No. 13-542

In The
Supreme Court of the United States

KARIN KLEIN,PETITIONER; Individually and
On Behalf of All Others Similarly Situated,
v.
TAP PHARMACEUTICAL PRODUCTS, INC.,
AND ABBOTT LABORATORIES,
RESPONDENTS

On Petition For Writ of Certiorari
to the United States Court of Appeals
for the Ninth Circuit

MOTION OF LUPRON VICTIMS HUB FOR LEAVE TO FILE AN AMICUS CURIAE BRIEF AND AMICUS CURIAE BRIEF IN SUPPORT OF PETITIONER KARIN KLEIN AND OTHERS SIMILARLY SITUATED

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Pro Se for *Amicus curiae*

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MOTION OF LUPRON VICTIMS HUB FOR LEAVE TO FILE AN AMICUS CURIAE BRIEF

Lynne Millican ("Millican"), founder of Lupron Victims Hub, ("LVH") respectfully moves the Court for leave to file an *amicus curiae* brief in support of Petitioner Klein, and in support of all others similarly situated, pursuant to Sup. Ct. R. 37.2. Notice of Intent to File Amicus was sent to all parties on November 20, 2013. This motion and *amicus curiae* brief is timely filed pursuant to Rule 37 and Rule 29; and in the format pursuant to Rule 33.2. Petitioner and counsel of record, Mr. Derrick, agreed to *amicus.* To date Respondents have not responded as to consent.

Millican requests the opportunity to present an *amicus curiae* brief in this matter due to extensive knowledge regarding the drug "Lupron" and it's effects and history, as a result of 24 years of research, patient advocacy, education, and support for Lupron Victims nationwide; including testifying yearly in various Massachusetts legislative committees 1992 – 1999 on Lupron's risks, invited to testify in Congress on Lupron's risks in 2002 and 2003; serving as a resource for academics, media and attorneys; prompting the first print media, first televised media, and first internet investigations into Lupron's risks, and founding LVH website in 2008, *inter alia*.

STATEMENT OF FACTS

At stake in the Klein matter are issues of due process in the context of deceitful, misleading, and inaccurate medical expert testimony on the risks of Lupron, and in the context of Respondents' and/or its agents' history of corporate and clinical malfeasance. 'LVH' is uniquely positioned to provide information and assist the Court in understanding the serious health and public interest, and case law ramifications, that require the Court's intervention.

As illustrated in the record of Klein v. TAP/Abbott, physicians and TAP/Abbott *do not* provide accurate information about Lupron's risks, and in fact *deny risks* that are already documented by the FDA and known by Respondents as acknowledged adverse events to Lupron. This is a very serious situation that has broad and deleterious medical and legal ramifications, especially considering that Lupron has become the 'standard of care' and is widely prescribed in many gynecological conditions. This bewildering dichotomy of actual Lupron risk

information vs. disinformation (uttered in doctors' offices and *now* in the Klein courts) underlies the Klein v. TAP/Abbott matter. Moreover, it highlights the obfuscation evidenced by the pattern found in the Klein record whereby there was complete shackling of Petitioner's evidence which would show jury the known and scientifically correct information on Lupron's risks.

BROAD IMPACT – PUBLIC INTEREST MATTERS

There are tens of thousands of Lupron victims nationwide – thousands have been requesting an investigation by Congress (beginning in 1994); and social media sites and internet searches of medication review websites for the drug "Lupron", will reveal the extent of the grievous medical, psychiatric, financial, and societal damage that Lupron has left in it's wake - including disability and death of young, previously healthy, women; and the ramifications upon families who must emotionally, physically and financially support the disabled Lupron victim. The 'silent' epidemic of Lupron victims is not widely known because Respondents' TAP/Abbott have a history of settling all prior Lupron litigation with secrecy agreements, as well as creating the choreographed apparition of "safety and efficacy" for Lupron to the medical community.

When consumers are irreversibly harmed from drugs such as Lupron, and the Courts, as in the matter at bar, allow scientifically false information on the risks of Lupron to be heard by the jury (and uttered in rulings by Ninth Circuit Court) while simultaneously refusing to allow the jury to hear the facts (known and documented Lupron risks of which Petitioner suffers) – a grave injustice has occurred, and the Court must intervene.

As a result of extensive independent research into the risks of Lupron since 1989, the 'LVH' website is a 'clearinghouse' for Lupron victims who seek answers, advice, support (emotional and financial), and direction for medical care and legal options. 'LVH' attempts, pro bono, to educate the public and professionals alike to the known risks of Lupron to men, women and children (risk information not readily found elsewhere) striving for the protection of the public interest through encouragement of transparency, accountability, and oversight in healthcare matters related to Lupron.

BACKGROUND of MILLICAN, 'LVH'

For a brief personal background: Prior to Millican's own prescription of Lupron for endometriosis and IVF (In Vitro Fertilization) in 1989, Millican was a career, full-time psychiatric registered nurse. Since 1989, post-Lupron, Millican experienced a multitude of medical problems, including being hospitalized 60 times since 2003 (at which point Millican became disabled due to 'gastroparesis' [neurological impulses to gut have been paralyzed from Lupron {and gastroenterologist has treated other Lupron-induced gastroparesis patients}], and have had arthritis and severe osteoporosis, *inter alia*). In full disclosure, Millican's paralegal certificate was obtained after filing a1992 pro se medical malpractice litigation related to Lupron (denied[1]), and Millican's sole paralegal experience was in 2002 as an RN/paralegal consultant hired to conduct discovery in Abbott's Lupron files (class action case settled, with secrecy agreement).

All other efforts, spanning 24 years, have been done pro bono, and done concomitant with serious health limitations. 'LVH' is not incorporated, does not receive

[1] http://www.lupronvictimshub.com//lawsuits/SJCbrief.doc

any funding from any source, has no parent corporation, has no stocks, and is a basic website that receives tens of thousands of hits each month (including from attorneys, courts, governmental agencies, and academia), and there is a steady stream of Lupron victims detailing their 'nightmare' and who are in need of much help.

Because of 'LVH's' informational content (all sourced and cited), Millican has received significant praise from the National Women's Health Network's editor, attributing and citing Millican's "research … work … articles … excellent website"[2]. Admittedly, the 'LVH' website needs organization, but because, as the Petitioner and others similarly situated would testify – "when life irrevocably changes post-Lupron, and consists of navigating serious chronic illnesses and it's attendant adjustments and financial morasses, one is simply unable to function as in the past and as one would prefer". And so, given the serious health crisis associated with Lupron, 'LVH' will continue to attempt to expose the serious iatrogenic (medically/pharmaceutically-induced) effects of Lupron to the best of it's ability; and prays that this Court will take note of these serious matters, and in the light of the matter at bar. To emphasize: 'LVH' is attempting to provide information and clarity to the Court regarding several Lupron issues, matters which are not found within Petitioner's or Respondents' briefs.

NINTH CIRCUIT COURT MISSTATED FACTS AND LAW

The issues presented in this case – did petitioner receive a fair trial where all probative evidence of Lupron's risks was excluded by trial judge and where Ninth Circuit misstated the facts and law regarding

[2] http://nwhn.org/lupron%C2%AE-%E2%80%93-what-does-it-do-women%E2%80%99s-health

Lupron; and does a jury deserve to know that Respondents knew of risks suffered by Petitioner but had removed warnings of these risks from the Lupron label provided to Petitioner – have profound ramifications upon Petitioner Klein, Lupron victims in particular, and society in general.

JUSTICE DENIED TO LUPRON VICTIMS SHIFTS COST OF DISABLED LUPRON VICTIMS TO U.S. GOVERNMENT FUNDED PROGRAMS

Many Lupron victims are attempting to access legal remedy for their disabling conditions and financial devastation. Many disabled Lupron victims are forced to turn to state and local governments for assistance (Medicare, Medicaid, SSI, SSDI). The government has a vested interest in assigning TAP/Abbott as the tortfeasor and as the responsible party for Lupron injury remedy. Klein v. TAP/Abbott is crucially positioned for precedence, and the Court's ruling will have bearing upon a large class of similarly situated plaintiffs, as well as a bearing on the U.S. government's coffers.

At stake in the Klein matter are issues of due process in the context of deceitful, misleading, and inaccurate Respondents' TAP/Abbott medical expert testimony on the risks of Lupron, and in the context of Respondents' history of corporate and clinical malfeasance. Lupron Victims Hub is uniquely positioned to provide information to assist the Court in understanding the serious health, public interest, and case law ramifications that require the Court's intervention. I pray the Court allows 'LVH' to provide input on these serious matters.

Wherefore, Lupron Victims Hub respectfully requests that its motion for leave to file an *Amicus curiae* brief be granted.

Respectfully submitted,

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES Page

U.S. CONSTITUTIONAL LAW

STATUTES

RULES

REGULATIONS

GOVERNMENT PROGRAMS

LEGISLATIVE MATERIALS

[3] http://articles.baltimoresun.com/2010-12-06/health/bs-md-senate-stent-report-20101205_1_midei-stent-abbott-laboratories

LAWS

MISCELLANEOUS

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[4] http://www.lupronvictimshub.com//history/TAP_RTP_Memo001.pdf

[5] http://open.nysenate.gov/legislation/bill/A6386-2011

[6] Dr. David Redwine. Review of Lupron submitted to FDA: 'Leuprolide – the "D" is Silent'. © 2011. [(Link to Dr. Redwine's report was supplied in this footnote in *Amicus curiae* sent to Court on November 29, 2013, however, per Dr. Redwine's wish to temporarily withhold the public posting of this link, the link has been removed from this footnote for the time being.)]

[7] www.lupronvictimshub.com

[8] http://www.petition2congress.com/1902/investigation-lupron-side-effects-leuprolide-acetate/

[9] http://nwhn.org/lupron%C2%AE-%E2%80%93-what-does-it-do-women%E2%80%99s-health

[10] http://www.lupronvictimshub.com//home/Millican03CongressionalTestimony.doc

[11] http://www.lupronvictimshub.com//docs&corr/SenateHELPcmtte04_02.doc

[12] http://www.lupronvictimshub.com//home/USAdraft.doc

[13] http://www.lupronvictimshub.com//docs&corr/LUPRNSUQok.doc

INTEREST OF AMICUS CURIAE[14]

Lupron Victims Hub ('LVH") serves as a clearinghouse for medical professionals, academics, attorneys, and the media for information on the history and risks of Lupron – but it is the contact from Lupron victims (nationwide, and from other countries) and their need for support and medico-legal advocacy, such as Petitioner Karin Klein in the instant case, that embodies the interest of *amicus curiae*.

'LVH' was founded in 2008 by a Lupron victim, Lynne Millican ("Millican"), and is located in Boston, Mass. 'LVH' has an intense interest in the Klein matter because of the important legal issues; and specifically because the deceitful facts, uttered under oath by Respondents' expert medical witness - which are demonstrably and scientifically incorrect and damaging – are legally, ethically, and medically unacceptable, and will have profound impact upon all other Lupron victims and the public at large.

The Respondents have a long, documented history of deceitful, illegal, unethical, and criminal behavior that should be taken into consideration in the Klein matter. In 2001, TAP paid $875 million, the highest fine in history at the time, for its fraudulent marketing scheme to promote sales of Lupron, involving violations of the False Claims Act, 31 U.S.C. §§ 3729, in a landmark case highlighting TAP's monetary incentive schemes to physicians to boost Lupron sales.

[14] Pursuant to Sup. Ct. R. 37.6, amicus certifies that no counsel for a party to this action authored any part of this amicus curiae brief, nor did any party or counsel to any party make any monetary contribution to fund the preparation or submission of this brief.

Significant anomalies noted within FDA FOIA documents describing TAP/Abbott's clinical trials for FDA approval of Lupron Depot 3.75 mg (herein 'Lupron') for the indication of 'pain management in endometriosis' were brought by Millican to the attention of the Assistant U.S. Attorney[15] prior to TAP's 2001 settlement with the U.S. Department of Justice[16], to no avail.

In 2011, Petitioner Klein's medical expert at trial, Dr. David Redwine (a world renowned endometriosis surgeon) had access through discovery to the unpublished, raw data from these clinical trials (data which remains under seal). Incidental to the Klein matter, and independently, Dr. Redwine conducted an exhaustive review of Respondents' TAP/Abbott's clinical trials' raw data, and submitted a detailed, alarming, 300-page review to the FDA in 2011, advising the FDA to "remove Lupron from the market immediately" - and Dr. Redwine suggested the "United States Department of Justice should consider examining this issue in further detail".[17]

Lupron victims have historically been told "your [X,Y,Z symptoms/diseases] have nothing to do with Lupron" – even when those very symptoms and diseases are already acknowledged by the FDA and Respondents as adverse events to Lupron. Thousands of Lupron victims have petitioned Congress to investigate the adverse effects of Lupron – to no avail.[18] In 2010, the FDA conducted a safety review of Lupron's use in men

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[15] http://www.lupronvictimshub.com/home/USAdraft.doc
[16] http://www.justice.gov/opa/pr/2001/October/513civ.html .
[17] Redwine, supra. at 6.
[18] Petition2Congress: http://www.petition2congress.com/1902/investigation-lupron-side-effects-leuprolide-acetate/act/ . See also Millican requests in 1999, 2002, 2003 @ http://www.lupronvictimshub.com//links.html, and see also http://www.lupronvictimshub.com//home/Kennedy94let[1].doc .

only, and enacted label changes to warn of the risks of diabetes, heart attack, sudden cardiac death and stroke.[19]

The 2011 review of Lupron's use in women for endometriosis sent to FDA by Dr. Redwine details "an unacceptable risk-benefit analysis" and included gross evidence of data manipulation, and "definitive evidence of long-term damage to ovarian function … resulting in a body-wide premature aging process that would explain many of the long-term symptoms that many women experience after Lupron therapy"[20]

Should the Klein jury verdict for TAP/Abbott be upheld, with no legal remedy available for correcting the misinformation provided to the Klein jury and to the Court, what other avenue is there to ensure that other Lupron (or any drug) victim will access justice, remedy, and truth in labeling?

TAP/ABBOTT'S LUPRON MISINFORMATION PUTS CONSUMERS AT RISK

Lupron Victims Hub, and all Lupron victims, have an enormous and inherent interest in raising awareness of the Court to the data manipulation and deceitful machinations of Respondents' TAP/Abbott, and of the resultant marginalized plight of Lupron victims. A Kafkaesque milieu exists whereby most physicians are unaware of and deny Lupron's risks ("the success Abbott has had in deceiving the profession [is] by hiding unfavorable data and manipulating data, aided and abetted by paid 'experts' who influence the profession"[21]), and in which Congress and DOJ and FDA's failure to

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[19] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm209842.html

[20] Redwine, supra. at 6.

[21] Redwine, supra. at 6.

substantively act for the protection of the consumer, and the Courts allow, affirm -- and are oblivious to -- the dis-information campaign of Lupron's alleged 'safety and efficacy'.

Lupron Victims Hub is interested in exposing the true risks of Lupron, and to assuring the rights of Lupron victims to truthful and accurate risk information, and to the rights of due process and a fair trial. Appropriate medico-legal health care policy that has transparency, accuracy, and the public's health interest is imperative in a climate of corporate malfeasance and government oversight agencies' inaction. Therefore, the Court's ruling on behalf of Petitioner Klein is crucial.

STATEMENT OF FACTS

Amicus incorporates by reference the statement of facts set forth in Petitioner Klein's Brief.

Briefly stated, in 2005, 17-year-old Petitioner Klein received 6 injections of Lupron 3.75 mg, with the accompanying 2005 Lupron 3.75 mg label lacking any mention of thyroid disorder or serious bone density loss adverse events. Petitioner Klein suffered serious thyroid disorder and bone density loss issues post-Lupron. TAP/Abbott, in pre-2005 Lupron 3.75 mg labels, and in post-2005 Lupron 3.75 mg labels (domestic and foreign), ***had*** warned of thyroid disorder and serious bone density loss adverse events, but TAP/Abbott removed this warning for the 2005 label.

Moreover, Petitioner Klein's Opening Brief, 6-6-12, (Addendum B-1, Lupron label 1995) shows Respondents' TAP/Abbott's 1995 Lupron label indicating a change in

bone density of "13.2%", but the 2005 label provided to Petitioner Klein was altered to display a change in bone density of "3.2%" (Klein Reply Brief, 4-8-13, Addendum B-5, Lupron label 2005).

ADMISSION OF THYROID DISORDER & SERIOUS BONE DENSITY LOSS EVIDENCE WRONGFULLY EXCLUDED BY TRIAL COURT, MISLEADING JURY

At trial, Petitioner was prevented from presenting to the jury any pre-2005 or post-2005 Lupron 3.75 mg labels acknowledging thyroid disorder and serious bone density loss adverse events, and the trial judge only allowed the jury to consider the 2005 label which lacked the warnings. Respondents' principal expert Dr. Blackwell[22] , under oath, falsely stated that "There are no receptors for GnRH. … Therefore, *it is biologically impossible* for Lupron to affect the thyroid gland. No textbook, no article has ever supported that contention. *It's simply biologically impossible."* (emphasis supplied). (8/5/2011 PM Tr. at 818:5-10).

The trial court wrongfully excluded critical failure-to-warn evidence, which would have proven that Respondents' TAP/Abbott was on notice of thyroid disorder and serious bone density loss with prior Lupron labels, MedWatch adverse event reports and scientific medical journal articles.

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[22] Dr. Richard Blackwell has a history of receiving TAP grant monies to study Lupron – see 'Birmingham Center': http://www.ncbi.nlm.nih.gov/pubmed/?term=Leuprolide+Study+Group+1991+Obstetrics+and+Gynecology+77+(5)%3A720&report=medline&format=text . Note latter study's lead investigator, Dr. Andrew Friedman, was found guilty in 1996 of fabricating and falsifying approximately 80% of data in 4 Lupron studies – http://www.lupronvictimshub.com//home/FedRegister5_1_96.doc . See also Millican 1995 MA. testimony identifying manipulated study data in a separate Lupron Friedman study (p.5): http://www.lupronvictimshub.com//docs&corr/Testimony95.doc

Upon appeal to Ninth Circuit Court, no abuse of discretion in excluding from evidence Respondents' non-2005 Lupron labels was found "because they all contained information regarding the side effects of *different* formulations of Lupron, rendering them insufficiently relevant, unduly prejudicial, and likely to confuse the jury". (emphasis supplied). (App. 2, citing Fed. R. Evid. 403). But the prior Lupron labels were all the same formulations and dosage as used by Petitioner – "Lupron Depot 3.75 mg.".

Petitioner Klein filed a timely Petition for a Writ of Certiorari on October 28, 2013.

Respondents' TAP/Abbott and/or its agents have a long history of unethical and illegal behavior, ranging from criminal Conspiracy to Violate, Illegal Remuneration, Sale of Drug Samples, Aiding and Abetting[23]; Perjury, Obstruction of Justice[24]; Violations of the False Claims Act (31 U.S.C. §§ 3729); and charges of "collusion and bid rigging" by the Federal Trade Commission[25], *inter alia.*

In order to understand how Lupron has become widely prescribed and the 'standard of care', it must be noted that Respondents' TAP/Abbott and its agents have a long history providing unethical bonuses to physicians and Lupron sales representatives and their managers:

> "Cash prizes, products, trips [including 'Excalibur'], … The Excalibur party was awarded annually to the top 30% of the TAP sales force … At times in the 1990's, the annual budget for the Excalibur party exceeded $4,000,000. Medical marketing specialists were employed by TAP to work with Lupron sales representatives, in part for the purpose of

[23] U.S. v. MacKenzie, et al. Criminal NO. 01-CR-10350-DPW. District of Mass.
[24] U.S. v. Richardson. District of Mass. Criminal No. 94- .
[25] http://www.leagle.com/decision/19941379853FSupp526_11280

> providing things of value to physicians. TAP employed specialty sales personnel to call upon institutional customers, including hospitals and health maintenance organizations[26]."

The 2000 Commerce Committee Hearings revealed TAP's profit scheme for doctors： If a physician had 60 patients, TAP proposed 'If all your patients were on Lupron, you would earn "$105,011.40 annually."'[27] Petitioner's expert witness Dr. Redwine identified in his written expert testimony that he refused this offer from TAP, especially since his practice had encountered women who presented with post-Lupron health problems (a total of 750 women with post-Lupron problems would eventually present themselves to Redwine's practice). Dr. Redwine was refused by the trial judge to testify to his knowledge and experience with women experiencing post-Lupron problems, denying Petitioner Klein due process and right to a fair trial, in violation of Amendment V and VII.

In one Lupron Qui Tam Complaint[28], statement #32 stated "By reason of these defendants' practices, as aforesaid, urologists have been induced to purchase Lupron [redacted] rather than recommending less expensive procedures, such as surgery." Another Lupron Qui Tam Complaint made it clear that the 'scheme' would be inclusive of gynecological Lupron purchase as well.[29]

In this latter complaint, it is stated that "Lupron 3.75 mg is *indicated for the treatment of* gynecological conditions, such as endometriosis, uterine fibroid tumors and ***infertility***."[30] (emphasis supplied). The U.S. was deceived here in the same manner as the consumer

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[26] US District Court, District of Massachusetts; Criminal No. 01-CR-10350-DPW.
[27] Supra. at 4.
[28] U.S.A. ex rel. Durand v. TAP Holdings, Inc. Civil Case No. --, filed 5-6-96
[29] U.S.A. ex rel. Gerstein and Tufts v. TAP Holdings, Inc., and TAP Pharmaecuticals. 98CV10547GAO
[30] Ibid.

receiving 'information' from Respondents related to Lupron: – neither Lupron 3.75 mg (a long-acting formulation), nor any other formulation of Lupron, is 'indicated', or approved by the FDA, for the treatment of infertility. According to the FDA and Respondents' Lupron product label, Lupron is a Pregnancy Category X drug ("any woman who is or who may become pregnant should not use")[31], according to OSHA, Lupron (leuprolide) is a "hazardous drug"[32], and Lupron (leuprolide) is a "recognized reproductive toxicant" and a "recognized developmental toxicant."[33] *Yet,* by 1990, 97% of assisted reproductive technology (ART / IVF) cycles were utilizing GnRH [gonadotrophin-releasing hormone] analogs, of which Lupron was (and is) the most frequently prescribed.

Millican, unaware of any profit incentive schemes, warned in written testimony to Mass. Health Care Committee in 1992 "... nearly every IVF clinic has mandated that women take Lupron - or they will not be allowed to [IVF] cycle ... they must use Lupron."[34] Yet, 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." [35]

Here again, as in the field of endometriosis, an entire field of medicine (ART) has been built and predicated upon the false premise of Respondents' TAP/Abbott's Lupron's "safety and efficacy". The

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[31] http://www.rxabbvie.com/pdf/lupron3_75mg.pdf
[32] https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html#app_vi:2_1
[33] http://scorecard.goodguide.com/chemical-profiles/summary.tcl?edf_substance_id=74381-53-6
[34] Testimony, Lynne Millican, to MA. Health Care Committee, 3-9-92: http://www.lupronvictimshub.com//docs&corr/MAtest92.doc
[35] Hotz, RL. Designs on Life. Pocket Books, New York. 1991. p.67.

corporate culture and history of Respondents' must be born in mind in light of the matter at bar.

TRIAL COURT PREVENTED JURY FROM RECEIVING PROBATIVE EVIDENCE ON THE RISKS OF LUPRON

Respondents' TAP/Abbott had all *in limine* motions granted, while Petitioner had her *in limine* motions denied, preventing the jury from seeing and hearing probative evidence on the risks of Lupron. When Respondent Abbott doesn't get its 'way', as reported in a 2010 Senate Committee on Finance (examining a "clear example of potential fraud, waste and abuse" involving Respondent's stents), "one Abbott official suggested that local connections or the "Philly mob" should intervene to silence Baltimore Sun columnist Jay Hancock for his coverage of the scandal, saying "someone needs to take this writer outside and kick his a**!"[36]

In the Durand Lupron Qui Tam Complaint, it was noted in #33: "By reason of these defendants' practices, as aforesaid, the United States has suffered substantial damage."[37] 'LVH' would argue that the United States has been compensated and recovered, while Petitioner Klein and all other Lupron victims have not.

As a result of the U.S.'s 2001 prosecution of TAP for its criminal behavior[38], TAP entered into a Corporate Integrity Agreement (COI) between the Office of Inspector General of the Department of Health and Human Services. While this COI focused on pricing issues, 'LVH' would argue that by Respondents providing an expert who would claim, under oath, a statement that

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[36] http://articles.baltimoresun.com/2010-12-06/health/bs-md-senate-stent-report-20101205_1_midei-stent-abbott-laboratories

[37] Supra. at 29.

[38] U.S.A. v. TAP Pharmaceutical Products, Inc. Case No. 1:01-cr-10354-WGY

Respondents' TAP/Abbott knows to be untrue – TAP/Abbott would be in violation of the spirit of its COI.

Respondents' TAP/Abbott claim in their 2005 label that Lupron does not carry the adverse effect of thyroid disorder and serious bone density loss problems, yet the Respondents' TAP/Abbott have included such a warning in 2004 and pre-2004 labels. The jury was not able to see Respondents' 2004 and pre-2004 labels identifying thyroid disorder and serious bone density loss problems. As a result of denial of all probative evidence offered by Petitioner, Petitioner Klein was unfairly prejudiced and Respondents' TAP/Abbott received preferential treatment, to the detriment of Petitioner Klein's right to a fair jury trial afforded by the Constitution.

SUMMARY OF ARGUMENT

Courts have understood that even a universal disregard of precautions does not excuse their omission. Truthful and accurate information related to an entire treatment modality (the administration of Lupron for endometriosis) has been distorted and muddied by Respondents' TAP/Abbott's manipulated and hidden Lupron data[39], as pertains to the matter at bar.

Under the Learned Intermediary Rule, Respondents TAP/Abbott had a duty to inform physicians and the medical profession about Respondents' TAP/Abbott's knowledge of the true risks of Lupron for endometriosis. Respondents had a duty to inform the medical profession, and the FDA, of the numbers and the seriousness of Lupron's averse events, especially in light

[39] See Redwine, supra. at 6; see also Headings II & III @ http://www.lupronvictimshub.com//home/USAdraft.doc

of Respondents TAP/Abbott's 1990's medical journal ads emphasizing 'Lupron = "Choice"'.

The opinions of Respondents' expert witness, as well as the accepted 'standard of care' in the use of Lupron for endometriosis, cannot meet the threshold requirements of *Daubert* (*Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579; 113 S. Ct. 2786; 125 L.Ed. 2d. 469, (1993)), and is "junk science", creating a genuine issue of material fact for a jury.

The Courts should not function as a facilitator in the Respondents' tried-and-true strategy of 'hide-the-Lupron-risk-info', as seen in Klein trial judge's prejudicial refusal to allow evidence on Lupron's adverse events to the jury, and as found in Ninth Circuit Court's misstatement of facts. In its order, the Ninth Circuit Court omitted U.S. Supreme Court case law, federal case law, statutes and regulations.

Petitioner Klein was denied the right to provide jury probative Lupron risk information which would have contradicted Respondents' erroneous expert testimony, which confused and misled the jury.

Amendment V of the Constitution guarantees the right to 'not be deprived of life, liberty, or property, without due process of law', and Amendment VII guarantees 'the right of trial by jury'. Petitioner Klein, and all Lupron victims, have a fundamental and constitutionally afforded protection of due process and right of trial by jury. Petitioner Klein was denied both these rights.

And the Court should clarify that Respondents' TAP/Abbott's expert's false statements under oath is deemed perjury, and is a criminal offense.

ARGUMENT

At trial, Respondents' principal expert Dr. Blackwell, under oath, falsely stated that "There are no receptors for GnRH. … Therefore, *it is biologically impossible* for Lupron to affect the thyroid gland. No textbook, no article has ever supported that contention. *It's simply biologically impossible*." (emphasis supplied). (8/5/2011 PM Tr. at 818:5-10).

The published, peer-reviewed studies entitled "Detection of GnRH receptor in normal human pituitary cells and pituitary adenomas using immunohistochemistry" (2000)[40], "The role of leuprolide acetate therapy in triggering auto-immune thyroiditis[41]" (2005), "Possible induction of Grave's disease & painless thyroiditis by GnRHa's[42]" (2003), "The first report to demonstrate the association of thyroid disorder with leuprolide injections[43]" (2000), and a 2009 article replete with "evidence of GnRH receptors" in multiple human body sites[44] should be information known to Respondents, Respondents' experts, and the medical community at large. Dr. Blackwell's testimony was false, misleading, and ignored basic brain physiology.

But if an entirely new treatment modality (utilizing Lupron for treatment of endometriosis) can be shown to be so fact distorted, and based upon manipulated data, yet has become the 'standard of care' - the duty of care as a concept has been imperiled.

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[40] http://www.ncbi.nlm.nih.gov/pubmed/11037346

[41] http://www.ncbi.nlm.nih.gov/pubmed/15689930?report=medline&format=text

[42] http://www.ncbi.nlm.nih.gov/pubmed/14558924?report=medline&format=text

[43] http://www.ncbi.nlm.nih.gov/pubmed/11228054

[44] http://www.ncbi.nlm.nih.gov/pubmed/?term=Effects+of+gonadotrophin-releasing+hormone+outside+the+hypothalamic-pituitary-reproductive+axis

ALARMING FACTS ABOUT LUPRON RISKS

To quote the alarming Lupron findings of Dr. David Redwine contained in his 2011 review to the FDA[45]:

> "The marketing efforts of Lupron's sponsor have been so successful over the past 20 years that many physicians erroneously think that Lupron is the best treatment available. … The sponsor of Lupron, and its agents, writing in the medical literature, have convinced two generations of physicians that Lupron is good treatment for endometriosis. … The scientific process has been corrupted in this process. … It is clear that the profit motive has completely replaced the concept of genuine therapeutics. … The most important finding of this review comes from study M84-042. This study provides the evidence that 62.5% of patients had not regained baseline estrogen levels by one year after stopping Lupron … This is definitive evidence of long-term damage to ovarian function. … The sponsor obviously knew about this specific adverse outcome of therapy and sought to keep it hidden for 2 decades. After finding this extremely serious outcome in M84-042, the sponsor ensured that future studies would not further illuminate this inconvenient finding. The sponsor did so by deliberately ending estrogen surveillance … ***Any intimation in any written form that estrogen levels return to normal after Lupron treatment is stopped is misleading by the evidence presented in the sponsor's own studies***. Low estrogen levels maintained throughout the treatment periods and for months, years, or forever after treatment has ceased would affect virtually every cell and every organ system in the body, resulting in a body-wide premature aging process that would explain many of the long-term symptoms that many women experience after Lupron." (emphasis supplied – See Respondents' Lupron 3.75 mg product label, under "Clinical Pharmacology" where it is claimed "This effect [decreased secretion of gonadal steroids {estrogen}] is reversible on discontinuation of drug therapy."[46]

Judge Learned Hand found in *T.J. Hooper*, (60 F2d 737; 2d Cir. (1932)) that:

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[45] Redwine, supra. at 6.; p. 281 - 284.

[46] http://www.rxabbvie.com/pdf/lupron3_75mg.pdf

> "Indeed in most cases reasonable prudence is in fact common prudence, but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It may never set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission."

In *T.J. Hooper's* case the issue was the availability of radios for seaworthy's safety sake, in the Klein matter it is the availability of honest and correct data on the risks of Lupron for the consumer's safety sake. Nobody claimed in T.J. Hooper that radios were not extant – but in the Klein matter, accurate information is nonexistent. Respondents' 'expert' Dr. Blackwell falsely claimed it was *impossible* for Lupron to cause thyroid problems – a deceitful utterance (that is given to many Lupron victims who have suffered post-Lupron thyroid problems) which can be easily refuted by an online PubMed search! (see footnotes 40 - 44)

'LVH' would argue that the Respondents' TAP/Abbott's principal witness Dr. Blackwell, as well as the accepted 'standard of care' in the use of Lupron to treat endometriosis, 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, Inc.* 509 U.S. 579; 113 S. Ct. 2786; 125 L.Ed. 2d. 469, (1993)).

U.S. SUPREME COURT CASE LAW & FEDERAL LAW SUPPORTING PETITIONER

It can be clearly shown through, *inter alia*, the above identified published medical journal articles, *it is possible* for Lupron to affect the thyroid (as has occurred in Petitioner Klein and other Lupron victims). Respondents and it's witness had a duty, in accordance to

Fed. R. Evid. 102 and 702 to provide truthful, accurate information, based on sufficient and reliable data, to the end of securing a just determination. Instead, Respondants' expert has unfairly misrepresentated the actual effects of Respondents' drug Lupron, thereby contravening Fed. R. Evid. 102 and 702. And by preventing Petitioner's cross-examination of these erroneous facts, the trial court prevented jury from learning probative facts (truthful information) in order to make a reasonable decision. Petitioner Klein had a constitutional right, under Amendment V and VII to due process and a fair trial. Petitioner did not receive either.

Lupron has been on the market for 30 years, yet it is doubtful Lupron would qualify under 21 U.S.C. §§ 355-1 (b)(3)(4)(5)(6). It would appear that Congress did not intend FDA oversight to be the only means of ensuring drug safety. In *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 173 L.Ed. 2d 51 (2009), it was noted that federal requirements create a "floor, not a ceiling" for state regulation. This point is reflected in New York state law, enacted 2012, which mandates the following warning:

> NO PHARMACIST SHALL DISPENSE OR SELL THE DRUG ... LUPRON DEPOT ...UNLESS THE CONTAINER CONTAINING SUCH DRUG PROVIDED TO THE CONSUMER IS LABELED WITH THE FOLLOWING WARNING: "CAUTION: THIS DRUG COULD CAUSE ADVERSE REACTIONS INCLUDING, BUT NOT LIMITED TO, HEART ATTACKS, DIABETES, CONVULSIONS, EXCESSIVE BLEEDING AND COULD LEAD TO DEATH."[47]

Also discussed in *Wyeth v. Levine* 555 U.S. 555, 129 S. Ct. 1187, 173 L.Ed. 2d 51 (2009) was the matter of the FDA relying for decades on state tort claims to uncover unknown drug hazards. In Lupron's cases, Respondents' TAP/Abbott have settled all previous Lupron product liability litigation with gag orders, removing the FDA's ability to rely upon torts to detect Lupron as a 'problem drug'.

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[47] http://open.nysenate.gov/legislation/bill/A6386-2011

FDA approval requires a drug to produce a benefit greater than placebo. The initial Lupron FDA approval in 1984, for palliative treatment of prostate cancer, has been described in the following light:

> "Had Amy Doseretz' [Harvard Radiation Oncology Program] study been submitted to the FDA for drug approval, the FDA would never have been granted approval for the use of the testosterone blocker, Lupron™, for prostate cancer. A detrimental result of 20 per cent increased mortality would spell disaster, and the FDA approval would be denied[48].

MEDWATCH REPORTS WRONGLY EXCLUDED BY TRIAL COURT – RESPONDENTS' WERE ON NOTICE

But the FDA did approve Lupron for palliative treatment of prostate cancer in 1984, and for pain management of endometriosis in 1990; and the FDA has received MedWatch adverse event reports from Respondents, healthcare providers, and consumers ever since. Petitioner attempted to show at trial through Lupron MedWatch reports that Respondents' TAP/Abbott *had* been put on notice, and therefore had a duty to warn, but the trial court wrongfully excluded this critical failure-to-warn evidence.

In *Wyeth v. Levine*, 555 U.S. 555 (2009), this Court addressed the relevance of evidence of MedWatch drug adverse event reports showing that the drug manufacturer was put on notice of risks. This Court's later ruling in *Matrixx Initiatives, Inc. v. Siracusano*, __ U.S. __, U.S. 131 S. Ct. 1309 (2011) reinforces this conclusion. Pursuant to 21 C.F.R. § 201.80(e):

> "Warnings. … the labeling shall describe serious adverse reactions and potential safety hazards … labeling

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48 http://www.bioidenticalhormones101.com/Low_testosterone_mortality.html

> shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.

A drug manufacturer's required due diligence includes taking into account 'new safety information', in particular "information derived from a clinical trial, an *adverse event report*, a post approval study, or *peer-reviewed biomedical literature* (emphasis supplied); 21 U.S.C. § 355-1(b).

There are tens of thousands of adverse event reports on Lupron, including 651 deaths as of 2009.[49] And "[i]n an article in the Journal of American Medical Association, then FDA Commissioner David A. Kessler revealed that 'only about 1% of serious adverse events are reported to the FDA'."[50] In illustration of the breakdown between actual and reported serious adverse events, 'LVH' has posted the MedWatch report submitted to the FDA in May 2013 by a Lupron victim who committed homicide while in a dissociative state induced by Lupron[51] – yet, according to an internet review site "based upon reports from FDA", "on November 27, 2013 No report [of homicide] is found."[52]

In the Klein matter, thyroid disorder and serious bone density loss problems were already documented by Respondents' TAP/Abbott as an adverse event to Lupron pre-2005, and *Daubert* and *Wyeth* 's rationale, as well as Fed. R. Evid. 401, show this evidence was relevant, admissible and competent proof that Respondents' TAP/Abbott were on notice of these adverse events prior to Petitioner's 2005 prescription. Respondents' failed to warn, and the jury should have been able to hear this evidence.

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[49] http://www.lupronvictimshub.com//aers.html

[50] Moore, Thomas J. Prescription for Disaster: The Hidden Dangers in Your Medicine Cabinet. New York. Simon & Schuster, 1998.

[51] http://www.lupronvictimshub.com//aers.html

[52] http://www.ehealthme.com/ds/lupron/homicide

Petitioner Klein attempted to introduce former Lupron labels identifying the known thyroid disorder and serious bone density loss adverse events, adverse event reports (MedWatch) and peer-reviewed medical journals, but was denied by the trial court, denying Petitioner due process and the right to a fair jury trial under Amendments V and VII.

Moreover, the Ninth Circuit Court found no abuse of discretion in excluding pre-2005 Lupron 3.75 mg labels from evidence "because they all contained information regarding the side effects of *different formulations of Lupron*, rendering them insufficiently relevant, unduly prejudicial, and likely to confuse the jury". (emphasis supplied) (App. 2 citing Fed. R. Evid. 403). In fact, Petitioner attempted to introduce pre-2005 Lupron Depot 3.75 mg labels, which are not "different" formulations of Lupron *but the exact same formulation and dosage* of Lupron Depot 3.75 mg. The Ninth Circuit Court has misunderstood and misstated facts and thus arrived at an erroneous conclusion.

CONCLUSION

Millican is attempting to ensure justice with this *amicus curiae* brief, and undertook this effort when other consumer groups had no time, and when Millican's request for Senatorial amici for Petitioner Klein was ignored.[53] Millican has endeavored to the best of her ability to adequately and accurately address the various issues involved in and surrounding the matter at bar.

The foregoing discussion makes apparent that Respondents' TAP/Abbott had a duty to warn and that Petitioner Klein is a victim of Respondents' failure to

[53] http://www.lupronvictimshub.com//lawsuits/Warren_amicus.docx

warn. And there are multitudes of victims just like Petitioner Klein, and Millican can testify that other Lupron victims suffering serious thyroid disorders and serious bone density loss have contacted 'LVH' seeking help.

Petitioner Klein is also a victim ensnared in an aggressive marketing campaign that has transcended and transmuted actual clinical science.[54] Doctors have been deceived, and the FDA doesn't have the time or wo/manpower to pore over thousands of pages of raw data to detect the gross manipulation that seems apparent in this Lupron matter. The FDA has also been denied a steady stream of Lupron product liability litigation as a result of Respondents' TAP/Abbott's settlement of prior Lupron adverse event cases with secrecy clauses.

Should Petitioner Klein's constitutional rights of 'due process of law' (Amendment V) and 'right of trial by jury' (Amendment VII) and 'right to recover damages' (in accordance with 28 U.S.C. § 1343(a)(4)) be denied, and the Court allows erroneous and false information on Lupron's risks to remain an uncorrected part of the legal record, a grave injustice – to many – will occur. And Petitioner Klein will grievously suffer life-long disabling medical conditions, without recourse or remedy.

The Respondents' TAP/Abbott have sought to hide Lupron's adverse events in the Klein matter (and from the public) by two judicial methods of interference: (1) a Federal Court seal on these Lupron clinical studies; and (2) a Federal Court order that these studies may not be discussed in Court. By upholding this self-serving veil of secrecy, Respondents' guarantee consumers claiming adverse effects due to Lupron will not be able to have a fair trial because relevant scientific evidence is deemed inadmissible. Moreover, this veil of secrecy fosters an unrestrained use of Lupron upon those who are at risk of

[54] See Redwine, supra. at 6; see also i.e. #'s 27 & 28 of LupronSUQS: http//www.lupronvictimshub.com//docs&corr/LUPRNSUQok.doc

serious adverse events – adverse events that have been identified by Respondents' but withheld from Petitioner and the public.

The Court seal on these studies must be lifted, in the name of a fair judicial process, allowing Petitioner Klein, and all others similarly situated, to access the evidence in those sealed Lupron studies to enable Petitioner Klein and all others similarly situated to prosecute their cases. This sealed information is vital data that the medical community at large needs to possess and understand, in order that a therapeutically derived and directed standard of care can develop. Lifting the Court seal would also provide a vehicle to foster the recognition and understanding of Lupron victims by the medical community at large, thus enabling the provision of desperately needed medico-legal assistance.

Lupron is scheduled to go off patent in 2015, there have been numerous generic leuprolide products on the market for years (thus no proprietary information), and the Lupron molecule has been publicly described – the 'secrets' the Respondents' TAP/Abbott wish to claim as 'proprietary information' are the data manipulation and lack of evidence supporting claims of safety and efficacy.

For all of the above reasons, a writ of certiorari should issue to review the judgment of the United States Court of Appeals for the Ninth Circuit Court and to vacate and reverse the decision of the court of appeals and remand the matter to the federal district court for the District of Nevada, in accordance with specifications made by Petitioner's counsel.

Pursuant to 28 U.S.C. § 1746(2), I certify under penalty of perjury that the foregoing is true and correct.

Respectfully submitted,

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