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"Cloning: A Risk to Women?"

Mr. Chairman, and Members of the Committee:

I am honored for the invitation to speak to you today on this very important issue. And although I am a registered nurse, I am here before you because of personal experiences as a patient undergoing superovulation during in vitro fertilization (IVF) attempts at several Boston fertility clinics over a decade ago - and because of what I've learned in the interim. My focus will be upon the adverse effects to the eggs, embryos, fetuses and women from one particular and commonly used drug, Lupron (leuprolide acetate), which is not FDA approved for fertility treatment; as well as addressing the risks from other fertility drugs and the assisted reproductive technology (ART) procedures in general.

For ease of reading and reference, this paper will be arranged under the following 13 headings:

(1) Preliminary Comments:

The drugs and fertility agents and the processes used in superovulation regimes for fertility treatments are exactly the same as that used to obtain women's eggs for cloning research (although numerous variations of the protocols exist within the core group of 'fertility drugs'). Cloning cannot take place without women's eggs, and therefore the information I have to offer concerning the risks of fertility treatment have direct application to the process of therapeutic

cloning. It has been estimated that some 8 million eggs per year may be necessary to sustain therapeutic cloning research -- how many women would that entail? My research into the medical literature revealed the maximum top three reports of numbers of eggs retrieved at one time as being: 91 eggs from one woman at one time (Source, ~1995), 71 eggs from one woman at one time (Lewit, 1995), and 56 eggs from one woman at one time (Lim, 1995). Since this research will require millions of eggs, this demand translates into the need to obtain as many eggs as possible from each woman per attempt. To quote from the consent form for egg donation for purposes of stem cell research at Advanced Cell Technology: "The idea is that the greater number of fully mature eggs, the greater the chance of successfully utilizing them in this research." (ACT)

A dozen years ago, an article examined "[t]he risks associated with ovulation induction", identifying that "epidemiologic studies are needed to determine the true risks associated with exposure" to the older, 'traditional' fertility drugs (St. Clair Stephenson, 1991). More than a decade later, the question is still being asked: 'Are we ignoring potential dangers of in vitro fertilization and related treatments?' (Winston, 2002). Costly complications from ART were, in part: a high incidence of first and second trimester bleeding, spontaneous abortion, toxemia, fetal growth restriction, anemia, anesthetic complications, ovarian hyperstimulation syndrome, culture medium infections (hepatitis and AIDS), visceral and vascular injuries, pathogenic infections, and breast and ovarian cancer. (Schenker, 1994). I believe it was Mirabella's August 1993 issue which carried 'A Doctor's Story', about a physician who took Clomid and was diagnosed with breast cancer. Large scale, epidemiological sound studies remain lacking on these earlier drugs, and yet in the interim years, the newer fertility 'agents' have been added and have themselves become 'traditional', standard, chemicals used in ovulation induction - but again, this standard has developed without any epidemiologically sound, long-term, safety data. It is noteworthy that while Lupron has become 'standard' within superovulation regimes, it is administered at various doses for various times, varying even within the various patients, and has varying effects.

There have been a number of past, as well as a flurry of recent, published reports of birth defects

in babies born from superovulation, IVF and other variants of ART, and it is widely acknowledged that critical long-term studies of the risks of ART are lacking (i.e., among others: Kola, 1988; Fischel, 1989; Saunders, 1989; Tanbo,1995; Silver, 1999; Aboulghar, 2001; Mitchell, 2002; BBC, 2002; Sutcliffe, 2002; Skloot, 2003). Titles often tell the story: "Ocular Manifestations in Children Born After In Vitro Fertilization' (Anteby, 2001), 'Congenital malformations in infants born after IVF: a population-based study' (Ericson, 2001), 'Hormone and Fertility Drug Use and the Risk of Neuroblastoma: A Report from the Children's Cancer Group and the Pediatric Oncology Group' (Olshan, 1999), 'Congenital malformations in infants born after IVF: a population-based study' (Ericson, 2001), 'Brain worry over IVF children' (Health, 2002), 'Low and very low birth weight in infants conceived with use of assisted reproductive technology' (Schieve, 2002), 'The Risk of Major Birth Defects after Intracytoplasmic Sperm Injection and in Vitro Fertilization' (Hansen, 2002), 'In Vitro

Fertilization May Be Linked To Bladder Defects' (Trock, 2003), 'Some Studies Sees Ills for In Vitro Children' (Mestel, 2003), 'Incidence of retinoblastoma in children born after in-vitro fertilisation' (Moll, 2003). March 2002 brought headline news that the highly promoted and touted low incidence of birth defects from IVF (always stated as "similar to the general population, about 2-3%") was now being reported as 9% - much higher than the general population. And now March 2003 brings news that IVF babies are at increased risk for urologic birth defects (Wood, 2003).

The American Society for Reproductive Medicine, in its Annual Meeting in 2002, released the following statement on October 14, 2002: "Studies Show Children of ART Develop Normally" (ASRM, 2002 - note link of 'kidsareallright'). Figures don't lie, but liars figure. (In 1990, the Federal Trade Commission brought complaints against 4 fertility providers for false claims in fertility treatment success rates [FTC, 1990]). To quote the New York Times: "Since the 1970's, fertility clinics have created almost a million children through experimental technologies. They've used untested and unregulated procedures ... Where is Washington in all of this?" (Skloot, 2003).

Online transcripts from the FDA's Reproductive Health Drugs Advisory Committee Public Meeting, held October 18, 1999, identified "the need for pregnancy registries of babies born resulting from such [ART] treatment. These drugs include GnRH agonists and antagonists, human menopausal gonadotropins, purified urofillitropin, recombinant follicle stimulating, chorionic gonadotropin, and progesterone". The United Kingdom recently announced plans to study 68,000 people born as a result of ART (Kaiser, 2002). Will the percentage of birth defects from ART continue to climb in the U.K., and the U.S., with further study? Do human embryos really need to be grown in human ovarian cancer cell lines (see Ben-Chetrit, 1996)? "Abnormal embryos" have been implanted into women (Munne, 1995) - what kind of consent did that experiment entail? One treatment, using intravenous immunoglobulin (IVIG), has raised questions about the "ability to screen for any diseases that could crop up 20 or 30 years down the road. Some doctors have even gone so far as to denounce [the] practice not as medicine, but witchcraft." (Arnot, 2000).

Children have been born from co-culture with animal sera that could potentially contain prions, viruses, and/or unknown infectious agents - and my questions from the mid 1990's about risks from such co-cultures to embryos, children, and women went unanswered. In 2002, the FDA sent a 'Dear Colleague' letter, announcing that the transfer of such co-cultured embryos "constitute[d] a clinical investigation involving xenotransplantation" (Letter, 2002), but no enforcement action would be based on already existing embryos; and FDA and U.S. Public Health Service guidance documents recommend, among others, "follow patients for their lifetimes and counsel them to be alert to any unusual symptoms ... [and] they and their intimate contacts should defer from donation of blood and other tissues." (CBER, 2002). Vero cells, from African green monkey kidney cells, have been used frequently in human embryo co-culture (i.e., see Veiga, 1999). In an online 1994 report of ART practices, it was stated that "[a]lthough the firm of Merieux refuses to accept any responsibility for the use of these [Vero] cells for the

culture of human embryos, they are already widely used for this purpose by many specialists in medically assisted procreation ..." (Report, 1994). Who is minding this store?
The nation's highest volume clinic was one of 10 participating clinics in a 1988 national study that attempted to look at the long-term health consequences of ART and drugs on the women and offspring - however the study made no mention of GnRHa's - the results were touted as 'reassuring', yet results were inconclusive (although "warrant[ing] epidemiologic study"), and with too few study subjects (NICHHD, 1992). Of note, this writer, who developed multiple health problems, was a fertility patient at this clinic during this study - but was never asked to participate in this study. More significantly, another patient who was asked and did participate in this study (and shared her study documents with me) was subsequently dropped from the study following her hospitalization for severe ovarian hyperstimulation syndrome during her fertility treatment - in which she went into kidney failure and nearly died.

Many follow-up studies I've read of ART children do not identify the specific drugs received. My own experiences highlight the lack of informed consent that women experience when they "agree" to take fertility drugs. The best illustration of this is found in the Boston Globe's quote of the Director from Boston IVF, the 'nation's largest volume fertility clinic' (one of the two clinics I attended) who proclaimed "women do not need to know about the lack of FDA approval [of Lupron for fertility treatment]..." (Kong, 1996) Years later, this clinic would receive "$180,000 over two years to cover the cost of providing the embryos" "to Harvard University scientists for stem cell research. ... Harvard researchers plan to offer the new stem cells to any interested scientist at no cost, with no commercial restrictions. ..." (Mishra, 2001)

The profit within the fertility industry that exists today, as well as the hyped potential profit of therapeutic cloning tomorrow, along with lack of informed consent, the risks, and inherent exploitation all point to this issue having very serious ramifications upon many lives.

A recent Popular Science article unintentionally highlights the issue of consent: in the March 2003 series, the McNamara's were featured as they had undergone experimental fertility treatment using cow uterus to grow their embryos. This Popular Science piece examined the risks of ART, and the McNamara's conclusion at the end of this article was "Yeah, there is [a possibility of long-term effects] ... But ... we would still have done it." (Skloot, 2003). However, Popular Science held a Popular Science Infertility Chat on America Online, and, in fact, the McNamara's stated in the chat - after they had read the article - that "I think it's important to point out that the information in the article wasn't available when we made our decisions. .... Honestly, if it was presented in a way that it would cause trauma to our offspring, we probably wouldn't have done it." (Chat, 2003)

(2) Dead Women Don't Talk:

Not until long after my fertility treatment did I learn that, before my treatment, there were questions raised and warning given regarding the fertility industry's use of lack of informed consent, deceptive advertising and manipulated statistics. The first survey in the world of IVF

clinics was done by two journalist/authors, Gena Corea and Susan Ince, and this survey revealed that while half of responding clinics had claimed high success rates, they had, in fact, produced not one baby (Corea, 1987). In 1992 I had begun legal action against my fertility treatment providers, and in 1997, Gena Corea (see also Corea, 1985) provided a statement to me intended for inclusion into the Offer of Proof for my medical malpractice tribunal (Millican v. Harvard Community Health Plan, Boston IVF, Natalie Schultz M.D., Brian Walsh M.D., Mahmood Niaraki M.D., Selwyn Oskowitz M.D., Michael Alper M.D.) The following 5 paragraphs are from that statement:

"... A lack of informed consent to IVF has been a constant and continuing problem with IVF from its earliest days when Lesley Brown, pregnant with the first IVF baby, Louise, was under the misapprehension that hundreds of such babies had already been born. She had no idea that she was in such an experimental program. ..."

" ... The exact number of women who have died in in vitro fertilization programs is not known. However I have information on the deaths of ten women: in Germany, Brazil, Israel, Spain, and Martinique (in all these countries, I have tape-recorded interviews with the physicians and/or relatives of the dead women), and in Australia, New Zealand and Canada. Women entering IVF programs do not know of these deaths. Even physicians practicing IVF do not know of most of the deaths or their causes. With the exception of the Israelis, the IVF teams involved are not writing reports on the deaths for their professional publications nor are they delivering papers on the deaths at international meetings ... No professional or governmental organization is recording the deaths in a data bank."

"Some Brazilians know of the first death -- of a woman named Zenaide Maria Bernardo, whose daughter and physician I interviewed in, respectively, Araraquara and Sao Paulo, Brazil. They know of her death because it occurred during a course on IVF for physicians and the course was a huge media event, covered by Globo, a national television station and the fourth largest in the world. The death could hardly be covered up when the television cameras were rolling. But aside from these Brazilian citizens, few in the public know of any IVF deaths."

"To date, IVF deaths are known to have occurred due to hyperstimulation of the ovaries through the administration of hormones; anesthesia for laparoscopy; infection following laparoscopy; bleeding following laparoscopy; bleeding following ultrasonically-guided puncture of egg follicles; and ectopic pregnancy."

"Physicians and the public relations firms hired by the IVF industry often give women the impression that IVF is a low-risk procedure. How do they know it is low-risk? I have interviewed physicians around the world on IVF deaths and without exception, I have known of, and had documentation on, more IVF deaths than any of them claimed to. Why is that? If scientists doing IVF do not know of the deaths their programs are causing, why don't they? What are the mechanisms by which this information has been obscured? Through their journals and conferences, physicians share information on every slight change in drug protocol for

inducing artificial ovulation. Shouldn't information on deaths, injuries, psychotic breaks, lengthy recoveries also be shared? It's not. ..."
(3) On The Count of Eggs and Money:

Early articles describe Lupron's application in ovulation induction regimes as "in special situations" (Blankstein, 1988), yet Lupron "began to be widely used for IVF in 1989" (Martin, 1994). By 1990 fertility industry figures, GnRHa's were utilized in 97% of reported assisted reproductive technology cycles (MRI, 1992), with Lupron identified as the "prevalent choice" and most frequently prescribed GnRHa in this country (Keenan, 1991; Martin, 1994). The fertility industry had already achieved the recognition of being more than a billion dollar industry by 1990 (Talan, 1990), and sounding like a trumpet, a 1991 publication proclaimed "Chronic indications for GnRH agonist therapy among IVF/GIFT patients are likely to increase significantly in the immediate future." (Gordon, 1991). Early on, Lupron's use had been described as increasing the use/purchase of Pergonal (manufactured by Serono) by 50% (Keenan, 1991), and it was known that "[t]he direct financial cost of cycles incorporating adjunctive leuprolide therapy was 40% greater than the cost of cycles in which no leuprolide therapy was used." (Dodson, 1991). At this time, the failure rates for IVF were around 80 - 85%: "rarely has a technology that has had such dismal success rates been so quickly accepted." (Raymond, 1993).

When I complained to my Harvard HMO about their use of this experimental drug, their response was an illustration in how definitions can easily be changed; they state that institutional review board (IRB) review was unnecessary because Lupron was not being used in "research", but rather Lupron was being used in a "therapeutic" manner. The Office for Protection from Research Risks has received reports from major research institutions of "startling ignorance" of IRB policies regarding informed consent in reproductive research (Ellis, 1995).

Because of my nightmare experiences as a fertility consumer, I became involved in drafting a first in the nation bill which would have required fertility clinics to have a license to operate, and which would have mandated informed consent of ART risks (Millican (2), 1992; Lasalandra, 1995). My collaborator in drafting this bill, Linda DeBenedictis, had also attended Boston IVF and had also been mandated to switch to Lupron - and her story was told over a 3 part series on Boston TV news. Doctors from Boston IVF told the DeBenedictis' that 3 eggs had fertilized and 3 embryos were ready for implantation the next morning. Upon arrival at the clinic the next morning, there were not 3 embryos for implantation - there were no embryos for implantation. The clinic maintained there had been an "error in communication", and that no embryos had fertilized (WHDH, 1989).

From 1992 - 1999, I provided verbal and written testimony to the MA. Health Care Committee in support of this bill (MA. H. 3308), and these documents are a testament to my experiences, my learning curve, and the mounting evidence against Lupron. My 1992 written testimony states: "... nearly every IVF clinic has mandated that women take Lupron - or they will not be allowed

to cycle ... Women are told that Lupron results in better quality and better quantity of eggs." In 1995, my testimony states I was told that I "must use Lupron" if I wanted to undergo IVF. Women reported successful IVF births without Lupron, yet were made to use Lupron nonetheless, and reported subsequent failure in these switched cycles. Other women using Lupron complain of failure to suppress and canceled IVF cycles, premature leutinization, and poor quality eggs with Lupron (see Chetkowski, 1989; Schoolcraft, 1991). The internet posts of women identify the badgering, and coercion, and manipulation, and threats used to convince women into taking Lupron for a variety of indications - many refer to their doctor as trying to "shove it down [their] throat".

Later I would learn that the first survey in the world of IVF clinics was conducted in 1986 (Raymond, 1993), revealing deceptive success rate claims and manipulated figures (Corea, 1987). As a result, the 101st Congress held hearings in the SubCommittee on Regulation, Business Opportunities, and Energy, House of Representatives, in which data from 191 fertility clinics was published. This clinic specific information shows a significant number of these reporting fertility clinics had recently "switched" and/or "began to use" Lupron in their superovulation regimes - without any IRB review (Hearing, 1989). One reporting clinic provided testimony identifying Lupron as "a costly, experimental medicine ..." (Kemmann, 1989).

One of the fertility clinics that I attended in 1990, Brigham & Womens, had as its protocol in its IVF brochure that "Lupron is only used in certain diagnosis", but in 1991 this clinic changed its brochure to read "Lupron is widely prescribed". I would later learn that the director of this IVF clinic, Dr. Andrew Friedman, had been a lead Lupron investigator, had received numerous grants and funds from Lupron's manufacturer, Takeda Abbott Pharmaceuticals (TAP), and had published extensively on Lupron. Dr. Friedman was ultimately found guilty of falsifying and fabricating approximately 80% of the data in four Lupron studies, two of which had been published and were subsequently retracted. Friedman had "altered and fabricated information in patient medical records, falsified research notes by changing dates and changing and adding text", and fabricated notes and fabricated patients for clinical visits that had not taken place. (Federal Register, 1996; see also Lasalandra, 1998; Millican, 1998; Kong, 1999).

My 1995 written testimony in support of MA. H 3308 identified "manipulated figures" in a fifth Friedman Lupron study (Millican, 1995). To the best of my knowledge, while confidential Harvard documents state further investigation into other Friedman Lupron data should be explored, no investigation has been conducted beyond the four, identified, fraudulent Friedman Lupron studies. Two years after the Federal Register publication of Friedman's fraud, the MA. Board of Registration 'acted' by temporarily suspending his medical license, however the published and cited bogus data is irretrievable. And in fact, one fraudulent and retracted Friedman Lupron study was cited as a credible reference and data source in an article published on Medscape (Women's Health) in August 2001 (Data, 2001). In a similar faux pas, FDA Consumer magazine recently had to provide a correction to an article in which it erroneously stated GnRHa's would "shrink fibroids" - a statement told repeatedly to women despite the fact

Lupron has only been approved for "the anemia associated with fibroids, when iron therapy alone has been ineffective". The indication of Lupron's use to "shrink fibroids" received the FDA's rejection in the past, and no FDA approval has ever been granted for this indication. (FDA, 2002)

NBC Dateline did a story January 2, 2000 about severe side effects experienced by women taking Lupron for endometriosis (adverse events such as joint pain, numbness, memory loss, irregular heart beat, suicidal depression, whole body swelling, grand-mal seizures). Quoting from the Dateline story transcript: "[Dateline] asked TAP about the complaints of these women, given TAP's marketing of Lupron as "perhaps making miracles possible." While the company declined an on-camera interview, [Dateline] met with several top executives, who told [Dateline] the preponderance of evidence suggests that Lupron works, otherwise women wouldn't continue to use it." Dateline's story concluded with "[Lupron] is also widely and routinely used for women going through fertility treatments." (Dateline, 2000).

In 2001, the U.S. Attorney's office in Boston would land the largest fine in history - $875 million - from TAP for its lucrative, unethical, illegal, conspiratorial scheme involving urologists and kickbacks, gifts, trips, TV's, computers, VCR's, as well as gifts of free samples of Lupron which were then billed to Medicare. Confidential documents of Lupron's "return to practice" scheme were revealed during Chairman Bliley's hearings (Oversight Hearings). This prosecution resulted in TAP officially earning the title of "a criminal enterprise", and a decade earlier TAP had profitably tarnished itself with receipt of Notices of Adverse Findings from the FDA due to its incessant and "deliberate campaign to promote this product [Lupron] for a wide range of unapproved uses." (FDA, FDC; 1990). "In addition to offering inducements to hospitals and doctors, TAP was encouraging its salespeople to approach patients in support groups." (Pitchmen, 2002). And I aware of one gynecologist who TAP approached and indicated he could clear $98,000 to his income by prescribing Lupron.

Government documents of the TAP prosecution reveal that TAP also attempted to make deals involving the costs of gynecological uses of Lupron. And, incredulously, these government documents state that "Lupron depot 3.75 mg is indicated for treatment of ... infertility". This statement contradicts the FDA's lack of approval of Lupron for the indication of infertility, but the presence of this erroneous and promotional language within these government documents well illustrates the extent of pervasive influence of the industrial mantra that 'Lupron is standard in fertility treatment' (U.S.A., 1998). The rationale for so many unreasonable heated decrees of "you must take Lupron if you want IVF (to get good quantity and quality eggs)", "you must take Lupron for your endometriosis (if you ever want to get pregnant)", "you must take Lupron for your fibroids (or you'll bleed to death or have to have a hysterectomy)" was now as clear as a solid gold bell struck with a silver spoon.

Fertility clinics have been generating in the multi-million dollar annual surplus range, and years ago claimed a 37.5% profit margin and physician salaries up to one million (Gabriel, 1996). For quite some time, reproductive endocriminology has enjoyed the label of a multi-billion dollar

industry. In such an area of 'obscene profiteering', every attempt at regulation has met with stiff opposition. The MA. bill (H. #3308) has habitually died and been refiled each session, although it has not been refiled this year to date. And I understand a recent provision by Senator Frist to study the adverse health effects of ART on women and babies was also defeated (Skloot, 2003). Patient protections are nowhere to be found, while patent and industry protections abound - and market/ing forces rather than science dictate the 'standard of care'.

When discussions of the lack of regulation within the fertility industry arise, the industry refers to the Federal bill, the 'Fertility Clinic Success Rate and Certification Act of 1992', as the answer. Yet this Act, Public Law 102-493 (signed into law by President George H.W. Bush on October 24, 1992), does not contain any language whatsoever to address or mandate informed consent to the risks of the drugs and procedures. And, in H.R. 4772 (which directs the Secretary of the Department of Health and Human Services to develop a model embryo laboratory certification program for the states), there are "Limitations" (in 'Section 3:i') which declare: "(1) In developing the certification program, the Secretary 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; [and] (2) In adopting the certification program, a 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 language, which was crafted at the behest of the industry (Lawrence, 1993), appears from my vantage point to illustrate the Lupron loophole well -- 'you can tell us what to do, as long as you don't tell us what we can't do ... including patentable, profitable, ventures involving injecting hazardous drugs without informed consent.' What we have here is unconscionable stealthcare: an entire 'profession' and industry utilizing hazardous and untested drugs and procedures upon vulnerable women attempting to conceive, without informed consent, under the guise of "science" and "under the law". For a preyed upon victim to have to try to sort this out without advocacy, and to have to learn how and then search applicable law to try to make sense of this outrageousness, is patently absurd. Judge Learned Hand precisely captured the essence of this matter: "... there are precautions so imperative that even their universal disregard will not excuse their omission" (T.J.Hooper, 1932).

Of critical note is the increasing number of states that have passed legislation that mandates insurance coverage for fertility treatment - in essence, promoting further use of experimental agents such as Lupron (and in the case of MA., it would appear that the state has become complicitous in the advancement of human experimentation in light of failure to pass informed consent legislation). These states have been, and/or are being, lobbied heavily by RESOLVE, Inc., an organization that alleges to "educate, support, and advocate" for the infertile, yet was taking thousands of dollars from TAP Pharmaceuticals as early as 1989 (before any female indication had ever been FDA approved for Lupron). RESOLVE, Inc. admits to receiving hundreds of thousands of dollars from numerous fertility drug manufacturers in its itemizations in Annual Report disclosures, however RESOLVE claims in published Boston reports that

RESOLVE "does not receive any funding from drug companies" (Seiffert, 2000).

RESOLVE has a history of opposing regulation of the fertility industry, including MA. H# 3308 (Millican (1), 1992), and of "mov[ing] quickly to downplay" information pertaining to risks from fertility drugs and treatment (Dezell, 1994). And, in similar fashion, the Endometriosis Association (EA), which testified at the FDA on behalf of, and claims an active role in the approval of, Synarel, the first GnRHa FDA approved for use in women with endometriosis - with the EA providing testimony to the FDA on behalf of Lupron as well ... yet the EA has also has received thousands upon thousands upon thousands of dollars from GnRHa manufacturers, including TAP (see www.lupronvictims.com , 'Endometriosis', for partial list of specific year$, companie$, and dollar donation amount$). Another younger endometriosis association, founded in 1997, the Endometriosis Research Center (ERC), like the EA, publicizes clinical drug trials for endometriosis. The "ERC March 2000" was "presented by the ERC and Amgen Praecis" (manufacturer of a GnRH antagonist) (ERC, 2001); and an ERC Board Member and Director of Operations is also the "co-ordinator of the AstraZeneca [manufacturer of Zoladex] Pharmaceutical Corporation website, the Endometriosis Zone" (Operations, 2003). While the disease of endometriosis and the havoc it wreaks needs as much attention as possible, the eternal presence of conflicts is quite troubling.

For years the FDA has been making annual seizures at ports of unlabeled and illegal fertility medications, including Lupron. I have also seen a publicly posted note on a fertility message board advertizing an ultrasound machine, and media reports have been made in the past of 'black market' Lupron and sales. Just what type of underground market exists out there? Just how many people are lining their plush pockets while their victims simply line and pile up?

'Follow the money' is an apt adage for this unregulated billion-dollar industry and all its associates groups. The value of eggs and embryos for research was clearly identified in the transcripts of the National Institutes of Health's 1994 Human Embryo Research Panel Hearings, wherein the profit from human embryo research in the form of vaccines, hormones, proteins, stem cells, gene therapy, cell lines, organogenesis, ectogenesis, parthenogenesis, chimeras, patents, etc. was amply highlighted. There were a few voices of caution: i.e., Dr. Van Blerkom stated "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 handfuls of patients." And C.A. Tauer stated "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." (NIH, 1994)

One patent relating to assessing eggs and pre-implantation embryos noted that "[s]ignificant improvements in ovulation induction, oocyte retrieval, and in vitro culture techniques have resulted in an abundance of embryos per patient or experimental animal." (Assignee, 1996). One gross eggsample of commercialism at its highest level of crass was the website auction of the eggs of "beautiful young models for as much as $150,000 a pop" (Oldenburg, 1999).

Hundreds of "egg donor wanted" ads litter the nation's newspapers and college campuses, with financial enticement as high as $50,000 for Ivy league eggs (Padawer, 2002) and $100,000 for the preference of 'proven college-level athletic ability' (Enge, 2000) -- and the industry proclaims the "shortage of egg donors" -- yet it would seem that the published medical literature tells a different story.
In curiosity, I added the number of human oocytes and embryos identified in a mere, random, 20 pages in just *one* of the numerous relevant medical journal publications available, and arrived at a total of 7,845 human oocytes [eggs] and 266 human embryos used in research in these few pages. These 20 pages contained roughly 80 abstracts, published in just *one* supplement of this *one* journal, from just *one* month, in just *one* year (Journal, 1995). This genetic 'research material' is described in the published medical literature as "coming from the IVF program", "surplus", "left-over", "discarded", "extra", "spare", "clinic", "donated", "research", "abnormal", "fertilized", "unfertilized", "nontransferable", "suboptimal", "nonviable", and "aspirated". In Britain's The Times, an article entitled 'Scientists pillaging foreign embryos' qualified that "the stem cells are derived from an anonymous embryo in the United States, left over from an IVF procedure." (Hawkes, 2000). And, again for curiousity, I tallied the incidence of 'egg donor wanted' ads published in the Boston Globe for the month of February 2001; and found 'egg donor wanted' ads published on February 4th, 6th, 7th, 8th, 11th, 14th, 18th, 20th (twice), 21st, 22nd, 25th, and 27th.

The Washington Post reported in 1998 on 'Experimenting with eggs': "... No one was paying attention ... The research required many eggs to practice on, said [][one] clinic's director, so doctors there turned to women who were donating eggs to infertile women and used some of the leftover eggs for their research. "We call it sharing with the lab" he said." (Weiss, 1998). And there are few embryologists who admit to "hav[ing] played around with embryos after hours." (Rogers, 2001).

The same researcher who recruited egg donors for Advanced Cell Technology's human embryo cloning endeavors has a mobile embryology lab - "a conventional-looking recreation vehicle with a connected trailer. Inside is nearly all the gear needed for in-vitro fertilization." (MSNBC, 2002). Currently this mobile embryology lab is utilized to serve HIV + clients who wish IVF, but it is noted that such a traveling lab "could potentially provide location-flexible ART for under served populations" (Foundation, 2002). In the matter presently before Congress, there is discussion that if therapeutic cloning were allowed, it should be removed from the fertility clinic setting. Are traveling embryology vans, pulling trailers and driving throughout the streets of the country, the answer? With the value of human eggs as research material increasing, imagine the obscene profit that an unscrupulous scientist could envision with a mobile IVF unit traveling the country, trafficking in underground egg sales.

The profoundly significant and despicable thefts ("conversion", "sharing") of women's ova and embryos by Drs. Ricardo Asch, Sergio Stone and Jose Balmaceda at the University of California at Irvine (Regents; Press; 1995) should be a serious reminder to the utter (and anesthetized) ease with which such menacing maneuvers can be executed. (And Dr. Asch had co-authored studies

of Lupron, "which was kindly provided by Abbott" [Guerrero, 1993]). The contemptible violations of stealing women's eggs and embryos should highlight the profitability of schemes to procure women's eggs and embryos for use in research and/or covert 're-$ale'. Dr. Asch reportedly 'left his office daily with briefcase stuffed with thousands of dollars'. And attention should be directed to the drug protocol(s) used - medications administered "deliberately" "so there would be a surplus of eggs" (Challender, 1995). Who is exerting any oversight over the field of reproductive ? Who would exert oversight over therapeutic cloning --- this same industry?

The conflicts within this arena are excessive and have had a tremendously negative impact upon care. For one example, I pursued initial rheumatology work up for bone pain post-Lupron at the renowned hospital which had first prescribed Lupron to me, and during the course of my visits I was met with the standard "(pain) has no connection to Lupron". Years later I would read that the head of this department had been a long-term highly paid consultant and scientific advisor for Lupron's manufacturer (with compensations rising each of the many years displayed) - and I've seen this doctor's signature on the contract where the pledge is taken to 'defend the company's products at all times in all ways'. In retrospect, I'm able to say 'no wonder no one there wanted to even hear about any connection between Lupron and problems' - but how many other patients know of conflicts of interest in their circumstance(s) ... and who will tell them?

(4) A Brief Overview of the "Hazardous", "Commonly Prescribed" Agent Lupron:

Lupron, referred to as a GnRHa (gonadotropin releasing hormone analog/agonist [and also previously referred to as LHRH]), will be the focus of my comments as it is one of the most commonly used agents, but it should be recognized that numerous other GnRHa's as well as the newer GnRH antagonists are being used in superovulation of women - and the risks from all of these agents should be taken into consideration. Thousands of women have become seriously ill after taking Lupron (and there have also been complaints about other GnRHa's, such as Buserelin, Synarel and Zoladex); and the alleged safety and mechanism of action of these drugs needs attention. A National Lupron Victims Network (NLVN) was founded in 1993, and when I learned of their existence in 1994, they were the only entity who was interested in the results of my searches into the medical literature; and this information, along with many other sources of information, continues to serve as the 'clearinghouse' of information on the risks of Lupron at their website, www.lupronvictims.com . The NLVN began a visit counter on January 1, 2000: as of 3/25/03 there were 2,119,422 hits made to this site. While the NLVN provides detailed information on Lupron, other internet sites contain public message boards about problems after lupron, i.e. Delphi message boards such as 'Julie's After Lupron Page' (Julie's Page), and AOL message boards, among many others.

The initial patent filed for Lupron involved ovulation induction (Patent # 4,005,063), and Lupron has been used in drug company funded studies to induce ovulation (i.e., Segal, 1992). Lupron has become the "standard of care" for some 15 years, for a variety of reasons, including to maximize number of eggs produced. A multitude of many, including numerous Internet

pharmacy websites, hawk Lupron as a "fertility medication" ... yet the FDA has never approved Lupron for infertility, or fertility treatment, or IVF treatment, or any variant of IVF or ART. According to the Physician's Desk Reference, the FDA classifies Lupron as a Pregnancy Category X drug, meaning any woman who is or who may become pregnant should not use. Lupron is a known teratogen (Shephard, 1992), and Lupron is a known developmental and reproductive toxicant (Scorecard). NIH and OSHA place Lupron (leuprolide) on its list of hazardous drugs (NIH, OSHA). Yet, inexplicably, medical literature reports Lupron to be the most commonly prescribed and "prevalent choice" of GnRHa used in fertility treatment (Keenan, 1991; Martin, 1994).

Medical literature regularly refers to Lupron as an antineoplastic and chemotherapy, with some references characterizing Lupron as an antineoplastic hormone. Yet, according to deHaen modified American Hospital Formulary System, Lupron is not listed in the antineoplastic / hormone category (Classification No. 10:00.10, as are the drugs Tamoxifen, Megestrol, Flutamide) - but rather Lupron is listed in the antineoplastic/OTHER category (Classification No. 10:00.12, listed along with Interferon) (deHaen, 1995). No one seems to know what the "other" in Lupron is! But it is known that Lupron was originally approved out of the FDA's Office of Biologics Research and Review. (NDA [New Drug Application] 19-010).

Clinical studies conducted by the manufacturer to evaluate lupron's efficacy (and *not* safety) in fertility treatment and in IVF occurred between 1988 through 1992, according to Abbott Annual Reports (see also FDC, 1988). The "IVF clinical trials" and "fertility treatment clinical trials" using Lupron "were discontinued", according to the manufacturer (Abbott correspondence, 1995), and I've been unable to learn whether these Lupron IVF and Lupron fertility trials were discontinued because of efficacy reasons, safety reasons, both reasons, or other reasons.

Lupron has never gained FDA approval for any type of fertility treatment, however, Lupron did gain FDA approval for use in women for pain management of endometriosis in 1990 - yet the clinical studies for these approvals are a joke - conducted on a handful of women, by paid investigators, and with an endpoint of establishing Lupron's efficacy in pain management of endometriosis while the women in these studies were simultaneously allowed to take narcotics, including Dilaudid and parenteral narcotics. These women were also expected to 'recall and record their adverse events at the end of the study month', yet were not informed that Lupron was known to affect memory (NDA 19-010; see also Newton, 1996). Problems with this trial alone could fill this document - never mind attempting to address the numerous and gross problems evident within other Lupron NDA's.

Lupron is alleged to cause menopausal symptoms such as hot flashes and headaches, and Lupron's categorization as a "hormone" is an allusion that is frequently conveyed to women. Women are often told by the physician, and TAP continues to state, that side effects to Lupron disappear after the 'drug' is stopped. Yet FDA documents for the endometriosis NDA identify that the majority of hot flashes occurred *after* stop of study (NDA 20-011). One clinical trial

evaluating memory loss and cognitive effects of Lupron in young women undergoing IVF showed that "[72%] showed difficulty with memory while on leuprolide" and there was "no correlation between estradiol levels and tests results on any test" (Varney, 1993); and another study showed 11% continued with memory complaints 6 months after stop of study (Newton, 1996). In the March 1984 FDA's toxicological reviews of Lupron, it is stated that "[rat] testes showed various degrees of testicular degeneration which were detectable within 2 days. The severity of the lesions were greater in the testes of rats sacrificed 7 days after cessation of treatment indicating that the effects continued after drug withdrawal. ..." (Jordan, 1984).

Women are told that Lupron will "shut down their system", allowing "control" over their system, and that the side effects are related to menopausal symptoms. But in fact, it was known prior to my 'treatment' with Lupron (but not disclosed to me) that Lupron causes a "hypophysectomy" (Holmes, 1988) - which, by definition, is "destruction or removal of the pituitary"; and it was known (but not disclosed to me) that "sustained treatment with GnRH agonists most likely abolishes pituitary function" (Bischof, 1988). I would also later learn that in the original rat studies submitted to the FDA for Lupron's initial approval of palliative prostate cancer, all rats at all doses developed pituitary adenomas (tumors) - and it was stated that "there is no obvious reason to suggest that the same process could not occur in humans" (NDA 19-010).

Years following these Lupron animal studies, it would be reported "[w]e cannot exclude that [GnRHa] may cause not only adenomas in rat pituitary glands as reported previously, but also a (nodular) hyperplasia of the pituitary gland in man." (Radner, 1991) While the industry maintains that the hot flashes from Lupron are due to lack of estrogen, women complain of hot flashes while on Lupron but not achieving 'suppression' (termed "Lupron escape"), and women complain of hot flashes while on Lupron plus estrogen, and women complain of hot flashes after stopping Lupron that do not go away. Years later, I'd read that it is the "interference with the pulsatile pattern of GnRH that causes flushes" (van Leusden, 1994) - thus, the alteration, impairment, destruction, of the pituitary (as never explained to me or others). To quote one investigator: "GnRH analogs are not like any other medication currently available for treatment of disease. As we continue to learn more about these analogs' mechanisms of action, it is increasingly apparent that they do not just affect the gonadal [sex] hormones, but are powerful modulators of autonomic neural function." (Mathias, 1995)

(5) Impact Of Lupron Upon Women's Brains, Bodies, and Bones:

By way of understanding the significance of this information, the hypothalamus and pituitary are considered the master glands of the body, and both are directly connected to each other by neurons and blood supply; and are responsible and required for proper functioning of the autonomic nervous system (involving hunger, thirst, temperature, heart rate, blood pressure), and the production of numerous hormones necessary for life. GnRH, gonadotropin releasing hormone, which is made by only around 1000 neurons in the hypothalamus (Wierman, 1995), is sent to the pituitary and causes the secretion of (among others) the hormones necessary for normal ovulation (leutenizing hormone [LH] and follicle stimulating hormone [FSH]). Lupron is

a synthetic copy of the GnRH found in pig and sheep, except that Lupron has an added, unnatural amino acid substitution inserted into the structure of the molecule, causing it to become an 'analog' of GnRH and far more potent than the original molecular structure. Which brings me to several pertinent comments made by the FDA that sum up some of the problems and concerns with the use of such a new molecular entity:

One year prior to Lupron's initial FDA approval for palliative treatment of prostate cancer, members of the FDA's Center for Drugs and Biologics wrote an article entitled 'Trends in Drug Development with Special Reference to the Testing of LHRH [GnRH] Analogues' - stating "[c]onceivably, LHRH analogues may be antigenic ... [and] may even cause immune-related disorders. ... The long-term safety of LHRH analogues have not yet been fully investigated, especially when we are dealing with structures drifting farther and farther from the original molecule." (Gueriguian, 1984).

Lupron's structure indeed differs from the original structure in that it contains an UN-natural amino acid, making the 'drift' of Lupron, in my opinion, far from the original 'natural' (pig/sheep) structure. Bear in mind that other GnRHa's have modifications of the original GnRH molecule with their own unnatural substitutions at different and differing places along the structure of the original GnRH molecule - and the newest 'models', the GnRH antagonists, are even further modified. It would seem that there was recognition by these FDA members that 'tinkering' with this molecule raised long-term safety issues for human health.

Five years following the publication of 'Trends in Drug Development with Special Reference to the Testing of LHRH Analogues', prior to any FDA approval of any GnRH analog use in women, the FDA Medical Review Officer of GnRH drugs for gynecology closed her comments at a public hearing with her "experience in observing the course of GnRH analog research over the past year." These were Dr. Ragavan's comments in 1989: "Most of the studies that have been presented for [GnRH] analog research are presently being conducted in young women for benign indications. ... The number of studies trying to use these drugs has by no means slowed down recently. Industrial sponsors have been quick to fund these studies on the drugs seeing a potential market. ... [The Committee] may wish to consider the ethical issues of continued intellectual searches for the use of analogs and the possible risks associated with such studies in this study population. We have always used with extreme caution in our abilities to render men hypogonadal albeit for different reasons. And have reserved this treatment for life threatening conditions in the male, such as prostate cancer. Should we use the same caution in women, especially when we treat benign chronic non-life threatening conditions such as endometriosis? In fact, I propose for you an even more caution in this population who must live with the consequences of treatment for a very long time." (Ragavan, 1989)

In 1994, the FDA issued recommendations (authored by FDA Medical Officer Reviewers of either Lupron's prostate or endometriosis NDA's) that "only pertain to GnRH analogs and should not be considered as guidance for the testing of any drug classes"; and with acknowledgment of "unpublished work" from TAP Pharmaceuticals, these Reviewers

recommended: “At necropsy, special attention should be given to the anterior pituitary, adrenal, pancreas, testes, and ovaries, since an increased incidence of neoplasia in these organs has been associated with GnRH agonist treatment. ... Following restoration of fertility after cessation of treatment, the possibility exists that some germ cells may have been permanently affected by drug treatment. It is therefore important to investigate the effects of fetal morphology (teratogenicity) and on postnatal development of the offspring.” (Raheja, 1994).
An FDA Medical Officer, in reviewing a proposed study for Lupron in high risk breast cancer patients stated the “[d]evelopment of this drug as a general contraceptive should meet with substantial reservations ... it is an adventure into the unknown”, and a Committee Chairman recommended “find out what its [Lupron plus oral contraceptives] long-term effects were, and then consider it for a larger population.” (FDC, 1994)

Medical literature reports that the use of GnRHa’s in IVF has caused neurological symptoms - migraines, numbness and tingling, paresthesia and weaknesses and sensory ataxia - “Transient cerebral ischemia is one possibility that may explain the symptoms ... a direct effect of potent GnRHa on the central nervous system resulting in neurological effects independent of the hypothalamic-pituitary-gonadal axis is possible ... [and] it is quite possible that mild cases with minor symptoms have escaped notice; thus, the occurrence of this type of complication may be far more common that we realize.” (Ashkenazi, 1990). Of note within the latter article’s Medline abstract on PubMed is the mesh heading: “Nervous System Diseases/*chemically induced”.

Another study using Lupron and Synarel, for endometriosis alone or with infertility, was titled “Memory complaints associated with the use of gonadotropin-releasing hormone agonists: a preliminary study” (Newton, 996). “Profound luteinizing hormone suppression after stopping the gonadotropin-releasing hormone-agonist leuprolide acetate” is another study’s title (Sungurtekin, 1995).

In 1995, the first bone biopsy was done on the bones of young women receiving GnRHa therapy for endometriosis, and results showed that after 6 months of GnRH use in young women, there was “severe disruption of the cancellous microstructure” of the bone, and the “results suggest that bone loss induced by GnRH analogs may be associated with adverse effects on cancellous microstructure which are unlikely to be reversed following cessation of therapy.” (Compston, 1995; See reprint of bone biopsy results before and after GnRHa at www.lupronvictims.com - ‘Effects on bone’).

Ovarian enlargement and development of ovarian cysts frequently occurs during superovulation, with ovarian cyst formation “occur[ring] in up to 35% of women receiving leuprolide acetate” (Serafini, 1988; Gocze, 1993). And during clinical trials of Lupron’s use in endometriosis, it is noted that no difference in ovarian enlargement/decrease was noted compared to control patients (NDA 20-011), yet in a separate study (co-authored by a Lupron endometriosis clinical trial investigator) it was noted that “significant changes were noted” and “the identifiability of the ovaries [by MRI] was significantly poorer ... The effects of [Lupron] therapy on the normal

uterus and the ovaries were statistically significant", predicting an "experienced radiologist should expect to be able to identify the ovaries on only 70% of the images." (Zawin, 1990)

In the Journal of American Medical Association, a letter reported "[p]ossible ocular adverse effects associated with leuprolide injections", and noted "11 reported cases of pseudotumor cerebri" (Fraunfelder, 1995) Thousands of women (and men as well) have contacted the NLVN, filled out surveys detailing their medical complaints after Lupron, and continue to report adverse events post-Lupron to the FDA, to TAP, to doctors, to lawyers, to legislators, to federal, state, and consumer agencies, and to the media). The FDA and TAP continue to receive these reports, and women continue to receive Lupron, without receiving informed consent.

(6) Known Effects Of Lupron On Eggs, Embryos, and Babies:

Ovarian cyst formation "occurs in up to 35% of women receiving leuprolide" (Serafini, 1988). Even though Lupron is allegedly prescribed to prevent ovarian hyperstimulation syndrome, the use of Lupron (including the sole use of Lupron alone, with no other fertility drugs) has caused the life threatening condition of 'severe ovarian hyperstimulation syndrome' (Yeh, 1989; Barbieri, 1991; Hampton, 1991; Droesch, 1994; Weissman, 1998). "[U]nacceptable level[s] and variability of stimulation prior to suppression" was encountered early with Lupron's use in ovulation induction regimes (Meldrum, 1988), and aberrant estradiol flares and an inability of Lupron to establish "any ovarian response" were noted elsewhere (i.e., Chetkowski, 1989; Penzias, 1992, 1994). Lupron is commonly used during the superovulation regime prior to egg aspiration/donation, and one study using Lupron in an egg donor program concluded that "continuous postaspiration GnRHa [Lupron] may be beneficial for oocyte donors whose ovaries are hyperstimulated". In this latter egg donor study utilizing Lupron, 1 of 6 patients required hospitalization. (Ng, 1995). "Fertility clinics will not be informing their patients that in Collingswood N.J. there flourishes a National Lupron Victims Network." (Millican (3), 1995)

Published medical reports have noted the occurrence of abnormal human pregnancy outcomes associated with the use of Lupron - 43.5% in one 1996 study (Karande, 1996). Another report, using the 'long Lupron protocol', showed a 38% abortion rate (Shanis, 1995), and a study of 'low responders' using Lupron showed a 66.6% spontaneous first trimester abortion rate (Droesch, 1989). In 'healthy women undergoing ovarian stimulation' using Lupron in another study, another 66.6% abortion rate was noted (Minaretzis, 1995). Another study's title states "Exposure to [Lupron] in Early Pregnancy is Associated With High Pregnancy Wastage That Could be Related to the Length of Exposure" (Sasy, 1997).

What are the known effects of Lupron upon eggs? In a 1994 study of chickens using Lupron, 1 out of 25 of the hens died, and at the end of the 30-day experiment, all egg shells had thinned (Burke, 1994). A study using two GnRHa's (including Lupron) involving rabbit ovaries, concluded "GnRHa act directly in the rabbit ovary ... increasing oocyte [egg] degeneration" (Yoshimura, 1991). In studies involving Lupron in human fertility cycles, it was reported that "some retrieved oocytes exhibit incomplete nuclear and cytoplasmic maturation after the use of

this agonist [Lupron]" (Racowsky, 1997) as well as "maturational asynchrony between oocyte cumulus-coronal morphology and nuclear maturity" (Hammitt, 1993). In 'Designs on Life', by Robert Lee Hotz, it was revealed that "[s]cientists ... noticed that Lupron embryos were different. They grew faster, developed more rapidly. They were more fragile when frozen and less likely to survive thawing. Nobody knew why or what it meant for the long-term health of the woman or any resulting child." (Hotz, 1991)

According to the 1998 text, 'Drugs in Pregnancy and Lactation', TAP communicated in 1992 that it was "maintaining a registry of inadvertent human exposure during pregnancy to leuprolide and currently has over 100 such cases. No cases of congenital defects attributable to the drug have been reported ..." (Briggs, 1994). And "[f]etal growth retardation was observed with increased frequency among the offspring of rats or rabbits treated during pregnancy with subcutaneous doses of leuprolide similar to those used in humans." (Friedman JM, 1994). In a study using Lupron and other GnRHa's on rabbit eggs, "[t]he rates of normal fertilization and early embryonic development were significantly reduced in the oocytes matured by GnRHa", and it was noted that "one cannot exclude the possibility that GnRHa in pharmacological dosages may be cytotoxic against oocytes." (Yoshimura, 1992)

In a patent for embryo culture composition, it is noted that "culture of primate embryos in the presence of a GnRH agonist ... unexpectedly dramatically reduces the rate of embryo attachment and cell differentiation." (Hearn, 2000). Using Lupron in fertility cycles, "some retrieved oocytes exhibit incomplete nuclear and cytoplasmic maturation after the use of this agonist" (Racowsky, 1997). Growth retardation has been noted in young monkeys given Lupron (Golub, 1997).

But TAP has maintained a registry from over a decade ago of more than 100 Lupron exposed babies in which no "attributable" defect has allegedly been found Perhaps someone needs to investigate the veracity of this data. There have been accounts by women, including on the internet, reporting birth defects in babies conceived on or after stopping Lupron - including Lupron use for fertility as well as use for endometriosis. It is not uncommon to see an internet infertility message board note stating "I have one Lupron 2-week kit for sale. I just lost my third baby and can't go through this any more". Public posts have described babies conceived spontaneously within several months of stopping Lupron, and born with birth defects such as Total Anomalous Pulmonary Venous Return, a heart defect. I personally know women who conceived babies from IVF using Lupron whose children have anatomic anomalies and developmental delays, and I know women who conceived babies after using Lupron for endometriosis who've experienced loss of child, developmental delays, esophageal stricture, attention deficit, and serious seizure disorders. I personally know 3 women, with 5 children (conceived on Lupron either through IVF or unintentionally during Lupron for endometriosis) who have serious seizures disorders, and I have heard of other similar cases. Internet message boards about parenting problems with ART children show notes of ART children undergoing a variety of tests (i.e. CAT scans) and surgeries (i.e. open heart) and being prescribed a variety of drugs for a variety of ailments including poor muscle tone, jerkiness, choking, esophageal

stricture, spinal cord abnormalities, GERD (gastroesophageal reflux disease).

The first published long-term study of babies born after accidental exposure to GnRHa's revealed that 4 out of 6 babies have severe neurodevelopmental abnormalities, and the conclusion of this study was that "[t]his observation ... justifies the need for long-term follow-up of more children previously exposed to GnRHa" (Lahat, 1999). When Lupron is used in superovulation regimes, upwards of 1 mg/day will be injected for several weeks to one month or more, and to within days of egg retrieval. Women are given both the daily Lupron and depot Lupron (monthly formulation) for superovulation regimes (i.e., Ruhlmann, 1993) - yet Lupron depot brochures for endometriosis and fibroids state barrier contraception should be used during depot Lupron and that pregnancy should not be attempted until 2 months after therapy (meaning 3 months from the last injection). Again -- TAP Lupron depot brochures advise barrier contraception during Lupron and recommend pregnancy not be attempted until 3 months after last injection, yet TAP has funded studies using Lupron depot and Lupron daily in infertility and IVF. Regardless of daily or depot Lupron use, women are told that Lupron will be out of their system before any fertilized egg is implanted - yet published medical literature by, among others, a TAP Medical Director, identified that detectable levels of Lupron remained after 11 weeks following the last injection. (Miller, 1990)

Women are prescribed anywhere from 10 - 45 days of Lupron during one superovulation regime (see, i.e., Nader, 1988), often being put on prolonged Lupron - a "delay". (Damario, 1997). And women are frequently prescribed birth control pills before Lupron to prevent Lupron-induced ovarian cysts that are known to develop. One woman from the 'Surrogates' Corner', having already given birth twice to twins in the past as a surrogate, describes how she's working with a new couple: " ... I have been on lupron since May 26 ... I can't take much more lupron!" - the date of her note was July 28th (Surrogate, 2000). A woman could receive a range of 5 - 22.5 mgs in one 'fertility' cycle with Lupron if using Lupron 0.5 mg per day, or she could receive a range of 10 - 45 mgs in one 'fertility' cycle if using Lupron 1 mg per day. Some women are prescribed more, some less, in a superovulation regime. Women receiving Lupron for endometriosis receive 3.75 mg per month in one injection - for a total of 22.5 mgs in 6 months of treatment (a limit recommended by the FDA due to occurrence of bone loss). The woman who undergoes one "controlled ovarian hyperstimulation" regimen may be very well be exposed to more Lupron than a woman undergoing six months of treatment for endometriosis.

While the endometriosis patient may undergo more than 6 months of Lupron 'treatment', women who undergo fertility treatment are well known to be 'frequent fliers' (given the failure rate and need for repeated IVF trials to attempt 'success'). One published study reported a woman undergoing superovulation 18 times (Check, 1988). Women who take Lupron for fibroids use 3.75 mgs per month for 3 months - although variations in dose and duration are often reported. Consider that men in the final stages of prostate cancer are currently prescribed Lupron 7.5 mg per month (depot), and not the daily Lupron, yet the daily Lupron was the initial form of Lupron first approved by the FDA (for palliative treatment of prostate cancer). Currently, daily Lupron is rarely used in prostate cancer, but it is this daily Lupron that is most frequently prescribed in

superovulation regimes, despite discontinued clinical trials and despite never having gained FDA approval for fertility or IVF.

(7) Examples of Iatrogenic Illnesses Induced By Exposure:

In 1999, the FDA reported on their review of MedWatch Reports for adverse events from Lupron. The FDA reviewed more than 6000 reports, concluding "there were high prevalence rates for serious side effects". The FDA's action was to reexamine the product label, "to ensure that these events are adequately addressed." (Lazar, 1999). It is my understanding that the FDA was to undertake another review. In the meantime, what, if anything, has been done "to ensure that these events are [] addressed"? After FOX 25's 2 part series on the adverse effects of Lupron, FOX informed Senator Kennedy of their series and quoted the Senator as stating he found their "report on possible side effects of Lupron was troubling. Physicians have an obligation to inform patients of the risks of drugs they prescribe, and promotion of potentially risky "off-label" uses of products by manufacturers is illegal and unethical." (Kennedy, 1999)

The medical literature offers numerous examples of iatrogenic illnesses following exposure to GnRHa's. For example, in a 1990 study utilizing GnRHa in IVF treatment, one of a group of women who had developed severe ovarian hyperstimulation syndrome and liver function abnormalities, had a liver biopsy performed (at the end of surgical removal of conceptus due to intrauterine death 2 months into the pregnancy). This liver biopsy showed "a striking abnormality consisting of macrovesicular fatty infiltration around and linking the portal tracts. This appearance could not be classified into any well-recognized clinical entity." (Forman, 1990).

These, and other, clinical reports are disturbing, especially as they pile on top of one another. Case report or study titles often tell the story: 'Adverse effects of leuprolide acetate depot treatment' (Friedman, 1993), 'Neuropsychologic Dysfunction in Women Following Leuprolide Acetate Induction of Hypoestrogenism' (Varney, 1993), 'Angina and myocardial infarction with use of leuprolide acetate' (McCoy, 1994), 'Memory complaints associated with the use of gonadotropin-releasing hormone agonists: a preliminary study' (Newton, 1996), 'Leuprolide Causes Pure Red Cell Aplasia' (Maeda, 1998), 'Transient thyrotoxicosis and hypothyroidism following administration of the GnRH agonist leuprolide acetate' (Kasayama, 2000), 'A case of atypical absence seizures induced by leuprolide acetate' (Akaboshi, 2000). Case reports of Lupron-treated fibroids having "striking vascular changes and histologic features of vasculitis and atherosclerosis" note that "[t]he florid and rapid development of vascular inflammation, fibrinoid deposits, and thrombosis after leuprolide acetate therapy ["rarely seen in non-leuprolide treated {fibroids}"] suggest an immune-mediated process. ... these observations are significant and worrisome if such changes affect other organs." (Mesia, 1997). Lupron has been listed among those medications that may cause lupus. (Greenberg, 1999).

Problems associated with Lupron are also identified in the titles of male uses of Lupron as well, i.e. 'Leuprolide therapy for prostate cancer. An association with scintigraphic "flare" on bone

scan' (Johns, 1990), 'Sudden death due to disease flare with luteinizing hormone-releasing hormone agonist therapy for carcinoma of the prostate' (Thompson, 1990), 'Possible Ocular Adverse Effects Associated With Leuprolide Injections' (Fraunfelder, 1995), 'Pituitary apoplexy after leuprolide administration for carcinoma of the prostate' (Morsi, 1996; multiple other similar case reports have been published), 'Localized Amyloidosis of the Seminal Vesicle: Possible Association With Hormonally Treated Prostatic Adenocarcinoma' (Unger, 1997), 'Incidence of bone fracture in patients receiving luteinizing hormone-releasing hormone agonists for prostate cancer' (Hatano, 2000), 'Altered cognitive function in men treated for prostate cancer with luteinizing hormone-releasing analogues and cyproterone acetate: a randomized controlled trial' (Green, 2002).

In the animal testing data submitted for Lupron's initial approval, the FDA Review and Evaluation of Pharmacology and Toxicology Data states, among others: "... There are other, inconsistent, effects of Leuprolide in the various toxicology studies but potentially the most serious effect of Leuprolide, in my view, is its effect on spinal column bone marrow. This increased fat deposition and subsequent hypocellularity was explained as a physiological response to the drug. ..." (Jordan, 1984). Years later, other animal testing would reveal "[a]lterations in thymic and bone marrow lymphocyte subpopulations in GnRH agonist [Lupron] treated prepubertal female mice" (Rao, 1993).

Many, many relevant studies and case reports are left unmentioned here. Many effects of Lupron, such as upon the bone, heart, immune, and other systems, have barely, if at all, been touched upon. But it is the people with real names, real faces, and real pain that is most upsetting. Many women, and sometimes family of these women, have contacted me over the years with varied complaints following Lupron - always looking for help. It is extremely difficult for me to hear these horror 'stories'.

As a former full-time career R.N. who has been able to effectively advocate for any patient, and did so for many patients in the past, after Lupron I suddenly found myself in a land somewhere beyond the upper level of nowhere - and all rules had changed. It was an awful moment when I realized that I was not alone and there were many other Lupron victims - comforted by company, but horrified at the scope involved. All other victims were echoing my words that "after lupron" thus and such started. And all other victims have interesting doctor 'stories' to tell. My experiences were simply inexplicable at times, and I quickly learned (but fiercely resisted) the fact that Lupron was not open for substantive discussion. I would self-triage my own various symptoms and prioritize before arriving at the doctor's office, otherwise s/he would be overwhelmed. One physician replied after I reported dizziness, pedal edema (swelling in feet), and gastric pain, that "those are bullshit symptoms". That atrocious answer and behavior is never a correct response to any patient, and after I changed doctors a small gastric bleed was diagnosed. These few personal details barely convey the level of destruction this drug and the subsequent unmerry-go-round has had upon my life and the lives of countless others. Here is a glimpse into the experiences of some other women who want you to know that they're hurt and they want attention paid to this public health issue.

Candace Hedin, of Marlboro MA., was told seven years ago, at age 25, that she'd need Lupron prior to undergoing fertility treatment with Clomid. Candace was put on Lupron for six monthly shots, and has suffered with multiple, unexplained, serious illnesses since. She's been hospitalized for unexplained chest pain and inability to breath about 15 times, and each time it just "goes away after 3 or 4 days" until the next time "it" returns. Candace also has extensive and extreme hives, including inside her mouth and throat, which become open sores and she cannot eat or drink anything - resulting in hospitalizations for dehydration. She also reports continued vaginal bleeding despite having undergone a total hysterectomy and a battery of tests (including full body CAT scan) to establish the reason(s) for this bleeding, and all tests have been inconclusive. In addition, her mammogram is normal, her prolactin level is normal, but she lactates daily. "Nobody's even looking at any of this - I can't get any diagnoses! All they tell me is my immune system stinks - I'm allergic to my own body is the diagnosis. My toenails are coming out and now my fingernails are coming out too!" Candace's husband says "How can you take a girl, at 25, who'd never had any medical problems, and suddenly become so sick and debilitated - we've gone to 5000 medical doctors and they say 'think of something that might have caused all these things to suddenly come about' and I tell them 'Ya! - she took lupron and she's been sick ever since'- but they say Lupron doesn't have anything to do with it. I think I'm watching my wife die in front of my eyes and no one wants to do a thing about it." (personal communications)

Wendy Camacho of Cherry Hill NJ took Lupron for IVF years ago, and as she puts it "my IVF baby is now 9 and my health is a mess ... it has been downhill since." Wendy writes "I have seen neurologists, rheumatologists and orthopedists, and none of them have any answers for me. I have been experiencing severe fatigue (diagnosed as fibromyalgia), trouble sleeping, nightmares, gross motor skills are disintegrating fast. I am unable to work as a waitress anymore because my arms can't balance anything, and my legs give out from under me at will. I also have severe osteoarthritis. During a routine eye exam, at which I was diagnosed with cataracts (rare at age 38), I was asked by the doctor if I ever took fertility drugs. When I said yes, I was told I was one of many, but she said she didn't know enough about it to go into detail. ... I now have the corneas of a 6 year old boy. ... I was diagnosed with MS, benign remittent, Thank God. I awoke one morning with a very weakened left side. EMG showed I have only 35% strength on that side. I have spent ages going to doctors. ... I would tell everyone - RUN in the opposite direction from Lupron." (personal correspondence)

Linda DeBenedictis, a teacher from MA., mandated to use Lupron without rationale, has testified at the MA. Health Care Committee regarding the health problems she's experienced. At the 1995 hearings for MA. H# 3308, at the close of her testimony, Linda stood up, faced the crowd, and removed her wig. She is totally bald, and has lost every single hair on her entire body (FOX News, 1999). [Unlike other chemotherapy/antineoplastics, hair growth had not returned years after Lupron.]

Gilda Radner posthumously is associated with ovarian cancer awareness, however little focus

has been placed upon her fertility treatment. In her book 'Its Always Something', Gilda questioned red meat and hair dyes, among other potential causes for her ovarian cancer - but never questioned her use of fertility drugs.

And Barbara Mays, and her offspring, are two others whom I believe deserve consideration as victims of fertility treatment: Barbara Mays was infertile for 10 years, underwent fertility treatment, and ultimately gave birth to a baby born with a heart defect. The Mays baby was intentionally switched in the hospital nursery, and the Mays went home with a healthy baby (named Kimberly 'Mays') who had been born to the Twiggs. The baby that the Twiggs took home, the biological child of the Mays, died at age 9 from congenital heart problems. Several years ago, a national news broadcast aired an interview with the dying LPN who admitted she was instructed to switch the babies and remained silent for fear of losing her job, but no rationale was offered for the switch. Based upon historical fact and my observations of the machinations of this industry, the field of reproductive endocriminology can be characterized as utilizing a multitude of slick maneuvers to deny, disinform, mislead, discount, dismiss, diminish, and suppress risks. The U.S. investigation of TAP's billing practices revealed that a computer program given by TAP to many doctors in the country (some 10,000 urologists received gifts from TAP), which computated the amount of money per Lupron prescription the doctor could earn, also harbored a 'secret key' - and in the event the secret computer program was in danger of discovery, a secret key was struck and !presto! all incriminating information disappeared. Given the history of the fertility industry, it appears plausible that !presto! any incriminating association between the use of fertility treatment and congenital birth defects could disappear if you 'remove' the association by 'simply' switching babies.

In a 1996 Boston Globe story, available industry figures (for 1993) showed that more than 50,000 assisted reproduction procedures were performed, and about 8,500 came home with babies - noting that "thousands of others bring home only disappointment and a lingering anxiety about the aftereffects of treatment." Susan McCarthy, attending Boston IVF, had 34 eggs ripen at once - which "led to kidney failure, and she developed a massive, life-threatening infection. She was hospitalized for days, connected to tubes delivering intravenous antibiotics and draining the fluid that was swelling her abdomen, making her look four months pregnant. 'I felt terrible for the longest time ... And it's not just that. I don't have anything to show for it. ... [Susan] recalls "ovarian hyperstimulation was mentioned by the clinic staff. But the risk was dismissed with the comment "it never happens""(Kong, 1996).

The story also described an egg donor, Debra Christensen of Divide, CO., who took Lupron, and suffered ovarian hyperstimulation, ripening 30 eggs, and experiencing a lot of pain. Following soon after Debra's egg donation, she became pregnant and experienced problems with this, her 3rd child, that she hadn't experienced before - "The placenta grew into her uterine lining, huge uterine cysts developed and her son had to be delivered two months prematurely. Nine months later, when the cysts had swollen her uterus to about six times normal size, Christensen - at 32 - had to have her uterus and ovaries removed." (Kong, 1996)

According to Stanford Magazine, Calla Papademas, a 22-year old Stanford graduate "slipped in and out of a coma in the intensive care unit at Stanford Hospital" after responding to an egg donor ad "promising $25,000 or more" and agreeing to donate her eggs for a $15,000 fee. ... A few days after Calla began the drug regimen [Lupron], a benign, undetected tumor on her pituitary gland - which Calla's doctors believe was stimulated by the Lupron - grew at a furious rate and ultimately ruptured, casusing a massive stroke. Calla suffered brain damage and lasting weakness on her left side. Her academic and career plans were derailed, and she and her family incurred $100,000 in uninsured medical bills. ..." (Hamilton, 2001)

In my own situation, within months of stopping Lupron I began to experience a variety of ailments, was unable to work for 3 years (and have yet to be able to return to full-time employment since Lupron), lost my job and home, and slowly came to the terrifying realization that I was in for the fight of my life at a time in which I had never felt sicker or had so many health problems. Six years later, in 1995, in preparation for written testimony in support of MA. H# 3308, I audited my health records and compiled a chronological list. All doctors visits, surgeries, labs, tests, procedures, ultrasounds, etc. were typed, in single space, on continuous computer paper - and the end product was 7 ½ feet tall. This sheet of paper represented: adenoma (tumor), breast cysts, cardiac arrhythmias, dizziness, edema (swelling), fatigue, gastritis, gastro-esophageal reflux disease (GERD), hyperlipidemia, immune system abnormalities, joint pain, knee pain (exacerbated), lymphadenopathy (swollen glands), myalgia (muscle pain), neuralgia (nerve pain), osteopenia, and spasms, to name a few. And, most importantly, knowing the many serious health problems of so many other very sick women post-Lupron, I consider myself to be one of the 'luckier' and 'healthier' victims - causing me to fight even more.

All my symptoms/diagnoses/diseases have been acknowledged as adverse events reported to the FDA following Lupron, yet none of my symptoms or diagnoses or diseases have ever been reported to the FDA as adverse events from Lupron. Since 1995 this list has grown: arthritis, ascites (abnormal collection of fluid in abdomen), adrenal problems (abnormal cortisol and ACTH levels - workup ongoing), degenerative disk disease, "dissolving jaw" per dentist, enlarged liver (pre-Lupron operative reports indicate normal liver), fibromyalgia-like syndrome, lesions in nerves in arms, lesions on skin, scoliosis (presently "mild", and childhood screenings and pre-Lupron X-Rays evidence normal spinal curvature), the osteopenia has now progressed to severe osteoporosis, telemetry monitoring of cardiac status (pulse noted at 38, blood pressure roughly 60/42) raised the specter of a pacemaker should I become symptomatic, and a few other problems I can't recall at the moment. In the last seven months, I've been hospitalized twice, and officially rang in this spring at the endocrinologists office, reviewing recent abnormal cortisol and ACTH levels, and heard orders I've never heard in my life: "[I] need to avoid stress".

For 'fun' during recent hospitalizations for gastritis, I'd ask the nurses to explain the following: at times (not always) when they'd check my resting pulse and the machine would register a heart rate of, say, 41 - I'd ask "do you know how I can make my pulse go down?" I'd get out of bed

and momentarily jog in place and the pulse oximeter would go *down* to 38. When they'd wonder what would make that happen, Lupron and autonomic nervous system dysfunction becomes the topic. Invariably, I've met nurses, phlebotomists, ultrasonographers, and fellow patients who've been prescribed Lupron without informed consent of the risks. And I've met a number of doctors who report seeing patients in their own practice with similar "bone, gastric, and cardiac problems after Lupron".

Nurses are also not informed, despite OSHA recommendations, to use two pair of chemotherapy gloves and a chemotherapy gown (among other precautions) when *handling* and administering Lupron. And any healthcare worker who is planning on conceiving or fathering a child is advised to avoid *handling* the hazardous drug Lupron at least 3 months prior to conception attempts (AHFS, 1999). Three years ago, I conducted a survey of random U.S. healthcare institutions, inquiring what policy and procedure they had for the administration of Lupron by healthcare workers. 100% of the respondents stated they had no such policy or procedure (unpublished data). I've met, talked to, and read online plenty of women complaining about Lupron, and I've never once seen anyone say their doctor or nurse was gowned and double-gloved during their injection. TAP states in its product literature that there are no hazardous components to Lupron. Would you consent to an injection of a hazardous agent for a benign condition from a gowned and double-gloved health worker?

Many women undergoing 3 months of treatment for fibroids or 6 months of treatment for endometriosis with Lupron have been complaining about post-Lupron problems for years, and again, sometimes these women can receive less Lupron than someone undergoing repeated IVF or egg donation. Some women use Lupron for endometriosis and IVF, as in my situation. And some women have also been maintained on Lupron for years on end. Dr. Mercola states Lupron for endometriosis "could be the Kiss of Death ... Lupron is a disaster drug that in no way shape or form treats the cause of the problem. I have seen it absolutely devastate many women's lives. It is one of the few drugs that I actually cringe when patients tell me that they have taken it. It is my experience and belief that this drug causes permanent neurological damage. This drug needs to be avoided at all costs." (Mercola, 2002)

Paula Andrade, an R.N. from Methuen MA., provided a statement of her experiences as supportive testimony for my 1997 Offer of Proof for my medical malpractice tribunal: "Four years ago I took a GnRH analogue [Lupron and Synarel] for problems with endometriosis. I took the medication for 5 3/4 months. The week before I was due to discontinue the medication I became ill. I experienced flu like symptoms with severe muscle pain, paresthesias, and bone crushing fatigue. Four weeks later I developed a host of neurological problems including vertigo, nausea, loss of balance, blurred vision, muscle twitching, and fasciculations with difficulty walking and constant muscle stiffness. Since then I have been seen by several neurologists and rheumatologists who remain baffled by my condition. I haven't been able to receive any help within the medical community. Prior to taking the medication I was an active and healthy individual who had worked as an RN for many years. I took care of my home and family. Since the medication I have been unable to work and have difficulty performing daily

activities. I have spoken with other women from around the United States who have taken this medication and are now suffering with similar problems and whose lives have been drastically altered. I swear under the pains and penalty of law that the above statements are true." Today Paula says she hasn't seen a doctor in years - "For what - they can't find out what's wrong and nothing they did changes the way I am, so what good is it to keep going?" (personal correspondence and communications)

Lisa Plante, Fall River MA., was a former congressional staffer who was prescribed Lupron for presumed endometriosis - and Lisa and I traveled to Washington together last year to speak to Senate staff on the issue of Lupron and its connection to cloning. Lisa experienced extreme and unbearable bone and joint pain from the time of her first of three injections, and this pain has gradually worsened. Eight years later Lisa says "I now have arthritic bones, very bad bone loss, constant bone pain and joint pain, and basically feel like I have aged 30 years since Lupron. I have not been able to live a normal life with my family because of this bone pain and want others to be fully informed of the dangers of Lupron. Women must not be put at risk like this and MUST NOT be used as guinea pigs!" Lisa recently went on a long promised overseas vacation with her family, fearing that her future might prevent her from ever going - and during this trip Lisa spent 50% of her time in the hotel bed, in pain. Lisa is not able to travel here today. (personal correspondence and communications)

Paulette Wilson, Newport News VA, took two monthly injections of Lupron for endometriosis, and after the second shot she "woke up with chest pain and needed to go to the emergency room." She was told she had 'reflux disease', a gastrointestinal disorder. "I never had any problem like that before ... Tests showed that I had acid burns from my esophagus to my rectum." Paulette now lives with severe pain, which sometimes affects her entire body." Paulette also has been diagnosed with fibromyalgia (Regush, 2002) and liver problems (personal correspondence).

Jeanne Wolf, from Orange County NY, had to have her gallbladder removed after Lupron, and was diagnosed with gastritis for years until stomach testing showed that she had gastroparesis - her stomach was paralyzed and was not emptying food. "I am waiting for these bastards to pay for what they poisoned me with. Funny thing is I was given the poison because they said I had endometriosis, well I obtained my laparoscopy biopsy results and no endo was ever found! My body and mind will never be the same." (personal correspondence)

Melanie Waldman Lloyd, Corvallis OR, took Synarel to treat her endometriosis prior to attempting pregnancy, and subsequently developed immune problems, suffered 8 miscarriages due to antibody formation, has developed thyroid problems, eye problems affecting eye muscles and seeing double, and now takes an IV treatment every 2 months (which runs at cost some $600 per dose). Melanie writes "My health is ruined from this drug ... No one should take this drug without knowing the risks." (personal correspondance)

Melody Hampton, Mt. Victory OH, more than 7 years after Lupron, continues to experience

tremendous headaches, rash, joint pain, nausea, heart palpitations, high white cell count, bone loss, high blood pressure, blood in urine, atrophy of muscles, leg swelling - all beginning shortly after her first Lupron injection. (personal correspondance; Regush, 2002)

Kimberly Bradford of FL, also started complaining right after her first injection, and continues with complaints a decade later. Kimberly suffered a miscarriage following her use of Lupron, experienced intense migraines, and has neuropathy and Adie syndrome in her right eye. She started to trip over everything and began to notice a smell of "burning" which led to an MRI of her brain. An MRI "showed lesions on my brain. There was a question of "demyelinating lesions" or MS, and Kimberly has come to call this "my spot" - "it's in the white matter, in the middle, near the pituitary gland, but not in an area they can biopsy without causing more injury." When Kimberly's doctor was filling out her Family Medical Leave Act paperwork, he stated that "this all started when [Kimberly] unknowingly got [her]self involved with the FDA's phase IV clinical trial of Lupron." Kimberly says: "I did not know until my own research that I was part of a clinical trial. I never signed a consent for this." (Bradford, 2002). [Kimberly is not the only patient with a diagnosis of brain lesions following Lupron use].

Diane DeFeo, a teacher from Yonkers NY, lost two teaching jobs as a result of being on Lupron. Diane writes "This was disabling. I was exhausted and still experiencing pain, had migraines, mood swings, bone and muscle aches and pains, not to mention that I gained 35 pounds. I have lapses of memory I call 'lupron moments'. I was constantly dizzy. And I waited for the symptoms of Lupron poisoning to diminish. Seven years later I still experience effects from this drug. And TAP Pharmaceuticals, the company that manufacturers this poison, simply - this is evil at work. The physicians that continue to prescribe this drug knowing the possible repercussions are the most evil of all. I pray for the day when people will take us seriously and that women do not need to suffer permanent illness and damage. (personal correspondance).

Julie Johnson, Chicago IL., relates how her doctor told her "its lupron or hysterectomy, so I agreed to the lupron. I had my first shot at the end of October 1996, and I was fine - for about 20 hours. Then I developed a terrible pain at the injection site and I could not move, walk, or sit, but my doctor said it was not the Lupron and I probably hurt my back and it eventually eased with a dull ache remaining at that site." She received a second shot and experienced achiness but attributed it to the flu and received her third shot, to awake the next day with hives. "And then my knees started to ache, and every morning for the next week I woke up with pain in another part of my body. By New Years I hurt very badly - even wiggling my toes to slip on shoes was excruciating. The pain went on for months and months and I noticed that I was losing strength in my legs." Julie continues to suffer from fibromyalgia, has lost her libido and has dealt with chronic depression since Lupron. She tells of her phone calls to TAP, in which "he refused to listen to me - I've often wondered, if they refuse to listen or take this type of information from the women who have taken lupron - how will they know what type of problems lupron causes?" (personal correspondance). Julie is the founder of 'Julie's After Lupron Page', on Delphi.com, a public internet message board where Lupron victims share information and experiences. (Julie's Page).

Susan Hayward, Lake Havasu City AZ, says "I would rather suffer with my initial diagnosis, endometriosis, than what this drug has done to the rest of my body and life". Susan relates how, in attempts to maintain her career amidst endometriosis, 2 doctors administered a total of either 19 or 20 Lupron injections over a five year period. "When I first started using the drug I had to purchase it like any other prescription. Later, both doctors had me skip going to the pharmacy and they obtained the drug for me. I believe I was sold prescription samples. The kickback schemes involved with TAP and physicians are well documented ...". Since Lupron, Susan reports experiencing "vertebrae bone loss diagnosed as degenerative disk disease, arthritis, myalgia, bone pain, fatigue, swelling in hands and feet, severe allergies, nausea, weight increase, severe memory loss, vision changes, sleep changes, rapid heart beat, and abdominal pain. ... After taking Lupron, I don't go a day without pain and am under constant doctor care to control pain and autoimmune problems. I left my home and moved to Arizona where I didn't know a soul so I could get relief from the arthritis problems. ... The total lack of support from the medical profession is appalling, and all lawyers say 'without a doctor saying your problems are related to Lupron you don't have a case'. ... I lost my career and am disabled, but more than that it has robbed me of any faith in our system of justice and what is right." Susan points out that her disability has resulted in "approximately $900,000 disability costs being paid by Social Security and the Federal Retirement Program, plus factor in the increased insurance premiums from hundreds of thousands in medical bills from hospitalizations, surgeries and tests." (personal correspondence; see also Lazar, 1999).

Judy Norsigian, Co-director of the Boston Women's Health Book Collective, also provided a statement for my 1997 Offer of Proof in my medical malpractice tribunal: " ... No fewer than 15-20 women have called our Women's Health Information Center over the past 5-6 years about totally debilitating and frightening reactions to this drug ...".

In 1995 Donna Kuha, of MA., entered one of Dr. Andrew Friedman's Lupron clinical trials for fibroids - "The doctor told me it would be good for me. ... He didn't tell me of any possible danger. ... I sure didn't expect a stroke." Donna Kuha, "who lost the use of a hand and most of the use of one leg, is one of a disturbing number of patients who have been harmed by clinical trials." (Lasalandra (2), 1998; personal communications, 1998). Publicly available court records in Kuha's medical malpractice trial, containing medical records, indicate Donna suffered her first stroke while in the Lupron clinical trial, and she suffered another stroke subsequent to Lupron discontinuation, as well as developing a seizure disorder. In my professional opinion, the medical records within these court documents compel one to entertain 'the magic clot theory' and are deserving of a close and critical review. According to the public records, Donna's expert medical witness concluded that a drug other than Lupron caused her stroke, and twenty-one pages into this plaintiff's medical expert's curriculum vitae it is learned that he's been an Abbott consultant since "1987 through present", and had served on Abbott Young Investigator Award Advisory Board in 4 previous years. (Kuha, 1997). Donna suffered her first stroke in March, 1995 - just prior to Lupron's FDA approval for 'anemia associated with fibroids when iron therapy alone is ineffective'. (NDA 19-943)

The Boston Herald did a 3-part series on Lupron, the second part entitled 'Women seek answers on drug's suspected side effects'. A dozen women were interviewed for this story, which began "Hundreds of women nationwide, with nowhere else to turn, are forging a campaign against a drug they believe has ruined their health and their lives." Quoting one victim in the series: "My knees tremble a lot and get very weak, and I have to use a cane now to go up and down the stairs," says Kimberly Savino, 17, of Easton, who was prescribed Lupron last year for a gynecological problem. Before taking the drug, Savino said she often rode horses and jogged. Today, three months after stopping Lupron, the teenager has trouble even walking and has been diagnosed with a degenerative arthritis, which usually develops over many years. Her mother is worried - and suspects Kimberly's strange bone problems were triggered by Lupron. "It's very hard to see her, all of a sudden, moving around like an old lady with a cane," said Susan Savino. "Now we don't know if she is going to end up in a wheelchair. This shouldn't be happening to someone who is 17." (Lazar, 1999)

This shouldn't happen to anyone at any age. And problems with Lupron appear throughout all ages and all indications. For example, a public internet post from another mother about her 15 year old daughter who at age 5 ½ was treated with Lupron for 3 ½ years. The mother reports her daughter had no problems on Lupron, but writes that "her period has never been real regular ... she has been having severe pains in her leg joints. Started in the knees and have moved to the hips. ... Now she is having similar pains in her elbows and shoulders. She was always a small girl until about the same time as the pain started, she gained almost 50 pounds and can't seem to get it off. Does anyone out there know if this could be some long term affects of Lupron???? We have had her to 2 different doctors and they can't seem to figure out what is going on. ...."

Numerous men have reported a multitude of adverse events following their use of Lupron for palliative treatment of prostate cancer (Abend, personal communication, 1994). Zoladex (goserelin) is another GnRHa used in prostate cancer, as well as used in endometriosis and infertility. Lupron, Zoladex, and Synarel are all advertised as "fertility medications" (Fertilitext, 2003; Members, 2003), yet no GnRH analog has been approved for fertility treatment or IVF or any variant of infertility treatment. In an overseas IVF study using GnRHa's Zoladex and Buserelin with clomiphene (CC) and hMG, "[i]f no selection against chromosomally abnormal oocytes takes place at the time of fertilization, more abnormal oocytes are harvested with GnRHa/hMG protocols than with CC/hMG." (DeSutter, 1992). Studies in pregnant baboons using Zoladex resulted in numerous abortions and stillbirths and neonatal death (Kang, 1989).

Debbie Arnason wants you to know about her husband's experience with Zoladex treatment: "Arne Arnason of Naples FL was diagnosed with prostate cancer about 18 months ago and was put on Zoladex 3-month depots with resulting side effects of debilitating hot flashes, extreme weakness, breathing difficulties, irritability, bone mineral density loss, hip, back and joint pain as well as muscle pain. He was unable to work. With each successive treatment, the symptoms became worse. We truly believe the 3rd and last shot was unnecessary - this treatment aged him 20 years in 9 months, requiring 2 ER visits, one for arrhythmia and one for a retinal tear. Arne

continues to have symptoms related to the calcium imbalances the Zoladex created - he was referred for surgery of the neck to remove his parathyroid gland. It's just been one scary thing after another. No one warned us of any of this!! I had to do all my own research. We feel for people who don't know the awful consequences of the use of this goserelin acetate drug, Zoladex by AstraZeneca (similar to Lupron)". (Arnason, personal communications and correspondence) [AstraZeneca "is in negotiations with U.S. state and federal authorities over the potential settlement" involving "improper claims for its prostate cancer treatment Zoladex, in a ruse similar to that of TAP ..." (Pharmafocus, 2003; Church, 2002)].

(8) Rita Abend, D.D.S. - Her Story & The Inception Of The NLVN:

The following is testimony of Linda Abend, D.D.S., dated December 5, 1997, and submitted into the public record as expert witness testimony within my Offer of Proof in my medical malpractice tribunal (Millican v. Harvard Community Health Plan, Boston IVF, Natalie Schultz M.D., Brian Walsh M.D., Mahmood Niaraki M.D., Selwyn Oskowitz M.D., Michael Alper M.D.; No. 92-2140A). At that time, in 1997, there was no medical expert that I could locate who was willing to publicly address Lupron's causality to adverse health problems. Linda Abend's testimony is reprinted below in its entirety:

"Dear Tribunal Members: Many years ago I founded The National Lupron Victims Network to inform people about the risks involved in taking the drug Lupron. The network does not accept any money from either victims or external sources. All of our information is available for free on the internet. I hope that the information I have found in my years of research will help other people so that they are fully informed of the risks involved in taking Lupron."

"Women and men from all over the world have contacted the network. Nearly all of the people I have spoken to were not informed of the risks involved in taking Lupron. The majority of the people who continue to have medical problems after taking Lupron are finding that they are having an unusually hard time getting adequate medical care."

"The individual case that I have the greatest knowledge of is that of my sister, Dr. Rita Abend. Before Rita took Lupron, difficulty in obtaining medical care was something neither Rita nor I could comprehend. Once she took Lupron everything changed. While on Lupron Rita experienced horrendous side-effects. Doctors had never informed Rita of any risks. Ultimately, we realized that she probably would never receive the medical care that she so desperately needed."

"Since taking Lupron, Rita has been diagnosed with seizures, autonomic nervous system dysfunction and myeloma/plasmacytomas (a rare form of bone marrow cancer). All of these diagnoses were given and then rescinded at one time or another. Results on her blood laboratory reports and numerous pages of medical documents were whited-out, and vials of blood lost by a physician before they even left his office. Doctor after doctor has refused to treat her including one who plainly stated that it would not be in his best interest to do so. Rita went all over the

country in search of medical care after taking Lupron. Rita, like many others who took Lupron, could not get honest medical care after taking Lupron. And without honest medical care and doctors to testify, due process in the courts is an impossibility."

"In one instance, Rita had to obtain a court order in order to get her medical records from one doctor, Orin Devinsky. Devinsky had threatened to "destroy" the continuous audio-visual video tapes that he had made of her electroencephalograms (EEGs) during a 9 day hospital stay in a specialized epilepsy unit, approximately two weeks after stopping Lupron. (Rita spent three of these days in intensive care). Despite the fact that these tapes had over 600 computerized "events" (alerting the viewer to abnormal brain activity) Devinsky wanted to destroy them. During the hospital stay Devinsky learned that Rita's IQ had dropped to 97 on an IQ test and her manual dexterity was in the bottom 8% of the nation. Instead of informing us of this drastic decline after taking Lupron, he informed us that the tests came back "normal". Although Devinsky's admitting diagnosis was "convulsions" (based on an EEG), he claimed that this was all a mistake and in the end nothing was wrong with Rita. Even with the court order Devinsky did not turn over all of the medical records. He claims to have "lost" some tapes."

"Instead of offering Rita anti-seizure medication, Devinsky tried to coax Rita into taking a derivative of pentamethylenetetrazole (PTZ), insisting that it was perfectly safe and that no one had ever been hurt by it. Rita refused the PTZ. After researching PTZ I discovered that PTZ is no longer given to humans since it is not safe. It has been found to cause seizures and effects the autonomic nervous system. It is used in the laboratory to make animals epileptic for experimentation purposes. When Rita finally found a doctor to monitor her seizure condition caused by Lupron, she was offered not one, but four anti-seizure medications."

"In another instance, Rita was experiencing extreme pain in her hip. An x-ray revealed that she had lost 30-50% of her bone density at the head of her femur. Lupron is known to cause bone loss at the head of the femur. Rita was instructed to use a walker because her hip could fracture from the loss of bone. Rita was referred to a specialist. He refused to treat her. He refused to run a single test, not even a blood test. Rita was left in bed suffering with excruciating pain for one year, unable to get up without the use of a walker."

"Today, my sister, a once actively employed, vital, energetic and intelligent woman who graduated from New York University Dental School, is now totally and permanently disabled. It is hard to say which is most difficult for Rita; relinquishing her dental license, relinquishing her drivers license, accepting the fact that comprehensive medical care (no testing, no answers) will always be denied because she took Lupron, or that justice will probably not prevail if one has been injured by Lupron."

"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 ackowledged 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."

"I certainly do not want to leave you with the impression that I believe all physicians are bad. There are many good, caring physicians out there treating people with all kinds of medical problems. But when Lupron victims turn to physicians for help and answers they get a deaf ear and the 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 testify, they are unable to obtain justice in the courts. If you have any questions, please feel free to contact me. Respectfully, Linda Abend, D.D.S., Founder, The National Lupron Victims Network."

Although Linda Abend closed this 1997 statement with an invitation for contact, attempts to contact the NLVN (by myself, other victims, lawyers, and media) have been in vain. Phone calls go unanswered and certified mail to their long-held address returned "unk". No new information has been posted at the NLVN website for years, and the private NLVN message group (where there had been postings by hundreds of members) has long been inaccessible. Thousands of women contacted the NLVN and had filled out the detailed questionnaire that the NLVN had mailed out, and was processing, in the 1990's. Now, the question is not only what happened to all that information -- but what has happened to Rita, Linda, and the NLVN?

(9) The State Of The ART, And The Art Of Stating:

In February 1995 I noticed a surrogate ad running in a college newspaper, offering $17,000 plus expenses to carry the gift of life for an infertile couple, and I called the ad. A Dr. Radecki answered the phone, and I heard all about the wonders of IVF and "there were no long-lasting risks" and "no one ever suffered serious harm from the drugs." On March 21, 1995, I was surprised to see CBS Evening News interviewing this Dr. Radecki - and became even more surprised to learn that Dr. Radecki was not a fertility doctor - he was a psychiatrist who had lost his license for sexually abusing his patients. By the end of March 1995, Dr. Radecki had closed shop - the telephone number for the surrogate ads was disconnected, the ads were gone, and he was under siege for misrepresentation.

A TAP advertisement in a fertility journal gives a glimpse into the sly canvas upon which the industry paints its picture: This TAP Lupron ad read: "Remote Control: Your patient with endometriosis doesn't have to remember her daily therapy - Lupron Depot 3.75 mg remembers it for her. ... She only needs to remember six monthly visits." (Ad, 1992). Nowhere does the

consumer learn that memory loss has been known to be "a commonly observed" side effect to Lupron, or that patient noncompliance with daily Lupron could likely have been related to a memory disorder (listed as a known adverse event to Lupron), or that clinical trials conducted for Lupron depot approval utilized methodologically flawed study design that was conducive to subjects forgetting adverse events (surveyed every 30 days).

In 1990, several Brigham & Womens physicians (including the lead author who would later admit to falsifying and fabricating approximately 80% of 4 Lupron studies) would write "not since the development of oral contraceptives has there been so much excitement and enthusiasm among basic scientists, clinical investigators, and practitioners of reproductive medicine." (Friedman, 1990). A coauthor in the latter article, Robert Barbieri M.D., has also been a lead investigator for Lupron, authoring or co-authoring (including with Friedman) many Lupron or GnRHa studies and books, and has received TAP funds for numerous studies, and serves also as a Medical Advisor on TAP's Lupron endometriosis website.

In 1997, Dr. Barbieri, representing the industry, testified in opposition to the MA. bill which would have mandated state regulation and informed consent of the risks of ART. Following the hearing, when I asked Dr. Barbieri why memory loss, along with all of the other hundreds of reported side effects, was not included in their IVF Clinic's consent form, he subsequently forwarded their consent form with an attached, handwritten note stating: "Here is a copy of our current Lupron consent form for IVF. I am going to ask Dr. Hornstein to add memory loss as a potential side effect. I don't think we can add 300 side effects. Do you have 3 or 4 others that would be important to add?" That such a lead and allegedly prestigious Lupron investigator should query me as to what adverse events are important to include within their Lupron informed consent document (presumably approved by an IRB) is troubling, disgraceful, and the epitome of the 'state of this art'.

"Inclusion of patients with a poor response to GnRHa therapy has not always occurred in outcome analysis in the published medical literature." (Redwine, 1994). Conflicts of interest are extensive, troubling, and have far reaching consequences upon standards of care and the state of science. Two cases in point: Another lead Lupron investigator alleged in a study that reduced bone mass was associated with endometriosis (Comite, 1989), yet another investigator with contrasting findings reported that "One explanation for the difference between the results of this study and those of Comite et al. is that they included women who previously had been treated with GnRH agonists and these agonists are associated with bone loss." (Dochi, 1994). (See www.lupronvictims.com, 'Endometriosis' for further elaboration on these studies). Claims of the disease endometriosis being associated with bone loss, while deliberately omitting patient's prior use of GnRHa (which is known to causes bone loss), is a perilous concept of manipulating iatrogenic, adverse, drug effects into a disease-related non-tort phenomenon - and deserves attention.

A 2002 Human Reproduction article, 'High rates of autoimmune and endocrine disorders, fibromyalgia, chronic fatigue syndrome and atopic diseases among women with endometriosis: a

survey analysis', co-authored by the President of the Endometriosis Association, failed to mention GnRHa's within the article (Sinaii, 2002). The survey upon which the article is based, which was sponsored by Zeneca (1998), does contain reference to GnRHa use in survey participants. Despite the presence of a National Lupron Victims Network, with many women complaining of autoimmune and endocrine disorders, fibromyalgia, chronic fatigue syndrome, etc. post-Lupron, this article makes no mention of these adverse advents.

I do not think any of this is funny - but if there were ever a game involving Lupron and/or GnRHa titled something like 'Patent - Conflict ...Yea or Nay', I'd participate. For example: Issue - Person involved with the testing of animals and Lupron and FDA approval submission ... Yea Patent! Yea Conflict! Issue - Person heading major reproductive research unit and member of RESOLVE's Advisory Board ... Yea Patent! Yea Conflict! Issue - Member of major Institutional Review Board, who has performed numerous TAP-sponsored Lupron studies, and published numerous articles on Lupron ... Yea Patent! Yea Conflict! Issue - Individuals promoting awareness of risks of Lupron and ART ... Patently NayNay!

(10) The Check Is In The Fe/male:

"GnRH and its analogs have led to exciting new avenues of therapy in virtually every subspecialty of internal medicine as well as in gynecology, pediatrics, and urology ... virtually every subspecialty of medicine will be touched by the GnRH analogues ..." (Conn, Crowley;; 1994).

The following is a fairly comprehensive, alphabetical, list of clinical uses, case reports, or studies involving Lupron's use in unapproved and off-label indications. These uses were mostly found within published medical literature, although some were noted within patents, or advertisements for clinical trials, and one was a personal clinical observation. Citations have been omitted for brevity, but are available upon request.

A: adjuncts for IVF; adjunct to fibroid surgery; anovulation; autism [management of sexual behaviors]; acute intermittent porphyria; Alzheimer; adenomyosis; severe adenomyosis; adhesions; amenorrhea [functional]; angiomyxoma of vulva; autoimmune disease; autonomic neuropathies; 'add-back' regimen [estrogen/progestin with lupron]; advanced breast cancer.

B: before hysterectomy for leiomyomas; benign prostatic hyperplasia; benign prostatic hypertrophy; birth control; breast cancer; breast cancer prevention; bioavailability following nasal and inhalation delivery to healthy humans.

C: catamenial insulin reaction; catamenial pneumothorax; chronic intestinal pseudo obstruction [in patient with heart-lung transplant]; cluster headaches; colorectal cancer, congenital adrenal hyperplasia with oligomenorrhea; contraception; cryptorchidism; controlled ovarian hyperstimulation in normal, abnormal and poor responders; combination therapy with flutamide and castration; colonic endometriosis; comparison of suppressive capacity of different

GnRHa's in women; comparison of hCG versus lupron for releasing oocytes.

D: dysfunctional uterine bleeding prior to hysterectomy.

E: egg donation; endometrial ablation; endometrial cancer, endometrial glandular hyperplasia; endometrial hyperplasia without atypia; endometrial cancer; endometrial stromal sarcoma; epithelial ovarian cancer; exhibitionism; effect of very high dose in prostate cancer; effects in animal and man; effect on embryos ("accelerated development"); endometrial preparation for transfer of frozen-thawed pre-embryos in patients with anovulatory or irregular cycles; effects on follicular fluid hormone composition at oocyte retrieval for IVF; effect on hair growth and hormone levels in hirsute women; effects on glucose metabolism in a diabetic patient; equivalency of hMG and FSH stimulation following suppression; effect on LH surge ; effect on adrenocorticotropin and cortisol secretion in premenopausal women; effect on seminal vesicles; effects of lupron on luteal-phase hyperprolactinemia during ovarian stimulation.

F: fallopian tube obstruction; functional ovarian hyperandrogenism, functional abdominal pain from functional bowel disease; fibrocystic breast disease; first cycles of IVF/GIFT; follicular development and oocyte maturation.

G: GIFT.

H: Headache, Huntington's Disease (for exhibitionism), hyperandrogenism, hysteroscopic surgery; hilus cell hyperplasia within ovarian cyst wall; hypermenorrhea in premenopausal women with acute leukemia; hypermenorrhea with severe thrombocytopenia; hypogonadotrophic hypogonadism; hypergonadotropic hypogonadism; hypergonadotropic amenorrhea; hypothalamic-pituitary axis disease; hypothalamic hamartomas and sexual precocity; hirsutism; moderate and severe hirsutism; hysteroscopic surgery; benign symptomatic hyperandrogenism in a postmenopausal woman; hidradenitis suppurativa.

I: infertility; IUI; IVF; IVF-ET in insulin-dependent diabetics; irritable bowel syndrome; intravenous leiomyomatosis with cardiac extension; intranasal lupron for endometriosis; intranasal/sc lupron for fibroids.

K: Kallmann syndrome.

L: leuprolide flare regime for IVF/GIFT & embryo cryopreservation; lupron screening test for IVF; luteal phase lupron flare protocol; luteinized unruptured follicle syndrome; leiomyosarcoma; leiomyomatosis peritonealis disseminata.

M: male contraception; *male* factor infertility (female is treated - male is not); Meniere's Disease; menstrual migraines; motility disorders.

O: ovarian cysts; ovarian cysts after ovarian transposition; ovarian epithelial tumors;

ovarian granulosa cell tumor; ovarian hyperthecosis; advanced epithelial ovarian carcinoma; ovulation induction; ovarian stimulation; ovarian stimulation with lupron and norethindrone in IVF/GIFT; ovarian hyperstimulation; oocyte release; ovarian hyperstimulation syndrome; severe ovarian hyperstimulation; oocyte donation, oocyte donation [post-menopausal]; operable breast cancer; ovarian carcinoma [refractory]; ovarian remnant syndrome [diagnostic].

P: pancreatic cancer; paraphilias; Parkinson's Disease symptoms, pedophilia, pelvic pain not associated with endometriosis; pituitary metastatic mass; polycystic ovarian disease; PMS; protection against chemotherapy-induced testicular damage; postpartum depression; premenopausal breast cancer; post-menopausal breast cancer [advanced]; pre-implantation [embryonic] diagnosis; prevention of hypermenorrhea in premenopausal women undergoing bone marrow transplantation; prostate cancer (Stage C adenocarcinoma]; endometroid adenocarcinoma of prostate; pseudo intestinal blockage, psychosis in PMS, resistant paraphilia, pulmonary endometriosis; pulmonary tuberous sclerosis; pulmonary delivery of leuprolide in health male volunteers; pre-myomectomy; poor prognosis patients for IVF/poor responders ; preservation of fertility in a woman with menorrhagia; pharmacokinetic studies in humans [iv and sc]; preoperative treatment of complicated myomata; pre-surgical treatment of fibroids.

R: resectoscopic endometrial ablation; rectal endometriosis; routine pituitary suppression before ovarian stimulation.

S: sexual offenders; sexual precocity; Sickle-cell anemia associated priapism; surrogacy, SUZI; steroid-cell tumor (advanced); systemic lupron erythematosis; submucous myomas; sexual behavior disorders; syndrome of familial virilization, insulin resistance, and acanthosis nigricans; stimulation test in Tourette's syndrome; small cell carcinoma of prostate.

T: transgender adjunct, testicular function effects; transdermal vs. subcutaneous leuprolide - a comparison; triggering follicular maturation.

U: urinary retention in prostate cancer; ureteral obstruction caused by endometriosis; urinary retention due to benign prostatic hyperplasia.

W: with or without medroxyprogesterone in treatment of fibroids.

Z: ZIFT

And the following list is simply an odd collection of TAP-funded Lupron studies that were jotted down along the way. This list should not be construed as any formal, complete, or even partial, audit of the numbers of published TAP funded Lupron studies. Even if the total tally of TAP funded Lurpron grants and investigators could be counted today, that figure would be obsolete with the next publication of TAP funded Lupron studies. But here's a few examples, with duplicative years indicating separate studies.

In Alabama, there was one of 13 investigative sites conducting TAP funded research; in Arizona, TAP funded a symposium; in California, numerous investigators for numerous indications; in Colorado, 5 physicians received TAP funds; in Connecticut, another one of the 13 investigative sites conducting TAP funded Lupron research; in Florida, another one of the 13 investigative sites conducting TAP funded Lupron research, and in Florida, a TAP sponsored educational program at Walt Disney for unapproved female uses (FDA memo by David Banks, 1990); in Illinois, numerous investigators supported by grants from either Abbott or TAP or both, in 1988, 1989, 1991, and another one of the 13 investigative sites conducting TAP funded Lupron research; in Kansas, another one of the 13 investigative sites conducting TAP funded Lupron research; in Massachusetts, another one of the 13 investigative sites conducting TAP funded Lupron research, and in Massachusetts in 1987 numerous investigators conducted TAP funded Lupron research, and in Massachusetts in 1988 numerous investigators conducted TAP funded Lupron research, and in Massachusetts in 1989 numerous investigators conducted TAP funded Lupron research, and in Massachusetts in 1989 numerous investigators conducted TAP funded Lupron research, and in Massachusetts in 1990 numerous investigators conducted TAP funded Lupron research, and in Massachusetts in 1991 numerous investigators conducted TAP funded Lupron research, and in Massachusetts in 1995 numerous investigators conducted TAP funded Lupron research, and in Massachusetts in 1997 Brigham & Women's website identified two grants were funded by TAP; in Maryland, another one of the 13 investigative sites conducing TAP funded Lupron research; in North Carolina, numerous investigators (including an FDA Advisory Committee member) received funding from TAP, and had Lupron "generously provided" by TAP for a study involving ovulation induction; in New York, another one of the 13 investigative sites conducting TAP funded Lupron research; in Pennsylvania, another one of the 13 investigative sites conducting TAP funded Lupron research; in Tennessee, one physician was on TAP's Speaker's Bureau and is an "active contributor" to the EA (personal correspondence, 1998); in Texas, another one of the 13 investigative sites conducting TAP funded Lupron research; and in Texas an educational grant from TAP to numerous investigators; and in Washington, another one of the 13 investigative sites conducting TAP funded Lupron research.

(11) Considering Cloning? Consider The Myths of Hype & The Realities of Scientific Misconduct:

It is outrageous to hype cloning research, which will involve superovulation with drugs such as Lupron, as probable cures for diabetes, Parkinson disease, Alzheimer, etc. -- when women who've received Lupron have now iatrogenically DEVELOPED these and other diseases. It is appalling that this debate has not centered on the adverse health effects of superovulation and Lupron upon the women, and especially the reports of adverse pregnancy and birth outcomes associated with treatment.

Without proper long-term follow-up study of the reports of adverse health outcomes to the superovulated women and without proper long-term follow-up of the adverse pregnancy and adverse birth outcomes in the babies conceived and exposed to drugs such as Lupron, how can

you propel recklessly forward to create a massive demand for more superovulation of women for research eggs?

The message of research and biotech has resulted in the impression of hope, promise, cure, and benefit. My personal experience can be summed up by the words hype, myth, research fraud, conflicts of interest, and injury ... and all without any medicolegal advocacy for the injured victim. It is a myth that public safety is being protected by the FDA, evidenced by the fact that some 20 million people have taken drugs that have been recalled - drugs that were initially deemed 'safe and effective during study', only to later learn that data identifying serious problems, including deaths, had been suppressed.

Somewhere it is written that it was a "comforting but erroneous myth" that research involving drugs and devices still serves medicine. Time magazine's 4/22/02 cover, of a woman crouched within a laboratory cage, epitomized the story within, depicting yet another research debacle in which data identifying adverse side effects was kept secret - and only revealed by a whistleblower (Lemonick, 2002). Time also noted that there were more than 60 institutions that "failed to protect human subjects adequately." Other recent articles have identified the dramatic disparity in research results and reporting, depending on who is paying for the research - with contracts allowing pharmaceutical companies control over disclosure of bad data. Furthermore, large sums of money in the form of grants, stock options, company ownership, patents, consulting agreements, scientific agreements, speaking engagements, symposiums, trips, gifts, etc. (which are disclosed in less than ½ of 1% [Stolberg, 2001]), have created an environment conducive to suppressing bad data and inducing outright fabrication of data. It would be nice to think that ethical behavior is the norm, but a review of recent news compels one to notice the increasingly rampant unethical machinations of research medicine.

To date there have been a number of renowned reproductive physicians/surgeons who have been found to have fabricated and/or falsified data: Dr. Andrew J. Friedman, a lead investigator for Lupron, recipient of many TAP grants to study Lupron, and director of Brigham & Women's IVF Program (where this writer was mandated to use Lupron), was found to have falsified and fabricated approximately 80% of the data in 2 published, and 2 unpublished Lupron journal articles (Federal Register, 1996). Is it any wonder that during the time Dr. Friedman was director of Brigham & Women's IVF Program, the criteria for the administration of Lupron with IVF changed from "Lupron is only used in certain diagnoses" to "Lupron is widely prescribed"? Where is the data to justify such widespread application of a hazardous, reproductive and developmental toxicant?

There has also been the brothers Drs. Nezhat (one of whom serves as a Scientific Advisor for the EA, according to the EA website) who have been found to have fabricated research involving laparoscopic surgery for endometriosis, resulting in the retraction of two published journal articles (Nezhat; 1991,1992). An attorney, as a result of litigation (on behalf of a client who believed she had signed an informed consent form to authorize surgery but had instead signed a waiver of right to receive informed consent), doggedly pursued to have this bogus published

surgical procedure data examined - and only after 6 years was the data finally produced, examined, and retracted. In one study, more than half of the patients were used for pre-market testing of a new, non-FDA approved, circular stapling device. "The Doctors Nezhats' retracted bowel surgery articles are included in Ethicon's coursebook for surgeons. ... While the Doctors Nezhat reported no "short or long term ill effects" with this new technique, there were significant complications in these subjects, some severe. A portion of one woman's bowel died during surgery, another's anastomosis (where bowel is rejoined) massively hemorrhaged a few days post-op requiring repair, one patient's bowels fell into the toilet post-operatively, several patients had bowel leaks in the staple line, several patients were incontinent of feces, some could no longer evacuate normally, etc. Yet, the operation was promoted for 185,000 women by Johnson and Johnson based on the Doctors Nezhats' research" (Attorney James J. Neal, 2003: www.mdjdfraud.com; see also Neal, 2002) .

The father of GIFT, gamete intrafallopian transfer, Dr. Cecil Jackobson, rounded off his accomplishments with 52 convictions of perjury and fraud. He had been substituting his own sperm for that of some 75 women's husbands' sperm resulting in these women (initially) unknowingly giving birth to children fathered by this 'expert'. To quote USA Today, "... His case taught a valuable lesson about the fertility industry: Self-regulation is not enough. ... Many of his most offensive acts were legal - like donating his own sperm. The only way Jacobson was stopped was on federal wire, mail fraud and perjury charges. ..." (USA Today, 1992).

The "Dyno Gyno", Dr. Niels Lauersen (and a cohort) were convicted of billing fraud, "falsif[ying] bills to get $2.5 million in payments from insurers for a variety of fertility procedures" (Barrett, January 2001), and Dr. Lauersen was "jailed as flight risk" (Barrett, March 2001). Dyno Gyno loyalists attempted to assign this fraudulent billing as nothing but 'an attempt to provide otherwise denied procedures', causing "prosecutors [to] fume that the case is not about health-care policy, but a thief with a medical degree and a lab coat." (Barrett, 2000). Of note is an aside mentioned in the latter article, which relates one loyal Lauersen patient's position that women's health issues don't get enough insurance coverage. The aside is a description of this patient, "whose three children all needed special attention from the doctor due to different complications at birth." (Ibid). No further elaboration is made on these "birth complications", and the implications of such "complications" appear to be unrecognized.

And the story of Dr. Asch, et al. is well known: Dr. Asch, who was overdosing women in superovulation to steal their eggs and then sell them to researchers and other unsuspecting women, reportedly often left his office with a briefcase stuffed with thousands of dollars in cash - while he was also preaching and publishing on the psychological effect of egg donation on women (Lessor, 1993).

A renowned group of fertility experts published a study, a report of "the first case of human germline genetic modification resulting in normal healthy children" (Barritt, 2001), however the expert group "failed to disclose that along with 15 healthy babies it produced two foetuses with a rare genetic disorder. Experts are horrified because the fault can be passed to future

generations" (Hill, 2001). The fertility clinic and fertility experts report published claims of healthy children from their procedure ... yet the Washington Post reported "[i]nternal documents from Saint Barnabas explicitly acknowledge that the novel technique may be causing the problem ..." (Weiss, 2001). The 'Birth Defects Research for Children' points out that "the two cases of Turner's syndrome should have been mentioned in the report so that doctors and others would be aware of all the facts" (Birth Defects, 2001). The group would later report that the "children born after IVF with cytoplasmic transfer have been carefully evaluated and one 18-month-old child was recently diagnosed with a pervasive development disorder ... a broad spectrum of disorders with mixed prognosis. .... Because the procedure is experimental, protocols have been supervised and re-evaluated in 1999 and 2001 ... However, this research has been suspended since early July 2001, pending clarification of new requirements suggested by the federal Food and Drug Administration." (Institute, 2001). Six years prior, in an abstract published by one of this group, 4 abnormal embryos were implanted into women - and this act brought little, if any, attention from anyone or anywhere. (Munne, 1995). At St. Barnabas' webpage on egg donation (in which Lupron is used), the question of "What are the risks of being an egg donor" is answered ... "Donors may risk psychological distress if they are rejected from the program ..." (St. Barnabas, 2001).

Falsified and suppressed data (which can set, alter, and impact standards of care), along with conflicts of interest and abuses of human subjects in research endeavors are poisoning medicine systemically. Shouldn't you begin to address the forces that result in profit via dictation of data and spin and to-hell-with 'first do no harm'? And should you really open the reproductive research doors wider to the inevitable abuses in human embryo cloning research? The criminal penalties of jail and fines of at least $1 million that President Bush has proposed should be applied not just to the use or importation of cloning technology, but rather should be applied like a heavy wet blanket over every research discipline in medicine in attempts to quash this destructive slow burn.

(12) The Marginalization of Victims and Lack of Medico-Legal Advocacy:

The consumer who has been victimized by the fertility industry and/or Lupron has no recourse. Consumer protections are woefully lacking in the fertility research enterprises today - and there is no reason to assume that adequate 'measures' will take place or be enforced in the cloning arena. Start cleaning up the mess in today's fertility clinic before you create nightmares at the human embryo farms.

Who or what is in place *now* to assist the injured egg donor, or the harmed fertility patient - and whomever or whatever is offered as an answer to that question, please then answer what are they doing *now* about Lupron victims? My complaints to the FDA about Lupron and lack of informed consent promulgate the mantra that the FDA has no supervision over the practice of medicine, which falls to state Boards of Medicine. State Boards of Medicine state a doctor can prescribe any drug they want off-label, and drugs are under the purview of the FDA. The Department of Public Health has no jurisdiction over fertility clinics, so refers one to the Board of Registration

in Medicine. The FTC round-robins the consumer to the FDA. And there you go, round and round ... no informed consent, no advocacy, no accountability, no protection. The consumer is left stranded, while profits and abuses exponentiate, and her medical needs, costs, tests, and doctor/hospital visits accumulate.

Fiscal prudence would seem to imply that insurance companies would audit their costs of members 5 years prior to and then 5 years post Lupron, for expenditure comparison. My medical bills, and the medical bills of others, both before and after Lupron, speak for themselves. After enjoying a full-time salary for many years, it would be 8 years post-Lupron before I had earned a total of my formerly annual years salary. Illnesses, medical costs, inability to work, no medical or legal advocacy - all are extreme hindrance to the effort, energy and time necessary to mobilize for survival. Eggs donors, et al. beware! My advice to those considering undergoing superovulation and Lupron is: first, establish independent wealth in the event you become disabled; second, you will not be able to recognize lack of informed consent or be able to rely on the information or advice given to you, therefore some type of healthcare degree, preferably M.D., is necessary; third having advanced chemistry will be especially helpful, so bone up there also; fourth, you may need to become quite familiar with the legal system and you might be on your own - so prepare yourself beforehand to save yourself a lot of grief; fifth, make sure you have family and friends available who can help you as you may find you are in need; sixth, make sure you can type real fast as you may find yourself having to write thousands of letters; and seventh, buy a head-phone because you will need to talk to as many people as you can.

It is "very bad", indeed, that reproductive experimentation has been conducted without informed consent, and with 'treatment' using hazardous agents propagandized as safe and as science - but is neither. "It no longer appears possible to consider the marketing of new drugs for stimulating the gonadicpituitary axis unless they have been tested within the framework of IVF" (Buvat - Laborie, 1988). The Health, Education, and Welfare Department, in 1979, advised that a global study be undertaken to establish the safety of IVF, and although no such undertaking was done, it was proclaimed at the 1994 Human Embryo Research Panel Hearings that former concerns about IVF's safety had been abated. The March 2000 study indicating a 9% rate of major birth defects from IVF represents a substantial increase from former reports. Dolly, the cloned sheep, became lame and was euthenized. And there are thousands of Lupron victims who appear to have no voice, and are crying out for medical care and legal representation.

The FDA has had a "fatal erosion of integrity" (Horton, 2001), and conflicts of interest on 18 FDA Advisory Committees were revealed several years ago. (Cauchon, 2000; Mercola(2), 2000). The protections allegedly in place for federal research subjects were recently shown to have failed - and in private research enterprise the consumer is just plain out of luck. Conflicts of interest abound in clinical trials - "Let's be realistic" said [the] commissioner of the FDA, "Profits do drive this business" (Agnew, 2000). Where are the consumer protections?

While there has been some litigation recently, in the early 1990's there was little legal recourse available, and I am aware of 2 other women who attempted to bring their own lawsuit involving

Lupron pro se because they couldn't find an attorney. I searched high and low, east and west, north and south, individual and firm and agency alike. Never having been inside a law library and needing to know everything about a foreboding and alien process with requirements and deadlines I'd yet to learn creates a most precarious and unfortunate position. Having to learn how to draft a complaint, and having to figure out the problem in terms of legal issues, identify the law and find other case law, file motions to compel, file answers and promulgate interrogatories and requests for production of documents, undergo 7 motions for summary judgment and a medical malpractice tribunal - without any attorney or real guidance beyond cursory advice by attorneys over the phone. I was told by numerous attorneys "you most definitely have a case, but without laws and standards - its a legal vacuum" and then years later, "if you can find the expert, I'll take the case".

Not until my case approached the MA. Appellate level did I pursue obtaining a paralegal certificate, but clearly, without counsel, and without laws and regulations, I understood that I had limited abilities to do justice to the case or the issue. I tried over and over, again and again, to find an attorney, each attempt to no avail - and it was very unnerving to try to prepare an appeal to the MA. Supreme Judicial Court pro se. Incredibly, a final online internet plea for some legal guidance was seen by an appellate attorney with endometriosis, Barbara Sosin, from Chicago IL. Barbara's reproductive endocrinologist "fired [her] because [she] refused to take Lupron". This doctor told her "I've been so patient with your irrational refusal to take this medication, and there's nothing more that I have to offer you". Therefore, through just a few phone calls of my presenting the legal issues, cases, and facts, Attorney Sosin was able to help me assemble this information in the most appropriate format, and I was very grateful for that last minute support. But, nonetheless, from start to almost finish (some 8 years), traveling that road alone is unacceptable; and was not the way for such an important matter to have had to be handled. Filing a case pro se is something that no victim should *ever* have to do.

Many product liability cases have been filed against TAP regarding adverse events to women following Lupron - and quietly settled. Through the grapevine, I became aware of 5 cases in the latter 1990's, and obtained court records for Villarreal v. TAP (Sacramento County, CA., No 528453; 1993), and Gantner v. TAP (Cook County, Il, No. 96L11379; 1997) - and have since become aware of a separate, additional settled case, and there are many potential-plaintiffs searching for counsel. I am aware that cases are being consolidated, and do foresee a class action suit looming on the horizon. But it has taken a very long time to get to that point, and an awful lot of wonderful, innocent, misled people have been hurt. My lawsuit was initially filed in 1992, and was terminated at the MA. Supreme Court level in 2000, the day Boston papers broke the Lupron urology kickback scam story - but I left nearly 1000 pages of medical, scientific, pharmaceutical, and governmental documents involving Lupron's risks for the next victim/case.

Since then, and after 11 years of seeing untold numbers of doctors and specialists, I finally received documentation that my "multiple medical problems [are] consistent with case reports following Lupron exposure ... [and have] an extremely complex, multifaceted, constellation of medical problems." I'd like to quote the final paragraph from my MA. Supreme Judicial Court

appeal: “Moreover, Defendants claims of lupron’s “menopausal” action does not correlate with known science. (Appendix p. 290 & 293). And studies for lupron’s use in IVF were “discontinued”. (Appendix p. 358). Therefore, her IVF treatment with lupron was not grounded in reliable scientific methodology. The opinions of the *Defendants,* as well as the accepted ‘standard of care’ regarding the use of lupron, cannot meet the threshold requirements of Daubert and is “junk science”, creating a genuine issue of material fact for a jury. (Daubert v. Merrell Dow Pharmaceuticals ...)” (Millican vs. Harvard Community Health Plan, Boston IVF, Natalie Schultz MD, Brian Walsh MD, Mahmood Niaraki MD, Selwyn Oskowitz MD, Michael Alper MD. Docket No. 98-P-1472.)

An online investigation of Lupron (www.redflagsweekly.com), as well as the NLVN, myself, other victims, and media such as FOX News and Dateline, have challenged TAP to produce data and to answer questions -- but there has been no response from TAP. The FDA was to take another look at its damaging 1999 review, but no word has been heard. The NIH just conducts more Lupron studies, while shielding consumers from its webpages for its Hazardous Drug List and Material Data Safety Sheets (MSDS). The MSDS for Lupron, available to all hospitals and healthcare institutions, states that leuprolide acetate is “hazardous per OSHA criteria”, and identifies that “women of childbearing potential must be excluded from working directly with product.” This is information necessary for consumers to make an informed decision about ‘treatment’ with a hazardous, toxic substance. Questions were posed to several NIH Lupron investigators inquiring whether their Lupron trials followed NIH and OSHA guidelines in use of protective gear for healthworkers administering Lupron, and these questions were responded to by several NIH investigators - however, the replies do not answer the question as to whether NIH Lupron clinical trials follow NIH guidelines (personal communications). More than thirty years after the debacle of DES, the CDC (in 2003) began a campaign to inform people about the potential health effects of DES (www.cdc.gov/DES). The CDC’s annual report of fertility clinic data has been questioned in the past, and issues regarding its reliability have again been raised, pointing out its “lack of reliable information”, citing data that is up to 3 years old, and clinic success rates that are “too easy to fudge” (Report, 2002).

In one aspect of my ‘fertility treatment nightmare’, the dates and details of an office visit were deliberately altered in the computer through collusion and deliberative machinations by several of the defendants in my case - and my HMO had steadfastly denied that I had ever received treatment or prescriptions on that date (Millican v. Harvard Community Health Plan, Boston IVF, Natalie Schultz M.D., Brian Walsh M.D., Mahmood Niaraki M.D., Selwyn Oskowitz M.D., Michael Alper M.D.; see also Donahue, 1996). Given the ease with which my computer record data was deleted and altered, along with numerous other experiences, as well as the known fraudulent Lupron data, and recent newsreports on fraudulent research elsewhere, “data” coming from self-interested parties should always be viewed as potentially unreliable, to say the least.

A few more comments from Gena Corea’s supportive statement for my lawsuit are pertinent here: “After discussing the death of a woman in the IVF program in a Seville clinic with Dr. Francesca Martinez of the IVF program at Instituto Dexeus in Barcelona, Spain, I said to her: If

it's so difficult for you, who are practicing IVF, to find information on women who died of IVF, how can you say what the risks of IVF are? She replied that she and her colleagues knew what happened in their own center and they had many cases -- 2,000. So she is telling potential IF candidates what the risks of IVF are based on her own clinic's experience. This is a pitiful situation." And Gena concludes by saying "I don't know what will happen with Ms. Millican's complaint. What often occurs in such situations is that women, with only their own limited financial resources, without even an attorney, doing the labor themselves when they come home tired from their jobs, seek justice. Few can do it. Few can break silence on the abuse to which they have been subjected. But it is vital to talk back, to insist one's reality into the fictional never-never land of miracle babies and ecstatic, unharmed mothers. I applaud [those women] for speaking [t]he[i]r truth."

The answers do not lie in continued exposure to Lupron, which would definitely occur should the Senate pass any bill allowing therapeutic cloning research Does Lupron sound like the kind of drug you want to give to young healthy women who are 'offering' to donate eggs? Does Lupron sound like the kind of drug you would want to take for any benign condition, without informed consent? It appears that the majority of women whose eggs are harvested use Lupron. How many women know Lupron has never been approved for fertility? How many women know the facts and the tragedies mentioned in these pages? If millions of women are needed to meet the demand for research 'material', what will these women be told? My advice to them is - instead of asking questions to the Industry ... read the Congressional Record.

(13) A Request To Congress Asking For An Investigation Into Lupron and ART:

In closing, the data in this paper barely scratches the surface of problems associated with Lupron and ART, and Committee members should know that there are unknowns and redflags beyond those described in this submission. Time limits did not permit further detail or elaboration, and wish to add that any references or further information are available upon request.

For all of the above stated reasons, I would respectfully urge the Committee to ban reproductive and therapeutic cloning.

And I would like to also respectfully urge the Committee and Congress to undertake a formal investigation into Lupron and its victims, as well as investigating the long and short term safety of ART drugs and procedures on women and offspring.

Respectfully submitted,

Lynne Millican

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