating room for egg retrieval.

An article in 'Fertility and Sterility' April 1992 ("The routine Use of Gonadotropin-releasing hormone agonists for all patients undergoing IVF. Is there any medical advantage? A prospective randomized study") states: "the routine use of GnRH-a (Lupron and others) for all patients undergoing IVF has practical but no significant medical advantages ... there have been very few prospective randomized studies comparing the use of GnRH-a with conventional stimulation regimes in patients who do not have a specific indication for the use of GnRH-a, and their results have been contradictory".

Another article of interest was from the 'Journal of Assisted Reproduction and Genetics', Vol. 9, No. 3, 1992 ("Hormonal stimulation for IVF: A comparison of fertilitzation rates and cytogenic findings in unfertilized oocytes), in which it is stated: "fertilization is known to be related not only to sperm quality and external factors (laboratory conditions, etc.), but also to the quality of the oocytes. Since oocytes used in IVF are harvested after hormonal stimulation, it is not unlogical to assume an effect of this stimulaion 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".

Yet Resolve, a group which advocates, educates, and supports the infertile - is not supportive of legislation that would mandate full disclosure; but instead supports legislation that does not provide for anything concerning clinical course and optimum treatment. This position appears inconsistent with their goals, which you'd assume to be supportive of any and all measures which safeguard the treatment of the infertile.

It would be interesting to learn the facts behind Resolve's reneging on their deal with MRI (as stated in the 1989 Congressional hearings) to provide a gift Resolve membership as an incentive for women volunteering in the study project initiated in 1988. Those gift memberships never materialized, and no one at Resolve can explain why. The 1988 goal of enrolling 13,000 women in this study to evaluate "the potential adverse health effects on women undergoing assisted reproductive technology treatment" (funding sponsored by the NICHD and Serono) has fallen far short of that number, and approximately 3,000 women are currently enrolled.

Why has there been difficulty enrolling the targeted number of 13,000 women, when it's estimated that 2 million women in this country are taking these drugs? What happened to the funds to enroll the 13,000 women? Grant money from the government to explore this issue has not been assigned as granted? Have any measures or incentives been undertaken "to study the potential adverse health effects on women undergoing assisted reproductive technology treatment"? Resolve boasts *a* membership of over 25,000 ... what reason could Resolve have for not encouraging its members to participate in a study to explore the health effects of ARTs? Does Serono, who regularly contributes to Resolve, have any

concerns about the results that any large scale study might reveal?

As a nation, we're making laws dealing with frozen embryos, fetuses, and dead sperm, and have regulated the testing of live animals; yet it's a major problem to regulate the testing of live women!

To date, the Sweden study and the Stanford study establish a link between the use of fertility drugs and cancer; and since the release of the Stanford study, there have been additional cases of ovarian cancer reported to the FDA (please see the 'Fertility and Sterility' 2/93 article entitled "Fertility drugs and ovarian cancer: red alert or red herring?" which was enclosed with my 3/30/93 testimony). Dr. Wagner from the World Health Organization has stated that babies born through IVF have "high risks for death around the time of birth, there's much higher risk of spontaneous abortion early in pregnancy, and there is also a higher risk that these babies will have some kind of a handicap, a permanent neurological handicap". These are the known risks, and there are other suspected risks as well. Clearly this information warrants attention.

Nearly three decades ago, mothers of DES babies thought they were blessed with a miraculous creation - yet the frightening results of that 'wonder drug' continue to pour in since no tracking was ever done on these women and babies. A tragedy such as this need not repeat itself.

In development of House Bill 2019, the priority must be placed on the woman, the child, and the safety of both. Every aspect of this bill, viewed in this vein, is entirely appropriate. To water down this bill, at the desire of the Industry, is to misplace those priorities.

Respectfully submitted,

Lynne Millican