COMMONWEALTH OF MASSACHUSETTS
SUPREME JUDICIAL COURT
SUFFOLK COUNTY

On Appeal from Appeals Court

DOCKET NO. 98-P-1472

PLAINTIFF'S PETITION FOR FURTHER APPELLATE REVIEW

Lynne Millican, R.N., pro se
Appellant (Plaintiff)

Vs.

Harvard Community Health Plan
Natalie Schultz M.D.
Brian Walsh M.D.
Mahmood Niaraki M.D.
Boston IVF
Selwyn Oskowitz M.D.
Michael Alper M.D.
Appellees (Defendants)

APPELLANT'S PETITION FOR FURTHER APPELLATE REVIEW

Pursuant to Rule 27.1 of Mass.R.App.P., the plaintiff appellant petitions the Massachusetts Supreme Judicial Court for leave to obtain further appellate review.

I. Prior Proceedings ...

II. Statement of Facts ...

... In January 1990, plaintiff learned from the lupron study group at Brigham & Women's Hospital ("B&W") that her lupron should have been discontinued months prior to IVF. (Appendix Page No. [App.].255,836) And beginning in 1990, plaintiff was diagnosed with a plethora of health problems, including, but not limited to, tumor. (App. 446,385-97) Also in 1990, she and another drafted and prompted H.3477, An Act Relative to the Treatment of Infertility. (App.405) This bill, first presented to the MA. Health Care Committee in 1992, would mandate informed consent of the risks of IVF and its drugs; and remains without passage.

In 1994, the plaintiff learned there was a National Lupron Victims Network. Since that time the plaintiff has received an **alarming number** of affidavits from other similarly afflicted lupron users, who, like

plaintiff, are unable to obtain counsel or expert opinion, (i.e., App. 499,502,503) The plaintiff has learned that lupron is a biologic agent, and an "antineoplastic/"other", with permanent side effects. (App.14,342,353,501) And the plaintiff has learned the National Institutes of Health, and Occupational and Safety Health Administration, refer to lupron as a "hazardous drug"; and that the California Environmental Protection Agency refers to lupron as a "reproductive and developmental toxicant".

Ill. Points Relied Upon for Reversal

1) The risks of assisted reproductive technologies and lupron claimed in the matter at bar present issues of first impression, which if decided, would formulate case law to guide the court in applying remedy to other similarly situated plaintiffs. ...

4) Since "hired gun" doctors in medical malpractice cases are commonplace in the courts, there is an unexplainable inability to obtain relief for plaintiff and similarly situated plaintiffs because of lack of counsel and medical expert who will testify.

5) Because of the existence of conflicts of interest, academic/industrial ties, scientific misconduct, lax post-marketing surveillance, dominated by pharmaceutical powers, as reflected in plaintiff's case, this matter requires resolution by this Court.

IV. Argument

#1. ... To plaintiff's 1993 question regarding lurpon's experimental status, Defendant Niaraki responds "[t]he side effects [to lupron] are minimal". (Ans. #23, App. 735-6,522-3,304). Information belatedly learned by plaintiff shows that Defendants opinions regarding lupron are "general and accepted" opinion - however "there are precautions so imperative that even their universal disregard will not excuse their omission." TJ. Hooper, 60 F.2d 737 (at 740) ... According to 1992 testimony before the Subcommittee on Health and the Environment, U.S. House of Representatives: "Promoters of medical services, including infertility services, who misrepresent their success, or WHO DECEIVE CONSUMERS AS TO THE SAFETY AND EFFICACY OF THE SERVICES THEY PROVIDE, put themselves at risk for challenge." (Emphasis added)

#2. ...

#3. ... The Appellate Court held that "[b]y August, 1989,[plaintiff] knew that she was experiencing severe side effects which she attributed to Lupron." (slip op at 6) Plaintiff's August 1989 letter to board, and its enclosed July 1989 letter to Defendant Schultz (App. 260) ("letters"), identify that she [was told] estrogens added to lupron may have eased her side effects; and that the "side effects from the injectable Lupron were intolerable (specifically insomnia and to a lesser extent hot flashes)" (App. 258) and were "a complaint [she] ha[d] never voiced before, and a ***complaint consistent* with *Lupron side effects***", (emphasis added) (App. 286)

But had Defendants Schultz, Walsh, Oskowitz, and Alper informed her that lupron is a hazardous drug, she would **never** have consented to treatment. (PI. Br. 37) Plaintiff's letters reported the side effects she **was informed** to expect; they do not contend she was treated without consent or with hazardous substances. (Pl.Br.36-7; Pl.Reply Br.10,12-3;App. 106,110-2 [contrast with statement by Dr. Kemmann within the 101st Congressional Hearing, in which lupron is described in March 1989 as "costly, experimental medication"])

In January 1990, plaintiff learned that the way lupron was used in her fertility treatment was inappropriate. (Pl.Ans. #17, App.836; Ans. #12, App.375) ... Years passed before she learned lupron is a "hazardous" "biologic agent", (App.110-1), but the event putting plaintiff on notice of injury occurred in January 1990. In 1989 she 'knew' lupron 'caused' her "menopausal" side effects; however, following research in 1990, she learned her symptoms were not 'hormonal' but rather due to a "hypophysectomy". (Stedman's, 1982, p.682]: "Excision or destruction of the pituitary gland")(App.645) ... None of the defendants ever suggested to plaintiff that lupron was experimental: all defendants deny lupron is experimental (PI. Br. 36-7). ... Defendant Boston IVF's brochure given to plaintiff declares "The adverse reactions that have been described with Lupron have occurred in ill patients with prostate cancer". (App. 578) Defendant Oskowitz reasons "women do not need to know about the lack of FDA approval [for lupron in fertility treatment] since Lupron is so widely used." (App.304,307,294) See also Stone v. Regents of the University Of California. 77 Cal.App.4th 736, for "refusal" to "provide information" on consent in IVF.

Plaintiff belatedly learned that FDA Adverse Event reports prior to her 'treatment' revealed serious side effects in young healthy women using lupron, and that "clinical studies for [the "efficacy" of] Lupron's use in treating infertility have been discontinued". "Safety" studies are not mentioned. (App.816a&b,355,358) "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each." Canterbury v. Spence, 464 F.2d 772, 780-81 (D.C. Cir. 1972), cert, denied, 409 U.S. 1064 (1973).

#4: THE APPELLATE COURT ERRED IN AFFIRMING THE TRIAL COURT'S ORDERS TO DISMISS BECAUSE EVIDENCE WAS NOT VIEWED IN THE LIGHT MOST FAVORABLE TO PLAINTIFF

In rulings on motions to dismiss, allegations as well as such inferences as may be drawn are to be taken as true. Summary judgment is not appropriate where trial, with its opportunity for cross-examination and testing credibility of witnesses, might disclose picture substantially different from that given by affidavits. U.S. v. Perry, 431 F.2d 1020 (1970), M.R.C.P. Rule 56, Reporters Notes. The introduction of material controverting the moving party's assertions of fact raises a genuine issue of material fact, precluding summary judgment. In this case, plaintiff claimed, among others, that she was treated without consent and submitted supportive documentation.

The plaintiff's matter before the trial courts involved issues of first impression affecting the public health and welfare. In a similar case, AZ v. BZ, 431 Mass. 150, - N.E.2d - (2000), this Court scrutinized consent forms for disposition of embryos in view of husband's lack of informed consent to paternity, and found them "legally insufficient", (at 159} (See also impounded complaint 'X' v. Boston IVF & Oskowitz', in which embryo transfer to estranged wife was performed without the consent of her husband) A Family Law Journal reporting on the AZ case pointed out that there is an inherent duty to "walk [patients] through the paperwork", and it concluded that informed consent is "grossly absent" when there is no "counseling around and about the forms to be contemplated and signed". 14 MA Fam.L.J.113,114 (1997)

However, AZ was silent on whether these impounded forms include

language on the **health risks** of IVF/drugs to the women, such as plaintiff, who produce the eggs in the first place. Plaintiff has shown that **NO CONSENT FORM** for risks of IVF and/or the drugs she took was ever provided to her. In her post-1990 requests for IVF consent forms, and guidelines and information on lupron, she was advised that "no such documents" exist. (App.482: Responses #2,11,27,48-54) Moreover, the holdings that a women's bodily integrity is not involved once her eggs are removed fails to weigh the **permanent** and adverse **alterations** in health ***after*** the use of lupron and IVF. (App.526,499,304) Davis v. Davis. 842 S.W.2d588 (Tenn. 1992), Kass v. Kass. 696 N.E.2d 174 (NY 1998), Roe v. Wade,410 U.S. 113 (1973)

Plaintiff belatedly learned that the FDA sanctioned the illegal promotional campaign of lupron in 1989, and no Defendant "recalls" attending any industry meetings. (App.307,692) Defendant Alper "do[es] not recall exactly what [he] discussed with the Plaintiff" regarding risks. (Ans.#28, App.691) A peer of defendants, a lead investigator for lupron from B&W, was found guilty of "falsifying and fabricating 80% of data" in peer-reviewed, published lupron articles. (App.293) And that Defendant Schultz, in 'IVF orientation' in 1989, collaborated with a TAP Lupron Medical Advisor for a 1990 publication. (App.566-7,559 [#11]) The plaintiff would ask this Court to take judicial note of recent news coverage on lupron. Senator Kennedy was quoted in Fox News' November 24, 1999 story, stating "Fox 25's 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." On April 12, 2000, the Boston Globe reported an indictment of a physician for conspiracy to commit fraud involving lupron billing, and the continuing grand jury investigation involves other physicians in at least 6 other states, including MA. The Chicago Tribune reported April 26, 2000 that inducements from TAP included "a physician employed by a health maintenance organization [that] was offered $65,000 to switch [to lupron]". [Plaintiff's HCHP's pharmacy reports show they falsely double-reported her lupron prescription for 6 of the 7 months. (App.p322)]

Moreover, plaintiff would ask this Court to take judicial notice of the pending trial of a woman who had a stroke, among others, during and after 'lupron with add-back estrogen therapy' in which her medical expert opined that her damages are due to causes other than lupron; and this medical expert is a 13-year Abbott Consultant. (Docket 97-3725, Suffolk County, 'Kuha v. Friedman'). See FDA reports on 'cardiovascular accident' with lupron (App.522)

Plaintiff has raised issues of conflicts of interest, and questioned Defendants' rationale for prescribing lupron. (Pl. Reply Br.14; App.192-8) Defendant Walsh alleges that plaintiff's endometriosis was treated with lupron due to its "pain-relieving effect", yet he provided opiods and a "referral to the pain service" months into her treatment. (App.193[Ans.#9],176) In addition, FDA documents for Lupron Study M86-031 show that "43% of placebo patients had pain improvement", facts that are material to informed consent.

Plaintiff submitted to tribunal and Appellate Court the MA. Dept. Of Public Health's reference to the "hazardous" nature of lupron's diluent. (App.361). Her appendices and exhibits submitted to trial courts were sufficient pursuant to M.R.C.P. Rule 56 and M.G.L. c.231 S60B. Defendant Walsh, on the Committee for the Protection of Human Subjects from

Research Risks in 1989, edited one of the journals within her offer, thereby qualifying it as proper under statute. (App.201) Murawski v. Laird, 116 N.E.2d 279 (MA. 1953) Plaintiff's offers were sufficient to raise the issue that she was treated with lupron inappropriately and without consent, and that defendants' summary judgment was precluded in accordance to M.R.C.P. Rule 56 and the standard established in Kourouvacilis v. General Motors, 410 Mass. 706, 575 N.E.2d 734 (1991). Furthermore, plaintiffs averments are admitted by defendants through their failure to deny. Rule 8(d)

Moreover, Defendants claims of lupron's "menopausal" action does not correlate with known science. (App.290/293) And studies for lupron's use in IVF were "discontinued". (App.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 y. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579,113 S.Ct.2786,125 L.Ed.2d469 (1993), Commonwealth v. Lanigan, 419 Mass. 15 (1994), Commonwealth v. Vao Sok, 425 Mass. 787 (1997) (Pl. Brief p.39; see also App.438-9,446,522-23,106,290,293-4,307-11,342-3,345-6,349,353,358,385-97).

Therefore, the Appellate Court erred in affirming trial court's orders to dismiss all Defendants. And plaintiff prays for a righteous and just remedy by this Honorable Court.