House Ways and Means Committee
State House
Boston, MA. 02132

re: House 3477
November 13, 1999

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

If children are claimed to be our future, then a saying I've just heard takes on a chilling connotation... 'I have seen the future, and it has corporate sponsors'. Since language within House 3477 would mandate informed consent of the risks involved with the multibillion-dollar fertility industry, it is not surprising that there has been no corporate sponsors or corporate supporters for House 3477.

House 3477 has been before the Massachusetts legislature since 1992 - and remains without passage. I would urge the Committee to act and to vote favorably on this piece of legislation before the closing of the session. In view of the compelling fact that human gametes are manipulated in 'reprotech', and that there are large numbers of consumers undergoing such 'treatment', along with the documented risks of such treatment and the myriad medical/research, legal, and ethical issues involved - the failure to protect the consumer by elemental safeguards is appalling.

Consider the language in House 3477, Section 15(a): Fertility clinics shall obtain written informed consent from each patient after providing patients with detailed written information on the following: i) the nature of the proposed treatment; ii) the success rate of performing said proposed treatment; iii) the experimental nature of the treatment or of any individual aspect of the treatment, including the use of fertility drugs; iv) all possible medical risks to the patient and to any possible offspring; v) all possible side effects of the treatment; vi) all appropriate medical and non-medical alternatives; and vii) the availability of independent counseling and support services.

Now consider that the Massachusetts **legislature mandated insurance *coverage* for fertility treatment** per St. 1987, c.394 [211 CMR 37.05]. Via this statute, the Commonwealth of Massachusetts has promoted fertility treatment, and in effect, ***the Commonwealth has become a sponsor for the utilization and purchase of reproductive technologies and their drugs and agents.*** Furthermore, since there is extensive published literature (largely unknown to the consumer) which acknowledges and documents the risks of reproductive technologies and the potent drugs, hormones, and agents used (please see my 1992-1998 testimonies for information and references) ,the Commonwealth has become complicitous in promoting and subsidizing these (multiple) risky endeavors ***while deliberately failing to ensure informed consent regarding the risks of reproductive technologies and their drugs and agents.***

In 1995, the Boston Fertility Society submitted written testimony in opposition to 'An Act Relative to the Treatment of Infertility' in which it is stated; "(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." Yet experts from the National Institutes of Health's (NIH) 1994 Human Embryo Research Panel Hearings stated "... 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 exchanged 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."** (Emphasis mine). (Please see my 1995 testimony for similar expert statements and citations).

Since the NIH classifies Lupron (leuprolide acetate), a commonly prescribed 'fertility' agent that lacks FDA approval for the indication of fertility treatment, as a "**hazardous agent",** should the infertile consumer of Lupron be informed of such information? Since the Occupational Safety and Health Administration classifies Lupron as a "**hazardous agent**" and recommends that ***healthcare professionals handling Lupron should use double chemotherapy gloves, gown, and respirator,*** should the infertile consumer of Lupron be informed of such information? Since the MA Department of Public Health lists a component of Lupron, benzyl alcohol, as a "**hazardous substance" -** should the infertile consumer of Lupron be informed of such information?

In addition, the 1999 American Hospital Formulary System includes a revised 'Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs', which recommends policy that ***healthcare personnel trying to conceive or father a child should abstain from handling Lupron for a least three months prior to conception.*** If healthcare personnel, who wear ***protective gear*** when *handling* Lupron - are advised to avoid such contact for 3 months prior to conception, why is Lupron being daily *injected* into women attempting to conceive or 'donate' eggs? Should the infertile/consumer of Lupron be informed of such information?

Why has this information been suppressed from the infertile consumer? Critical and profound information - information which is blatantly central to an informed decision - when withheld from the consumer precludes, by definition, an ability to make an informed decision. Without such information and knowledge the consumer does not consent to "fertility treatment" but rather to human experimentation.

Despite the MA. Department of Public Health's (DPH) jurisdiction over 'hazardous substances', the DPH remains without jurisdiction over the utilization of these hazardous substances in a fertility clinic setting. In fact, no state agency has jurisdiction over fertility clinics. While Public Law 103.493 has constrained the ability of fertility clinics to inflate success rates of assisted reproductive technologies, and has set up a voluntary model embryo lab certification program which states may or may not adopt - there remains *no* language or mechanism to monitor the clinical aspect of a fertility clinic. Neither the MA DPH, Board of Registration in Medicine, Division of Insurance, Attorney Generals Office, etc., nor the Federal Trade Commission, Food and Drug Administration, or Department of Health and Human Services, among others, has any jurisdiction over this matter.

Consumers who find themselves with negative health sequelae following 'fertility treatment'

are left in a legal vacuum (see The National Lupron Victims Network <http: www.lupronvictims.com>). Without standards, regulations, laws, and expert medical witnesses - lawsuits involving damages caused by fertility treatment are made impotent. This writer has submitted volumes of expert medical statements regarding the risks and negative health sequelae of fertility to the MA legislature as well as to the Courts, yet **no medical expert will step forward and address the published documentation on this matter.** Compound this by the MA legislature's protection for healthcare professionals - the medical malpractice tribunal, which requires expert medical witness statements before a plaintiff can proceed in a medical malpractice action - and virtual suppression of the consumer's unwitting participation in and negatives health effects from human experimentation becomes certain.

Without medicolegal advocacy and protective public policy, the MA consumer is left stranded. As a result, this writer filed her own malpractice action without an attorney, and without an expert medical witness statement (Please see: Appellate Court No 98P1472 - Millican vs. Harvard Community Health Plan, Boston IVF, Natalie Schultz MD, Mahmood Niaraki MD, Brian Walsh MD, Selwyn Oskowitz MD, Michael Alper MD). To quote Dr. Linda Abend (DDS), a dentist and founder of the National Lupron Victims Network, in her expert opinion statement submitted at my medical malpractice tribunal:

"Doctors who prescribe Lupron are denying people the accurate information they need in order to make an informed decision. Once people become ill on Lupron, these physicians are denying the temporal relationship between Lupron and the onset of symptoms. They even deny information in respected peer-reviewed medical journals. For example, two studies reported memory loss with Lupron occurring in 72% and 75% of the studied populations. Both studies were published in the Journal of Assisted Reproduction and Genetics, and Fertility & Sterility respectively. The percentages reported are quite high. In fact, if an individual does not experience memory loss with Lupron that individual is in the minority. Yet, doctors who prescribe Lupron are continuing to deny that Lupron causes memory loss. Doctors who prescribe Lupron are also denying that Lupron can cause other side-effects that have already been acknowledged in the medical literature and printed in the package insert. They deny the correlation of side-effects while on Lupron. They deny the correlation when one stops taking Lupron and the side-effects persist. ... when Lupron victims turn to physicians for help and answers they get a deaf ear and run-around. Lupron victims are not victims of Lupron alone, but are also victims of a medical system that has failed them. And without medical care and doctors to testily they are unable to obtain justice in the courts."

To quote my (Appellant's) legal brief, Argument V: "Making false statements under oath, as defined by Black's Law Dictionary, is perjury. All Appellees [Harvard Community Health Plan, Boston IVF, Natalie Schultz MD, Mahmood Niaraki MD, Brian Walsh MD, Selwyn Oskowitz MD, Michael Alper MD] in Answers [to Interrogatories], Affidavits, and Request for Production of Documents, and by brochure by inference deny that Lupron is experimental: the standard of care known to Appellees at the time of this cause of action can be shown to be otherwise. ... In the [1989] Hearing before 101st Congress, Lupron is described as "... costly, experimental medication for [IVF] induction cycles merely as a cosmetic exercise to polish the data without clear evidence of benefit...". Appellees had duty to disclose the known and material risks from treatment. Appellant had a right to know that Lupron was approved out of the FDA's Division of

Biologics, and that Lupron is **not** a hormone, and that "memory loss is commonly observed", and that Lupron contained a hazardous substance according to MA DPH, and that it was known in 1985 that "There is no obvious reason to suggest that the same process [pituitary adenomas {tumor}] could not occur in humans [as it did in rats given Lupron]". ... Massachusetts has mandated fertility treatment coverage per St. 1987, c.3894 [211 CMR 37.05]. The U.S. Supreme Court recently ruled that infertility is a disability according to the American's with Disabilities Act. Public Law 103.493 contains limitations protecting reproductive practitioners. The MA DPH doesn't require a fertility clinic to have a license, therefore has no enforcement power. The Appellees and the DPH and MA legislature have failed to protect the public, [and] Appellees have committed a battery upon Appellant, for which she has sustained numerous health sequelae Given the material evidence submitted within and to Court below, Appellant would argue there exists a violation of due process under the law for protection of health, safety, and welfare..."

As a clear example of the silence this issue generates within the medical and legal establishment - the Defendant/Appellees completely failed to address Argument V in their reply brief to the Court. Another example of this issue involves the embryologist who was found by a state inquiry to have "known his error had caused the wrong embryo to be implanted ... but remained silent" (Boston Globe, 4/18/99). And another example is the clinic that relegated large numbers of "donated" eggs that were intended for infertile women, but instead diverted these eggs into research material for the cryopreservation process - a diversion that was referred to as "sharing with the lab" (Washington Post 2/9/98). Note that these reproductive professionals have redefined theft and deception as "sharing".

There are many terms used by the fertility industry to define "extra" human eggs or oocytes used in research. A read of reproductive medical journals has revealed that there are so many synonyms for these research oocytes that some of my notes are lost, but a partial list is as follows: "surplus" oocytes, "abnormal" oocytes, "left-over" oocytes, "discarded" oocytes, "spare" oocytes, "fertilized" oocytes, "unfertilized" oocytes, "suboptimal" oocytes, "nonviable" oocytes, "aspirated" oocytes. In a random 20 page examination of how many "extra" oocytes were being "shared" with fertility labs, I plucked the March 1995 Supplement to the Journal of Assisted Reproduction and Genetics [Vol. 12(3)] off the shelf and opened to page 123 S. I then counted 7,845 oocytes and 266 embryos used in research within a 20 page span. This is just 20 pages - from one journal, from one month, from one symposium, from one year, at one library. The Commonwealth's medical library stacks are full of reproductive journals, and the Commonwealth's fertility clinics are full of women. Women are full of oocytes, and the labs are full of gametes and genetic materials. Yet there is a lack of informed consent, lack of passage of House 3477, and the unconscionable lack of medicolegal advocacy.

The vast profit potential of the fertility industry, inclusive of bio-tech, has been addressed in my prior testimonies - but I wish the Committee to further consider this issue, especially in light of the inherent health risks involved. Where does "human tubal fluid" and "human follicular fluid" come from? "Human r[ecombinant] FSH (hRSH-293) [is] produced in human embryonal kidney cells" ("Commentary - Tools of the Trade. Fertility & Sterility, July 1995). Lots of companies sell lots of 'products' and make lots of profit ... where do the "materials" for these 'products' come from?

Human embryos are being cocultured in human ovarian cancer cells (see page 666 of Fertility & Sterility [March 1996] calling for "more intensive research"), and human embryos are being cocultured with cell lines from different species and organs - such as Vero cells, derived from green monkey kidneys. Women are likely told their embryos might grow better in a 'growth medium called Vero cells', but it is unlikely they will be told their embryos will be bathed in cells derived from green monkey kidneys. What are the risks of transferring retroviruses, prions, etc, in such an experiment? And should the infertile consumer be informed of such known and unknown information?

In an area that "shares" women's genetic material surreptitiously, utilizes hazardous substances, embarks on risky and novel 'adventures' which lack underlying science yet are termed as "scientific", complete without informed consent - while the specter of genetic experimentation, human cloning, human-animal cross-species research, chimeras, artificial wombs, genetic engineering, etc., looms ... the minimum safeguards that House 3477 offers seems to be the least the Commonwealth could do to protect the safety and welfare of consumers.

Respectfully submitted,

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