Massachusetts House of Representatives
Health Care Committee
State House
Boston, MA. 02133

re: House #1833
March 28, 1995

Testimony in Support of
An Act Relative to the Treatment of Infertility

Dear Health Care Committee Member:

The 'Seven Blunders of the World', according to Mahatma Gandhi, were "wealth without work, pleasure without conscience, knowledge without character, commerce without morality, science without humanity, worship without sacrifice, and politics without principles." Gandhi called these disturbances "passive violence". It is with great regret that I intend to show within these pages that many of these "blunders" can be observed in the machinations of the fertility industry. I see their actions more in line of a very active 'passive violence', while the Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE) has labeled it a "declaration of war" (Hepburn, 1992).

As one of the two women who prompted the origin of this bill (first presented in 1992), I appear before you again to strongly urge your support of this piece of legislation. Although I am dismayed that the requirement to mandate licensure of fertility clinics was removed from last years bill, House #5050, I nonetheless wish to take a moment to thank you for voting the latter favorably out of Committee. I would encourage the Committee to return to the issue of licensure, as more rather than less oversight of this business is indicated. As but one primary indicator of this exigent need, the very testimony submitted in Opposition to House #5050 serves up it's own incredulous evidence, begging for the closest scrutiny possible.

Brigham & Women's Hospital IVF Program Director and President of the Boston Fertility Society, Dr. Mark Hornstein, submitted testimony to the MA. Senate Ways and Means Committee on January 12, 1995 opposing House # 5050. This testimony, which is signed 'sincerely', is the only public position offered on behalf of all interested parties within the Massachusetts fertility industry. This testimony identifies itself as speaking for the Massachusetts members of the Executive Committee of the Boston Fertility Society - a title that paints a noble impression, but is replete with none.

Dr. Hornstein and the Massachusetts members of the Executive Committee of the Boston Fertility Society have provided the following testimony to the Massachusetts Senate:

> "(House #5050) duplicates significantly the Fertility Clinic Success Rate and Certification Act of 1992 signed by President Bush on October 24, 1992. That federal legislation encompasses most of the aspects contained in Senate Bill 5050. Specifically, it sets up a reporting mechanism for clinic-specific reports to be handled by the Centers for Disease Control (CDC) and mandates the licensing of laboratories performing assisted reproductive technologies. The CDC is already

> setting up mechanisms to report results. They have published a Draft Guidelines for the Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Clinical Programs in the Federal Registry [sic] and have solicited comments to their plan. They plan to begin reporting success rates from U.S. programs in the fall of 1995. That legislation, sponsored by Congressman Ron Wyden, is comprehensive, well thought-out, and sufficient for the needs of the Commonwealth of Massachusetts."

The fact that These Statements Are Patently Untrue, Deceitful, Misrepresentative, Misleading, And Nonfactual ... becomes Crucial. As burgeoning numbers of the Commonwealth's population (including not just the infertile but increasingly more so the fertile) look towards these technodocs with naive and vulnerable eyes, it is what these trusting consumers don't and won't see that becomes the matter.

For example, just for openers, the federal legislation never once "mandate(d) the licensing of laboratories". This legislation, Public Law 102.493, merely established a voluntary model program that individual states may or may not adopt, and it was openly acknowledged within the fertility industry that 'in this era of fiscal constraint it is unlikely that states will be adopting this program'. Since 'voluntary' and 'mandated' are not synonymous, the Massachusetts members of the Boston Fertility Society has conveyed to the Commonwealth, the Senate, and the fertile and infertile public, untruths.

Also, Public Law 102.493 does not address in any manner whatsoever the issue of informed consent. However, the issue of informed consent regarding the risks of these technologies and the risks of the fertility drugs is THE central theme of the Massachusetts legislation. The Boston Fertility Society portrays the federal bill as being 'significantly duplicative' - and yet, in the area of informed consent, the federal bill is devoid of the provision while the Massachusetts bill abounds with informed consent language. And were you to be a Massachusetts consumer of fertility treatment, truthful and accurate information would be paramount to any decision for treatment.

But apparently, the right culture in which to grow honesty has yet to be found. Another testimonial counterpoint for illustration: the federal legislation, Public Law 102.493, is dead in the water! And the Boston Fertility Society and every other reproductive endocrinologist in this country knows the federal law has been reeled in and cast afar. The CDC is not "setting up mechanisms to report results." The CDC has not "published a Draft Guidelines for the Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Clinical Programs in the Federal Registry [sic]". The CDC has not "solicited comments to their plan." There was NEVER a notice published in the Federal Resgister, and there was therefore NEVER any solicitation of comment, because the CDC "lacks the resources to implement the bill". (Dalmat, personal communication). Hence, the Boston Fertility Society's assertion that Public Law 102.493 "is comprehensive, well thought-out, and sufficient for the needs of the Commonwealth of Massachusetts" is telling. Since this public law isn't even existent, it cannot be "sufficient to protect the citizens of the Commonwealth".

Before continuing with more evidence of the Boston Fertility Society's perversions of facts, it is germaine to pose the question 'How can these statements be made if they are not true?'. Logically, it is assumed that the Boston Fertility Society either knew these statements to be true or they knew them to be false. If they believed their statements to be true and accurate, then they clearly suffer from extreme attention deficit - and regulation and legislation is surely in order. If they knew their statements to be false and misleading, then they have demonstrated the behavior

that germinated House #1833 - and arrogantly displayed utter contempt for the Senate, the public, and especially fertility patients. Whichever way their perception lies, the result remains detrimental to the safety of fertility patients

And yet it is the statements that the Boston Fertility Society makes concerning the "non-experimental status of IVF" and the impossible reporting standard" of "recording all possible medical risks and side effects of treatment" that is most troubling. Their testimony reads:

> "(House #5050) implies that in vitro fertilization is an experimental procedure. This is not the case. This is a standard treatment utilized throughout the United States and the world."

The fact that there is a national IVF failure rate of 86.7% and no long-term studies of woman and children exposed to these fertility drugs or assisted reproductive technologies should speak to the experimental nature of these procedures in and of itself. But the American Fertility Society (AFS), the Office of Technology Assessment (OTA), and a half dozen IVF experts further define this point.

The Ethics Committee (which includes a renowned Boston fertility doctor) of the AFS has maintained consistently since 1986 in the publication of it's policy statement, 'Ethical Considerations of Assisted Reproductive Technologies', that in certain circumstances the "procedure (IVF) should be viewed as an experiment" and "there is merit to the position that charges should be reduced until the clinic has established itself with a reasonable success rate". This policy was just restated again, word for word, in November 1994. (Ethics Committee, 1994). These circumstances were "when a procedure is being done for the first time by a practitioner or for the first time at a particular facility, that procedure should be viewed as an experiment." It seems illogical to assume that this one initial attempt, labelled as an experiment, is THE requirement to attain precision. A glance at the amount of recruitment ads that pepper medical journals proclaiming "research is strongly encouraged", "experience preferred" or "will train" illustrate the prevalence of research and the novice state. And as Congressman Wyden has stated 'practitioners are tripping over themselves to get into this field'.

To the AFS's Ethic Committee's conclusion that 'IVF is experimental in certain circumstances', the OTA (which contracted with, among others, a renowned Boston ethicist) commented in it's May 1988 report that "this line of reasoning could be troublesome because it is unclear whether it is the number of times a procedure has been done or the success with which it is used that determines its experimental status. Further, even an experienced practitioner might encounter reduced success upon changing laboratories or laboratory personnel. ... Some commentators have suggested that there is no clear line between experimentation and therapy." (OTA, 1988).

It would seem reasonable to include in this discussion that a change in culture media and equipment would be a noteworthy variant as well, not to mention the myriad of responses that would arise from the spectrum of the drug protocol(s). Since today's IVF protocols routinely entail various chemicals at various doses at various times, varying even within the various patients, it is ludicrous that the Boston Fertility Society refers to this treatment as "standard". For the Boston Fertility Society to state that IVF is "non-experimental" is misleading, and is a direct contradiction to the position of the AFS, the OTA, and good science.

It is the repeated and deliberate misrepresentations made by this industry that "IVF is

safe, is effective, is proven, is non-experimental" and "the fertility drugs are safe and effective and proven" that epitomizes the plea for regulation Lack of informed consent is rampant. Reproductive endocrinology is one of the highest paid medical specialties at an estimated annual $259,750 (DeWitt, 1993) - and that is without considering the inherent grant monies, patents, commercial by-products, business adventures, etc., that follow. This is the fast lane of a profit driven multibillion dollar technobusiness, and it is not about to gore it's own breadbasket by acknowledging prevalent risks. That is ... unless it becomes more profitable to pronounce that there are in fact such risks.

And so it was with amazement that I read the recent National Institutes of Health's Human Embryo Research Panel hearings - admittedly comprising this country's leading experts on in vitro fertilization. A major focus of these hearings was to establish the source of oocytes for research purposes. Much debate centered on oocyte sources from 'spare embryos' (excess oocytes from stimulated IVF cycles) or from 'research embryos' (women consenting to either undergo hormonal stimulation and egg retrieval to serve as an oocyte donor, or women requiring gyn surgery who consent to hormonal stimulation pre-operatively to then incidentally serve as an oocyte/ovary donor during surgery).

A distinct desire of many of these leading experts is to accomplish 'in vitro maturation' of the oocyte, thereby eliminating the need to obtain "mature oocytes from a woman. Surgically removed or fetally obtained ovaries, with their requisite millions of immature ooctyes, would yield an infinite ovadose of 'source material'. In the panels vigorous pursuit towards this end, a frank discussion of the experimental nature of IVF and the risks of hormonal stimulation becomes commonplace. Direct quotes from the various testimonies by these expert physicians and scientists vividly display the frightening fact that honesty occurs freely amongst those doing the research - but shielded from the very women who are (mis)led to believe they're undergoing "safe and proven treatment":

"Address(ing) infertility treatments, to IVF methodologies and techniques. Should they be classified as experimental? If so, how should the findings be evaluated before clinical introduction? I raise this because there are procedures done that I think a lot of you would consider experimental that are in clinical use. They have received no oversight, they have received no real evaluation. They're just done. This field is based on methodologies being introduced into clinical practice based on a few papers, based on a few studies based on exchanges of information at meetings, without a thorough evaluation. So I would argue that a lot of the clinical procedures that are currently used, including invasive manipulations, should be classified as research." (Van Blerkom, l994a).

"I think we need to say something about the detrimental things that have occurred in the last 15 years, the fact that clinical work has gone on without the basic science to underlie it ... I think the fact that the research enterprise has gone on out there without peer review and without the appropriate safeguards is something very bad that has happened." (Taer, 1994).

"The (medical) literature is the quality of the science in the field, and without offending anybody who might have a vested interest, I think the quality of science in this field has been awful, in this country at least, from the very beginning, awful because there are reports that get into journals based on handfulls of patients." (Va.~ Blerkom, 1994b)

"It is generally felt among scientists that one of the problems is that the hormonal stimulation that's given to women to collect these oocytes for fertilization may stimulate certain oocytes that are rather immature to be ovulated and collected, and that these oocytes do not have

all of the properties which enable the chromosomes to be handled correctly, and that after fertilization the chromosomes may become disorganized in their segregation, and that you can develop chromosomal abnormalities. So what one very strongly would like to try is to take ooctes during a natural cycle, without hormonal stimulation, and to mature them in vitro, in culture, and to control this process much better" (Hogan, 1994a).

"Having been in this field for quite some time, I'm generally appalled, to put it delicately, by the fact that most people who are in the field of clinical in vitro fertilization, the clinicians and technicians, really don't understand the fundamentals of the system they're working on, that is, the biology of the human embryo." (Van Blerkom, 1994c).

"I think the long-range adverse effects of this have not really been resolved. I think that when a women goes into an IVF clinic for the purpose of having a child, she's certainly willing to accept more risk for what she perceives as her reward from it." (Eppig, 1994).

"The most salient argument is the risk to [egg donating] women who would, for financial incentive, undergo a risky and dangerous procedure." (Green, 1994).

"Most of the people who are involved in the enterprise don't understand the biology of the system they're working on, and they feel that if you change this factor or do this invasive manipulation or add this ingredient to the culture media, that it's going to be the breakthrough or the magic bullet. That's just simply not true." (Van Blerkom, 1994d).

"I think the troubling case would be the patient who is going to have elective stimulation [for oocyte donation for research]. If I were writing that consent form, what I would say to that woman is that you will have daily injections of medications, that this will require multiple visits for monitoring, that there is an unknown future risk to the receipt of these medicines - it's not been established or identified, but we don't have the data that says it's completely innocuous." (Martin, 1994).

"It is very important that this uterine surface is in the right receptive state. ... if this uterus epithelium is not in the right state, which may happen as a result of hormonal overstimulation a few days before to obtain the embryos for in vitro fertilization, then this will be a very, very inefficient process" (Hogan, 1994b).

"First, is their long-term risk? Has this been studied? Do we know if there are long-term risks?" (Answer:) "There are a lot of uncertainties about the long-term effects, for one thing about the long-term effects of the fertility drugs. This is a subject of concern" (Lo & Martin, 1994).

"If you look at some of the procedures that are done in the field of IVF - for example, co-culture of human embryos on foreign tissues from pig, bovine, and human sources; procedures called assisted hatching ... - these, I think, are procedures that are used throughout the field in many programs that have become widespread, yet I don't think anyone really understands, especially from the patient's perspective, that they are really research types of efforts. As a result, one of the unfortunate things in this field that has emerged is that many procedures are done in clinical IVF which have received no oversight whatsoever ..." (Van Blerkom, 1994e).

"Pregnancy loss after IVF increases from 18 percent for women under 24 years of age to 42 percent for women over 40." ... "There are arguments to be made that implantation, when you're not under all these drugs, the effects might be better under a natural cycle."

..... those infertile couples who go through IVF and have this pathetic 14 per cent success rate ..." (Hughes, 1994).

But it is not simply the success/failure rate that is pathetic - this is unabashed c/overt human experimention. Women in Massachusetts (and throughout the world) have a fundamental right to be provided informed consent. Women need to know that the safety and efficacy of assisted reproductive technologies and the safety and efficacy of fertility drugs has not been proven.

Of note is the report of the 1978 - 1980 Ethics Advisory Board (EAB) of the Health, Education and Welfare Department (HEW) following it's examination of the ethics of reproductive technologies: HEW "should take the initiative in collecting, analyzing and disseminating data from both research and clinical practice involving in vitro fertilization throughout the world." ... HEW should "assess the risks to both the mother and offspring associated with the procedures." (Federal Register, 1979). HEW subsequently did NOT endeavor to collect this data, therefore NO analysis has taken place. However, the Director of the NIH concluded in the 1994 Embryo Research Panel Hearings: "Concerns about the risks associated with in vitro fertilization were intense at that [EAB] time. ... Since then many of the initial concerns about safety have abated" (Varmus, 1994).

Concerns haven't abated - but safety has. To curtail human embryo research because of 'concerns about safety' would be detrimental to those with a vested interest. These panel members stand to gain personally as well as professionally from future federal research grants. Already "eleven panel members have been awarded, between 1987 and 1993 alone, $20 million in NIH grants." (Rini, 1994). One renowned member of this panel, who has received $4 million in federal grants, hails from the institution that has provided the nonfactual and misleading testimony in opposition. to House #5050. Clearly, conflicts abound. And safety suffers.

The fields of IVF, embryo research, and pre-implantation diagnosis are symbiotic. It would behoove the Health Care Committee to envision the future ramifications of these arenas in the context of inadequate or absent regulation. Invisibile to the average individual is the palpable profit that the industry foresees in 'Huxley's hatcheries'. The extent of gain to be had in commercialization is phenomenal. For starters: ‘therapeutic agents’, vaccines, hormones, proteins, stem cells, gene therapy, cell lines, organogenesis, ectogenesis, parthenogenesis, chimeras, patents, iatrogenic revenues, etc, etc., etc. No doubt there is much more to this list that remains beyond the public eye.

Presently, in Boston as in around the world, women are pumped full of risky drugs to produce multiple eggs which are then analyzed - with the goal of implanting only the 'good' eggs. The 'bad' eggs, those that 'look bad', are 'immature', or have 'chromosomal abnormalities' are discarded. However, since there is no science and/or standardization to govern this analysis - many "bad" eggs are in fact not "bad" at all .. it is merely the judgment which is bad. Dr. Van Blerkom, testifying to the NIH on "The State of the Science of Human Embryo Research":

"If you look at these eggs, you‘d say that these eggs unfortunately were fertilized abnormally - more than one sperm got in. It occurs not infrequently, and those eggs would be discarded. We'd determine those embryos to be triploid, with three sets of chromosomes. It turns out that IF YOU LOOK CAREFULLY, these eggs are fertilized normally .. I'm told that quite a few babies have been born from embryos of this type. So the fact that an embryo has an abnormality of this type, or maybe others that are described, does not necessarily mean that it will compromise development." (Van Blerkom, 1994f). (Emphasis added)

"Here is a surprising finding, and that is that human ooctyes that are immature are penetrated at a very high frequency ... Despite the fact that they have not completed their meiotic maturation, they are nevertheless penetrable by sperm, and more importantly, developmentally viable. ... So again, we're surprised by the fact that even though the egg is immature, and I think most of us working in this field would never have thought these eggs fertilizable, in fact they are fertilizable." (Van Blerkom, 1994g).

So as IVF clinicians discard viable eggs, unable to accurately assess and diagnose ooctye quality - they simultaneously promote to the fertile population that pre-implantation diagnosis (with it's inherent drugs and technologies) will virtually guarantee that an ooctye with a 'bad' genetic predisposition can be identified, discarded or 'fixed', and the condition will be prevented. Cogent to this discussion is the fact that many genetic diseases (e.g. Down's syndrome, muscular dystrophy, cystic fibrosis) are undetectable within the first few weeks of the embryo's development - thereby falling beyond the time period in which pre-implantation diagnosis 'works' (Rayner, 1986).

It is also acknowledged that a number of chromosomal abnormalities, though present upon DNA analysis, in fact do not result in the development of the associated disease/handicap in the individual examined. Many healthy people "carry" these genes, but do not express them phenotypically - therefore chromosomal analysis cannot be uniformally assigned as an accurate predictor of the embryo's potential. Yet it is promoted as such.

But inaccurate and misleading statements eminate freely from this industry, which again illustrates the need to legislate informed consent for the unsuspecting consumer. Virtually no information regarding the lack of scientific basis for judgments or the lack of established safety of the drugs is delivered to the high paying customer. Yet, the literature abounds with discussion of the "ethics" of these technologies. How can you discuss ethics without first establishing safety? Shouldn't it be unethical to do otherwise?

Helga Kuhse, as a Research Fellow in the Centre for Human Bioethics at Monash University, argues that "in order to be tenable, ethical judgments must pass two minimal tests: they must be consistent and in some sense universal." (Schukraft, 1983). In my opinion, the 'ethical' statements made by the AFS fail this test.

In it's November 1994 "Ethics Committee Report", the AFS makes mention of then-alive Public Law 102-493 in it's chapter on 'Quality assurance in reproductive technologies'. Several statements juxtaposed on page 815 indicate that the fertility industry intends to continue to inflate success rates. In discussing how it "would be possible for a clinic to have no successes vithout the patients ever realizing it", it is stated "with respect to IVF, the current average maximum pregnancy rate is below 30% per treatment cycle. Couples who failed to achieve pregnancy might believe they were among the unlucky 70% ...". The same page states "the live birth rate was 15.2% deliveries per retrieval cycle". Both of those statements are indeed true - current average below 30%, and 'live birth rate was 15.2% per retrievals' ... but neither figure reflects the #1 provision in Public Law 102.493 or MA. #1833: "the number of live births calculated by dividing the number of pregnancies which result in live births by the number of ovarian stimulation cycles".

Of the clinics that volunteered data, the Society for Assisted Reproductive Technology (SART) concluded that in 1991 (the most current information available) there were 24,671 stimulations cycles, 21,083 retrievals, and 3,215 live deliveries. Therefore, given that

information, the first figure required to be reported under P.L. 102.493 and MA. House #1833 is 13.3%. This primary reporting figure of a 13.3% success rate is in stark contrast to their generalized assertion of 30% and is less than their stated 15.2%. The figures of 30% and 15.2% are misleading and deceptive to the women who will undergo ovarian stimulation.

But the effect of misrepresenting success/failure rates pale when compared to the impact of misrepresentation of the safety and efficacy of the fertility drugs. When clinical decisions regarding the drug regime of an IVF cycle are made without a scientific basis - that treatment is or becomes experimental by definition. Period. Brigham & Women's own IVF documents and policies expose this issue. In the April 1990 Brigham & Women's "Instructions for IVF therapy", it is stated "Lupron is given along with Pergonal and is only prescribed to persons with certain diagnosis." In the December 1991 Brigham & Women's "Instructions for IVF therapy", it is stated "Lupron is given along with Pergonal/Metrodin and is widely prescribed." In 20 months the use of lupron in an IVF cycle went from "only in certain diagnoses" to "widely prescribed" - and upon what scientific basis was this decision made?

In October 1990, after one prior unsuccessful IVF stimulation regime with lupron, I became a patient of Dr. Hornsteins at Brigham & Women's IVF Program. Despite my objection to using lupron again (based upon past history of severe side effects, no estrogen rise, and no follicular development), I was told "if you want lVF you must use lupron". Despite not having the "certain diagnosis", I was assured that lupron was indicated, was effective ("had been used successfully around the world"), and was harmless. This cycle resulted in the same outcome: cycle cancellation due to no estrogen rise, no follicular development, and side effects. Unbeknowgst to me at the time, my initial IVF cycle records stated "poor response, question secondary to lupron. Try IVF again, same regime - without lupron". Even more significant is my complaint of neuralgia (nerve pathway pain), myalgia (muscle pain), and arthralgia (joint pain) in my legs - a condition deemed trifling.

Later I would read the Director of Brigham & Women's IVF Program's study on the adverse effects of lupron:

> "Twenty-five percent of women experienced arthralgias and myalgias in a variety of joints ... The mechanism of joint pain remains unclear and warrants further investigation. Two of the most disturbing adverse effects experienced by women receiving lupron were depression and short-term memory loss. ... fewer than 10% of women experienced these symptoms. ... Although the mechanisms of these symptoms are unclear, GnRH-a (lupron) treatment should be discontinued if depression or short-term memory loss develops." (Friedman, 1993).

Not only are figures manipulated in this study, but the investigator is not even cognizant of his own recommendations - and indeed violates them. This study enrolled 102 women, "only 6% terminated treatment because of adverse effects (majority due to hot flushes, insomnia, vaginal dryness)", which leaves 96 women to participate. The 26 women who experienced arthralgias/myalgias is calculated to be "25%" if the total enrolled population figure of 102 is used. Therefore on that basis, the 9 women who experienced depression represents 8.8% of the total population, and the 6 women who experienced memory loss represents 5.8% of the total population. However, Friedman identifies the fact that 6 women terminated for other causes - therefore the remaining population (96 women) should logically serve as the basis upon which to calculate the adverse effects experienced by those who participated in the study.

Calculated at that rate, the 9 women with depression translates into 9.3%, and the women with memory loss becomes 6.25%. In taking the total number of women with depression (either

8.8% or 9.3%) and with memory loss (5.8% or 6.25%), the sum of women who experienced "these symptoms" (depression and memory loss) is a total of either 14.6% or 15.55%. This is not "fewer than ten percent" as stated. Certainly, it is possible that one women experienced both symptoms but nonethe1ess each of the two symptoms would need to be recorded as separate events. And if "lupron should be discontinued if depression or short term memory loss develops" - then it would appear that the termination rate for this study should not have been "only 6%", but an additional 15% as well. This would translate into a termination rate of 21% for adverse effects.

The title "Neuropsychologic Dysfunction in Women Following Leuprolide Acetate Induction of Hypoestrogenism caused a shudder at first glance. Lupron was "administered to all subjects as part of IVF": "A significant proportion of women, more than half in some cases, showed significantly worse performance on one or more memory tests while on leuprolide acetate. ... a substantial majority of the patients showed difficulty with memory while on leuprolide acetate. ... slightly more than half of the patients showed performance decline. ... the potential iatrogenic induction of neuropsychologic dysfunction in given individuals requires further investigation." (Varney et al, 1993).

"More than half", more than 50% of women taking lupron for IVF in this study experienced memory problems. It could be said that it is possible that more than 50% of the patients taking lupron could be at risk for memory loss. According to Friedman, more than 50% of the patients should have been terminated from "treatment" (rather than studied). And accordingly, it could be said that more than half of the women taking lupron - shouldn't be.

In May 1994, documentation of the dearth of information on the efficacy of these lupron protocols was published: "In the initial studies evaluating the use of GnRH-a (lupron) as an adjunct to ovulation induction ... doses were selected without specific regard to the nature of the initial endogenous gonadotropin surge or its ability to initiate and sustain a multifollicular response. ... Stated in another way, no dose-response studies were performed to determine if these flare up protocols could be refined further to improve clinical responses and patient outcome." (Scott & Navot, 1994).

I have discussed lupron in my previous testimonies to this Committee. Briefly, lupron is an unapproved pregnancy category X drug (that is, there is evidence of fetal risk that clearly outweighs possible benefits), which has been documented to "have no significant medical advantage but does have practical advantage (that is, a 2:30 A.M. egg retrieval can be scheduled for 8:00 A.M.). This drug has been investigated since the 1970's as an ovulation inducing agent yet has never gained FDA approval for the indication of ovulation induction. This fact is significant.

To my question "what information does the FDA have, or is undertaking to obtain, that would indicate lupron is NOT teratogenic" - the FDA's response was: "We are unable to answer your specific questions because information that is submitted to this agency as part of clinical trials is considered trade secret, commercial, confidential information and, as such, is not releasable." (FDA, 1994). "Clinical studies for Lupron's use in treating infertility have been discontinued." (Abbott, 1994). Why were these clinical trials "discontinued"? When were they discontinued? Were they completed - or were they abandoned ... and if so, WHY? And what does this mean to those who are routinely being prescribed lupron for infertility?

In the 1990 approval fqr lupron in treatment of endometriosis there were no dosing studies done on women. The dose of lupron administered to women with endometriosis was

based on the dose for male prostate cancer patients. There are no long-term studies looking at the approved indication of endometriosis, and there are no long-term studies done for unapproved use in infertility. And the ONLY double blind placebo controlled study done for endometriosis approval (30 lupron, 30 placebo), according to the Summary Basis of Approval, was found by the FDA to be "only viewed as a supportive study and not as a separate controlled study because of the high dropout rate". Upon requesting the FDA's Summary Basis of Approval on lupron, it became obvious that there are volumes of pages that have been "removed". Purges are frequently found throughout the pages that were provided, especially in discussions of adverse events and the percentages of bone loss. In addition, the FDA makes numerous statements concerning the sponsor providing "heavily censored data" (data presumably from the clinical trials in which Boston hospitals and Boston doctors participated in).

The operant phrase of "heavily censored data" has frightening connotations. This is best illustrated by the ease in which my right to free speech was violated on April 9, 1994 - just three days after last year's hearing on this bill. I phoned Boston's talk radio show to correct the statements by the guest speakers, several Boston area fertility doctors. The latter proclaimed that "there was no birth defect risk associated with fertility drugs" and "the drugs have demonstrated safety". Upon accessing the air, I said I wanted to discuss the risks and the lack of regulations - to which the doctors reiterated their position. I asked how could such statements be made when there was evidence to the contrary in the medical literature -but the doctors were speaking over my words ... "studies have shown there is no risk of birth defects", "studies have shown safety". Attempting to talk over them, I identified the 'Sweden study', the 'Australian study', and a half dozen other sources countering their claim ... but I was told "Lynne, this issue has already been discussed, if you have something else to say - we'll come back to you after the break." They not only never 'came back to me' - but my voice never made it on the air. A tape recording of the show reveals that only my initial statement "I wanted to discuss the risks and lack of regulation" made it over the airwaves. After that, a switch was flipped and I was silenced.

Not surprisingly, in a review of the nursing literature on reproductive technologies, many fine articles on ethics or conflict in infertility can be found - but there is a dearth of data on the risks. Had I chosen to enter the realm of reprotech as a professional rather than as a patient - I'm sure I would have heard the same "information" on the safety of IVF and the drugs. But interestingly, an Australian nursing perspective on 'The Social Impacts of Reproductive Technology', comments that nurses hold a "unique position in witnessing the often hidden, unglamorous and frequently unrecognized outcomes of technology" and "can contribute a unique perspective about the recent explosion of technological 'fixes'" - however nurses "have been described in some of the nursing literature as 'silent' or 'silenced'." (Devries, 1994).

At a recent "information forum", I identified myself as an R.N. to the speaker, a prominent Boston fertility specialist, and showed him the aforementioned study on lupron resulting in memory loss. He claimed no knowledge of the study or of the adverse event. Typically, during the hour plus talk this fertility doctor gave to the audience of women, the only risk identified was that of "the risk of multiple births" (a bonanza to the infertile). It took questions from the audience to raise the spector of carcinogenesis. And again, typically, this fertility expert emphasized that the studies identifying a risk of cancer with fertility drugs "were poorly designed, and with few numbers". The fact that no large scale study has been undertaken is germaine, but even more outrageous is the fact that never is it disclosed that the drugs themselves were approved based upon a "poor design", and "with few numbers". Without any long term study design, no conclusion about their long-term safety can be made.

Of note is the recent Rossing study from Seattle which identified a potential causal

relationship between clomid and ovarian cancer. Significant among this study is the identification that 'more than 50% of the patients received clomid for either tubal problems or male factor'. A fertile women, with no history of infertility, who takes fertility drugs to 'treat' male factor infertility, and then develops ovarian cancer - surely would be a picture of causality.

As I mentioned in previous testimonies, the 1988 NICHHD/Serono study intended to target 13,000 women - but in fact only studied 3,400. I have since learned that my initial IVF treatment took place at one of the centers participating in this study . .. but I was neither informed about nor asked to participate in this study. But I have met a woman who was: she was informed about the study, asked to participate, joined the study, was provided documentation and a number - and never heard from the study again after she developed hyperstimulation syndrome and nearly died. This is not only revealing, but it is validating. "Heavily censored data" abounds. In keeping with this theme, the two studies that the National Cancer Institute is now undertaking is not open to any women undergoing reprotech - the select women are "chosen" to participate.

Although I have detailed many facts in these pages, there is something else that I have written that actually sums everything up in a split second. It's only one piece of paper, but it is so dehumanizing that it is very difficult to show. In fact, I contemplated showing the Committee an 80 million year old sea creature from my fossil collection (an ammonite, from pre-Rocky Mt. terrain, complete with it's phosphorescent scales) in one hand, while holding in the other hand articles that I've published - about a cabin I built in the woods (without electricity or water), excerpts from my near completed wild edible plant field guide, a wonderful story of red squirrels I raised, an essay on the pet therapy program I instituted for my previous psychiatric patients. I thought to do this because this one piece of paper is so ugly, I would like all who see it to be able to visualize something, anything, about the positive and vibrant aspect of my life. I am more than this one piece of paper, although this is indeed what has become of me after undergoing 'safe and proven' fertility treatment.

Before I was prescribed lupron and pergonal, I had endometriosis, was infertile, and had a knee injury. When I sat down at' the computer and listed every doctors visit, lab, test, procedure, and surgery that I have had in the six years since taking these drugs - single spaced on continuous computer paper ... this is what I got:. This piece of paper is seven and a half feet long - it's taller than I am.

Dignity aside, it is important that I disclose some of the medical maladies I have encountered: A - ademona (tumor); B - breast cysts; C - cardiac arrythmias; D - dizziness; E edema (swelling); F - fatigue; G - gastric ulcer; H - hypertension; I -immunoglobulin disorder (immune system dyfunction); J - joint pain. I'll stop there, but the list doesn't end there. The significance of this is, as these health problems arose - I asked the revolving door of physicians "is A, B, C. D, E, F, G, H, I, J, etc." related to lupron? To pergonal?" The answer was 'no", "unrelated', no relationship", "just your time".

However, in fact, each of these symptoms, complaints, and diagnoses is an acknowledged adverse reaction to lupron according to the Physician's Desk Reference (PDR) and the Spontaneous Reporting System of the FDA. This list (attached) was compiled by The National Lupron Victims Network - a Pyramiding group of Hundreds of victims nationwide who suffer from a myriad of the 576 listed reactions. Of profound concern is that we share not just symptoms, complaints, and diseases - but universally many of these complaints (never mind their causality) are not even being acknowledged by the physicians they are presented to (a.k.a. censored).

The medical community has acknowledged 'off the record' that 'it is known that lupron causes myeloma (bone marrow cancer)", and has referred to the drug as "agent lupron". At some of the finest emergency rooms in this country, lupron victims have been told "you're just another lupron patient making the rounds". (Abend, personal communication).

Clearly, if physicians are denying that these symptoms, complaints, and diagnoses are related to lupron - that physician will not be reporting any such adverse event(s) to the FDA. Hence the FDA has received somewhere in the realm of 3000 complaints about lupron. Data being collected by the National Lupron Victims Network indicate that the numbers of complaints reported to or by the FDA is not accurately indicative of the volume of women with complaints. (Abend, unpublished materials).

"Physicians and the pharmaceutical industry are making huge profits treating infertility, and hyperstimulation drugs are central to their limited success in producing healthy infants. A powerful incentive exists to overlook or downplay any bad news." (Napoli, 1994)

Fertility doctors have historically committed "misadventures", prescribing toxic substances to infertile women (DES, hGH, thalidomide), and fertility doctors have historically shown a poor track record for follow-up (Millican, 1994). And, history in the making, the Boston Fertility Society (with all the aforementioned vested interests), states that the (non-existent) federal bill is sufficient for our needs. A Boston physician, no doubt respected. wrote not that long ago: "It is misleading to refer to an antithyriod compound such as aminotriazole (an efficient weed killer) as a carcinogenic". - and this Boston doctor justifies his prescription of this herbicidal thyroid "medicine" by stating "diethylstilbestrol, though used for one-quarter of a century and in millions of people, has given no suggestion of being carcinogenic, but I am no expert in these matters." (Astwood, 1960). The Editor of the most prestigious 'Journal of American Medical Association' upholds and reiterates Astwood's opinion of the safety of this drug. (Talbott, 1960). As history unfolded, neither this Boston doctor nor his collegue, both of whom were "respected physicians", were to be found "expert in these matters": the herbicide was found to be toxic, carcinogenic, mutagenic, was banned, removed from the thyroid "medication", and, and the fate of DES and it's recipients needs no further elaboration. These doctors were wrong, dead wrong - but it was the patients who suffered and died.

I find many of the facts detailed in this testimony disconcerting to say the least. In aggregate, they are terrifying. The ramifications exponentiate when you factor in the occurrence (recognized and unrecognized) of past human experimentation, some sponsored by our own government. Radiation experiments were done on tens of thousands of unsuspecting patients (Lee, 1994). During this same time period, the CIA was involved in a 25 year, $25 million program to learn how to control the human mind, and secretly involved several prominent medical research institutions and government hospitals in which secret funding conduits existed everywhere, with documents showing that "precautions must be taken ... to conceal these activities from the American public" (Kihss, 1977). And FDA chemists have "plead guilty to an assortment of illegal gratuity charges" in cases where "pharmaceutical companies provided false test data to win drug approval" (Popular, 1989).

The chilling reality of this is not that human experimentation has been documented to have happened in the past - but that these horrors are being revisited today. To protect the fertile and infertile citizens of Massachusetts, nothing less than maximal regulation of the fertility industry is necessary and House #1833 is a start. Opposition to this bill filed by the Boston Fertility Societv should be viewed as a disgrace, and the costs cited as reason for opposition by the MA. Department of Public Health should be balanced with the costs of high risk pregnancies,

neonatal intensive care, sequelae of low birth weight, iatrogenic disease and death.

House #1833 would not be necessary if fertility clinics and fertility doctors informed patients of the experimental nature of the technologies and drugs ... but this is not so.

House #1833 would not be necessary if fertility clinics and fertility doctors informed patients of the carcinogenic and teratogenic potential of the drugs ... but this is not so.

House #1833 would not be necessary if fertility clinics and fertility doctors were keeping accurate records ... but this is not so.

House #1833 would not be necessary if fertility clinics and fertility doctors were tracking the health of the women and children exposed to reprotech .. but this is not so.

House #1833 would not be necessary if fertility clinics and fertility doctors were mandated to be adequately trained ... but this is not so.

House #1833 would not be necessary if fertility clinics and fertility doctors were mandated to provide for quality assurance ... but this is not so.

House #1833 would not be necessary if fertility clinics and fertility doctors were honest ... but this is simply not so.

Gandhi died for what he believed in. The women who've died from these drugs never had a clue, and the women who are sick aren't being believed: a heineous blunder indeed. Given what I have seen, heard, read, and experienced, it is my opinion that in the end, when all the elements are known, and the final analysis is exposed - the experimentation that is currently being performed on women in this arena will make the radiation experiments look like child's play. Not until then will the truth be known about reproductive endocriminology.

Respectfully submitted,

Lynne Millican R.N.

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