No.

IN THE

Supreme Court of the United States

KARIN KLEIN, PETITIONER

v.

TAP PHARMACEUTICAL PRODUCTS, INC.,
AND ABBOTT LABORATORIES

PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Where petitioner claims that in 2005 respondents failed to warn her in their packaging label that she risked thyroid damage and severe bone density loss if she took their drug Lupron, does a jury deserve to know that respondents warned of this very association in their prior labeling of the drug but then removed these warnings from the 2005 packaging label for the Lupron they sold petitioner?

2. Did petitioner receive a fair trial where the trial judge excludes from evidence respondents' labeling of Lupron prior to 2005 and its awareness of Medwatch and other adverse event reports all showing that respondents knew there was a nexus between Lupron and the thyroid damage and severe bone density loss which petitioner sustained but removed those warnings anyway from their 2005 packaging label for the Lupron they sold petitioner?

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The unpublished opinion of the United States Court of Appeals for the Ninth Circuit in *Karin Klein v. TAP Pharmaceutical Products, Inc. et al.*, U.S.C.A. No. 11-17250, decided and filed May 17, 2013, affirming the District Court's decision to exclude from evidence several of respondents' former Lupron labels as well as other adverse event reports about this drug, is set forth in the Appendix hereto (App. 1-3).

The unpublished motion *in limine* by petitioner in *Karin Klein v. TAP Pharmaceutical Products, Inc. et al.*, the United States District Court for the District of Nevada, Las Vegas Division, U.S. District Court No. 2:08-CV-681-RLH-RJJ, filed June 12, 2011, seeking admission into evidence of several of respondents' former Lupron labels and the warnings contained in former Physician Desk References, is set forth in the Appendix hereto (App. 4-6).

The unpublished calendar call of the United States District Court for the District of Nevada, Las Vegas Division, Hunt, Ch. J., in *Karin Klein v. TAP Pharmaceutical Products, Inc. et al.*, U.S. District Court No. 2:08-CV-681-RLH-RJJ, dated July 15, 2011, denying petitioner's motion *in limine*, is set forth in the Appendix hereto (App. 7-11).

The unpublished partial trial transcript in *Karin Klein v. TAP Pharmaceutical Products, Inc. et al.*, U.S. District Court No. 2:08-CV-681-RLH-RJJ, dated August 1, 2011, where the trial judge denies petitioner's motion to admit into evidence various

Medwatch reports, is set forth in the Appendix hereto (App. 12-17).

The unpublished partial trial transcript in *Karin Klein v. TAP Pharmaceutical Products, Inc. et al.*, U.S. District Court No. 2:08-CV-681-RLH-RJJ, dated August 1, 2011, where the trial judge denies petitioner's motion to admit into evidence respondents' former Lupron labels and reaffirming his pre-trial ruling denying petitioner's motion *in limine*, is set forth in the Appendix hereto (App. 18-20).

The unpublished judgment after jury trial in *Karin Klein v. TAP Pharmaceutical Products, Inc. et al.*, U.S. District Court No. 2:08-CV-681-RLH-RJJ, dated August 25, 2011, is set forth in the Appendix hereto (App. 21-22).

The unpublished Order of the United States Court of Appeals for the Ninth Circuit in *Karin Klein v. TAP Pharmaceutical Products, Inc. et al.*, U.S.C.A. No. 11-17250, filed July 30, 2013, denying petitioner's' petition for rehearing and for rehearing *en banc*, is set forth in the Appendix hereto (App. 23-24).

JURISDICTION

The unpublished decision of the United States Court of Appeals for the Ninth Circuit affirming the District Court's decision to exclude from evidence several of respondents' former Lupron labels as well as other adverse event reports about this drug, was decided and filed on May 17, 2013; and its further order denying petitioner's timely-filed petition for rehearing

and for rehearing *en banc* was issued and filed on July 30, 2013 (App. 1-3;23-24).

This petition for writ of certiorari is filed within ninety (90) days of July 30, 2013. 28 U.S.C. § 2101(c). The jurisdiction of this Court is invoked pursuant to the provisions of 28 U.S.C. § 1254(1).

RELEVANT PROVISIONS INVOLVED

United States Constitution, Amendment V:

> No person...shall be deprived of life, liberty, or property, without due process of law....

United States Constitution, Amendment VII:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.

21 U.S.C. § 314.80(b):

> (b)*Review of adverse drug experiences.* Each applicant having an approved application under 314.50 or, in the case of a 505(b)(2) application, an effective approved application, shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical

> investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers.
> Applicants are not required to resubmit to FDA adverse drug experience reports forwarded to the applicant by FDA; however, applicants must submit all followup information on such reports to FDA. Any person subject to the reporting requirements under paragraph (c) of this section shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA.

21 CFR § 201.80(e):

> **Labeling Requirements for Over-the-Counter Drugs.**
>
> **Specific requirements on content and format of labeling for human prescription drug and biological products; older drugs not described in § 201.56(b)(1).**
>
> Each section heading listed in § 201.56(d), if not omitted under § 201.56(d)(3), shall contain the following information in the following order:
> ....
> (e) *Warnings.* Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling 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 specific warning relating to a use not provided for under the "Indications and Usage" section of the labeling may be required by the Food and Drug Administration if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard. Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the Food and Drug Administration. The frequency of these serious adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, shall be expressed as provided under the "Adverse Reactions" section of the labeling.

Fed. R. Evid. 102:

Purpose

These rules should be construed so as to administer every proceeding fairly, eliminate unjustifiable expense and delay, and promote the

development of evidence law, to the end of ascertaining the truth and securing a just determination.

Fed. R. Evid. 401:

Test For Relevant Evidence

Evidence is relevant if:
(a) it has a tendency to make a fact more or less probable than it would be without the evidence;
and
(b) the fact is of consequence in determining the action.

Fed. R. Evid. 402:

Relevant evidence is admissible...[and] [i]rrelevant evidence is not admissible.

Fed. R. Evid. 403:

Excluding Relevant Evidence For Prejudice, Confusion, Waste of Time, or Other Reasons

The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.

Fed. R. Evid. 407:

Subsequent Remedial Measures

When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove:

--- negligence;
— culpable conduct;
— a defect n the product or design; or
— a need for a warning or instruction.

But the court may admit this evidence for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.

Fed. R. Evid. 803(3):

The following are not excluded by the rule against hearsay, regardless of whether the declarant is available as a witness:
....
(3) Then-Existing Mental, Emotional, or Physical Condition. A statement of the declarant's then-existing state of mind (such as motive, intent, or plan) or emotional, sensory, or physical condition (such as mental feeling, pain, or bodily health), but not including a statement of memory or belief to prove the fact remembered or believed unless it relates to the vitality or terms of the declarant's will.

Nevada Revised Statutes § 48.095:

1. When, after an event, measures are taken which, if taken previously, would have made the event less likely to occur, evidence of the subsequent measures is not admissible to prove negligence or culpable conduct in connection with the event.
2. This section does not require the exclusion of evidence of subsequent remedial measures when offered for another purpose, such as proving ownership, control, feasibility of precautionary measures, or impeachment.

STATEMENT

Petitioner Karin Klein ("petitioner") was seventeen years old when she suffered from endometriosis. Her gynecologist prescribed Lupron Depot 3.75 mg. ("Lupron"), a drug manufactured and marketed by respondent TAP Pharmaceutical Products, Inc., in a joint venture with respondent Abbott Laboratories ("respondents" or "TAP/Abbott") and Takeda Chemical Industries, Ltd. The drug marketed under the brand name Lupron 3.75 mg, known in the medical literature as leuprolide acetate for depot suspension, acts to decrease the amount of estrogen that is produced by women thus inducing the body to simulate menopause. The drug was originally developed and marketed to men as a palliative treatment for advanced prostate cancer and in 1990, the federal Food and Drug Administration ("FDA") approved Lupron for the temporary management of pain in women suffering from endometriosis.

Consistent with the protocol recommended by respondents packaging label (dated January 2005) which accompanied the Lupron they sold petitioner, she received six injections from her gynecologist, once per month, from August of 2005 through January of 2006. These injections of Lupron caused petitioner to sustain significant thyroid disease, extreme and permanent bone density loss, a permanent inhibition to bone mass development as well as chronic neck and back pain, all symptoms which collectively have left her totally and permanently disabled.

Petitioner thoroughly read the packaging label provided her by respondents after her first injection. However, respondents' packaging label provided *no* warning that she risked exposing herself to any of the serious adverse events which she experienced after undergoing this series of six injections. Had respondents adequately communicated such risks to her in their packaging label, she would not have agreed to take these injections of Lupron.

On February 8, 2008, petitioner filed her complaint against respondents and Takeda Chemical Industries, Ltd. in the Eighth Judicial District in Clark County, Nevada. Her state complaint alleged three causes of action under the substantive law of Nevada: (1) strict liability for failure to warn petitioner of known risks; (2) negligence; and (3) breach of warranty. Petitioner sought compensatory and punitive damages. The defendant Takeda Chemical Industries, Ltd. was never served, did not make an appearance and is no longer a party to petitioner's action (App. 2). Respondents thereafter removed the action to the federal district court for the District of Nevada, Las

Vegas Division, pursuant to 28 U.S.C. § 1441, on the grounds of diversity of citizenship

After discovery was concluded, the matter came on for trial in federal district court on August 1, 2011, before Hunt, Ch. J., and a jury. Prior to trial, on June 12, 2011, petitioner had filed a motion *in limine* seeking an order from the trial judge admitting into evidence certain Lupron labels used by respondents in the United States before 2005; respondents' foreign Lupron labels after 2005; various Physician Desk References to Lupron 3.75 mg for women with endometriosis (including those for 1995 and 1996); a children's label; and a men's Lupron label from 1990 and 2010 (App. 4-6). The reason for her motion, explained in a supporting memorandum, was that all these Lupron labels were relevant to show that respondents knew of the association between Lupron and bone mass density loss and thyroid disease yet failed to warn petitioner of this connection in the packaging label of Lupron they sold to her in 2005 "in an effort to bolster sales while compromising drug safety" (App. 5).

As petitioner wrote in her memorandum, respondents' acknowledged a connection in their United States labels between Lupron and these adverse effects----known by respondents before 2005 when it sold petitioner Lupron with a packaging label which contained *no* warnings at all about this association----was relevant "both to [respondents'] notice of the effects of Lupron as well as their failure to adequate[ly] warn Karin Klein of those adverse effects." Moreover, that respondents after 2005 acknowledged this association in their foreign labels of Lupron was relevant and admissible in order to

establish respondents' knowledge of the risks and their failure to adequately warn petitioner of these known risks.

For the same reasons, petitioner contended that the PDRs of 1995 and 1996----warning of a clear association between Lupron and thyroid damage and severe bone density loss----were relevant as admissions of a nexus between the drug and these adverse events by respondents who as drug manufacturers prepare the PDRs as a compilation of their drug labels, warnings and package inserts in order that "physicians will rely upon [them]...in the prescription and administration of the manufacturer's drugs."

On July 15, 2011, Judge Hunt denied petitioner's motion *in limine* in all respects (App. 7-11). He "believe[d] that any information with respect to any other label, particularly of products that were not used by [petitioner] to be totally irrelevant to this case and would be highly prejudicial and very confusing to the jury" (App. 10). Furthermore, he thought that any of respondents' labels issued after 2005 were irrelevant and would discourage parties from correcting things that need to be corrected and "then having that thrown back in their face for doing it" (App. 10). As the trial judge saw it, the only issue at trial was "whether or not the warnings on *this* medication were sufficient" and "warnings, or actions, or reports that involve other renditions of even Lupron Depot" were irrelevant (App. 10) (emphasis supplied). He also ruled that respondents' foreign labels of the drug "involves different formulations" of Lupron and were therefore irrelevant (App. 10).

On August 1, 2011, the first day of trial, Judge Hunt reaffirmed his earlier ruling on petitioner's motion *in limine* by preventing her from showing the jury any of respondents' labels of Lupron prior to 2005, labels which contain warnings about thyroid enlargement and extreme bone density loss, the very adverse events sustained by petitioner (App. 18-20). He denied petitioner the opportunity to show the jury respondents' foreign labels which established that they knew of the association of Lupron with the known adverse effects of enlarged thyroid and extreme bone density loss; and he disallowed petitioner's attempt to admit into evidence respondents' 2009 and 2010 Lupron labels to show that they were on notice of the connection between this drug and these specific adverse effects (App. 18-20).

In furtherance of this ruling, the trial court prevented petitioner's general causation expert (Dr. John L. Gueriguian) from mentioning respondents' prior labels, the PDR entries for 1995 and 1996 or the foreign labels. It also disallowed petitioner's specific causation expert (Dr. David Redwine) from testifying about his 750 patient experiences with Lupron or about the subject Lupron label or any other Lupron labels because he was not a "labeling expert."

Nor was petitioner allowed to cross examine respondents' FDA expert (Dr. Peck) regarding any other Lupron labels besides the 2005 label which accompanied the Lupron which petitioner received. Likewise, petitioner was prevented from effectively cross examining respondents' principal expert (Dr. Richard Blackwell) even after he testified that it was "biologically impossible" for Lupron to affect the

thyroid gland. As he told the jury without contradiction,

> There are no receptors for GnRH. So there is no basic key on the thyroid gland for Lupron. Therefore, it is absolutely *biologically impossible* for Lupron to affect the thyroid gland. No textbook, no article has ever supported that contention. *It's simply biologically impossible.*

(8/5/2011 PM Tr. at 818:5-10) (emphasis supplied).

Besides ruling that no other labels of Lupron could be relevant or admissible to petitioner's claim that respondents were strictly liable or negligent for failing to warn her in their packaging label of thyroid damage or severe bone density loss, the trial judge prevented petitioner from telling the jury through her FDA expert Dr. Gueriguian that respondents were on notice of certain Medwatch reports and other adverse event reports showing a nexus between Lupron and substantial thyroid disorders and severe bone density loss (App. 12-17).

Petitioner's evidence of Medwatch reports, made in an offer of proof, showed that many other women reported to respondents and the FDA adverse events from Lupron treatment, the same or similar adverse events as those suffered by petitioner; and yet respondents failed to identify them in their packaging label of the Lupron they sold to petitioner in 2005, making a conscious business decision to remove these warnings from the packaging label (App. 14-15). As the trial court ruled,

> ...we're not going to get into these specific reports, the number of specific reports, the source of the specific reports or the validity of the specific reports. *We don't have the time and it isn't important.*

(App. 15;16) (emphasis supplied).

Moreover, the trial court prevented petitioner from cross examining respondents' principal expert (Dr. Blackwell) with these adverse event reports, proof which would have dramatically undercut his credibility with the jury about the asserted lack of a connection between Lupron and thyroid damage and about his claim that respondents were not on notice of any association between Lupron and thyroid damage or severe bone density loss.

The jury therefore never heard petitioner's relevant proof that respondents were on notice that Lupron was associated with the thyroid damage and severe bone density loss which she suffered before they sold her this drug because they had *already* warned of this connection in their *earlier* labels of Lupron, the very same drug petitioner used. The jury likewise never knew that respondents were on notice from Medwatch and other adverse event reports that there was an association between Lupron and the very injuries sustained by petitioner and many other women.

Without this crucial, relevant evidence about respondents' notice and knowledge of the risks attendant to Lupron's use prior to August of 2005 when they sold the drug to petitioner, and without proof of these prior labels wherein respondents warned of the

very risks omitted from the 2005 Lupron label, the very adverse events petitioner sustained, and absent proof of the Medwatch and other adverse event reports giving respondents the same notice, the jury was left without the most probative proof by which to measure the sufficiency of the respondents' warnings on this particular medication sold to petitioner in 2005 or the credibility of respondents' expert witnesses who testified that the warnings were sufficient.

On August 10, 2011, the jury returned a verdict in favor of respondents on all of petitioner's claims (App. 21-22). On August 25, 2011, the district court clerk entered judgment in favor of respondents upon the jury's verdict (App. 21-22).

Petitioner appealed contending *inter alia* that the trial judge's exclusion of this probative, persuasive evidence about respondents' notice and knowledge of the risks attendant to the use of Lupron prior to 2005 fatally undermined her ability to establish by respondents' own admissions in the form of their conduct prior to and after 2005 that they knew about these risks and yet still failed to warn petitioner of them in their 2005 packaging label. She characterized the trial court's rulings in this regard as denying her a fair trial and due process; and she further asserted that the totality of the district judge's rulings and conduct throughout the trial exhibited such a pervasive bias against her as to deny her a fair trial.

On May 17, 2013, the court of appeals, without affording the parties oral argument, affirmed the judgment in a three-page, unpublished opinion (App. 1-3). It determined that Judge Hunt did not abuse his

discretion in excluding from evidence respondents' Lupron labels prior to 2005 "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" (App. 2 citing Fed. R. Evid. 403) (emphasis supplied). Nor did it think that there was error in excluding the adverse event reports since they were "hearsay reports of uncertain reliability, lacking evidence relevant to causation" (App. 2). Finally, the court of appeals ruled that petitioner had "not even remotely established" that the district judge had exhibited such bias against her as to make a fair trial impossible (App. 3).

Petitioner timely petitioned the court of appeals for rehearing by the panel or for rehearing *en banc*, contending *inter alia* that the United States Lupron labels prior to 2005 which she sought to introduce into evidence all involved *the exact same formulation of Lupron* as petitioner received, as clearly reflected in the record; that the trial judge never found otherwise; and that the Medwatch and other adverse event reports were offered not to prove causation but to show that respondents were on notice of the nexus between Lupron and the injuries sustained by petitioner, relevant proof which the jury deserved to hear under the Federal Rules of Evidence and this Court's decisions. On July 30, 2013, the court of appeals denied petitioner's petition for rehearing or for rehearing *en banc* (App. 23-24).

REASONS FOR GRANTING THE PETITION

1. The Jury In This Failure-To-Warn Case Deserved To Know That Respondents Admitted In Their Prior Labeling Of The Drug Lupron That There Was An Association Between It And Thyroid Disorders And Severe Bone Density Loss—The Very Adverse Effects Petitioner Suffered After She Took The Drug----And That They Were Also On Notice Of Medwatch And Other Adverse Event Reports Which Substantiate This Connection.

Petitioner's complaint originally filed in state court alleged three causes of action against respondents under the substantive law of Nevada: (1) strict liability for failure to warn petitioner of known risks; (2) negligence; and (3) breach of warranty. One of the key elements of petitioner's failure-to-warn case was proving that respondents were aware of the thyroid damage and severe bone density loss which could follow the use of their drug Lupron, risks of which they failed to warn petitioner in 2005.

The best method of proving that respondents in 2005 knew or were on notice of these risks which attended the use of their drug Lupron was to show by competent evidence that they had *already* warned consumers of these specific risks in their prior packaging labels because their prior acknowledgment of this association is tantamount to an admission on their part of the harm which could ensue from petitioner's use of Lupron in 2005, of which they failed to warn petitioner.

Consistent with the provisions of Fed. R. Evid. 401 and 803(3), petitioner sought to adduce before the jury evidence of respondents' packaging labels for the exact same formulation of Lupron prior to 2005, all of which contained warnings about thyroid enlargement and severe bone density loss; Medwatch and other adverse event reports prior to 2005----of which respondents had notice--- which showed that many other women besides petitioner suffered thyroid damage and severe bone density loss after using this exact same formulation of Lupron; and PDRs prior to 2005----which respondents helped compile----which showed an association between this same formulation of Lupron and the harm which befell petitioner.

The court of appeals, however, allowed the district judge to nullify by his serial rulings the robust bias of the Federal Rules of Evidence favoring the admissibility of such evidence about the most crucial issue in this case, i.e., respondents' notice and knowledge that their warnings on the 2005 packaging label of Lupron which they sold to petitioner insufficiently warned her of the risks attendant to the use of the drug and that this failure to warn petitioner proximately caused her injuries. Hamstrung by the lower court's pre-trial and in-trial rulings excluding this evidence in her case in chief and restricting her cross examination of respondents' experts, petitioner was prevented from telling the jury that respondents knew about and had notice of these risks and yet failed to warn petitioner of them in their 2005 packaging label.

By preventing petitioner her right to adduce for the jury the most relevant, probative evidence of respondents' liability for their failure to warn her of

known risks, the decision below undermines the fundamental notions of relevance under the Federal Rules of Evidence and usurps the decisional law of this Court which encourages the admission of such evidence to show respondents' notice or knowledge in order for a jury fairly to assess their liability.

Fed. R. Evid. 402 is the baseline. It provides that all relevant evidence is admissible and that "evidence which is not relevant is not admissible." "Relevant evidence" is defined by Fed. R. Evid. 401 as that proof which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence;" and this rule of relevance "is a liberal one." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 587 (1993). Indeed, this Court made the point in *General Electric Co. v. Joiner*, 522 U.S.136,147-150 (1997) (Breyer, J., concurring), that the bias of the Rules of Evidence favors the admissibility of such evidence so that the their fundamental objectives are achieved, i.e., "the ascertainment of truth and the just determination of proceedings." *Id.* at 150.

In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Court addressed the relevance of evidence which established the duty of a drug manufacturer to provide adequate warnings incident to the marketing and sale of its anti-nausea drug Phenergan. Contained within its discussion of whether federal preemption should relieve the defendant of its state law strict liability duty to safely market the drug with adequate warnings, the Court made several important points which pertain to this proceeding. It determined that FDA approval for

the marketing of a drug as labeled establishes a floor, *not* a ceiling, for drug regulation; that drug manufacturers remain primarily responsible for updating their labels to conform to newly acquired information about adverse events as they accumulate over time; and that when a given risk becomes apparent due to this newly acquired information, the drug manufacturer is charged both with crafting an adequate label and with insuring that its warnings remain adequate "as long as the drug is on the market." *Id.* at 568-571;579 citing 21 CFR § 201.80(e) (drug manufacturer must revise label to include a warning as soon as "there is reasonable evidence of an association of a serious hazard with a drug.").

By holding drug manufacturers like respondents to the duty to update their warnings when they are on notice of newly acquired information about adverse events associated with their drugs, the *Wyeth* Court made *notice of such adverse events* the touchstone for respondents' continuing obligation to make sure their warnings in the packaging labels conform to the evolving reality that their drugs could cause harm to consumers; and that without updated warnings which reflect this changing dynamic of evolving facts, a jury could find that the drug as marketed is defective.

Thus even if adverse event information such as Medwatch reports are not reliable enough themselves to prove causation in the legal sense, they are clearly probative proof to show that a drug manufacturer was on notice that there is reasonable evidence of a serious hazard with its drug, enough to prompt revising its label to include a warning to consumers about it. *Id.* at 570-571.Clearly implied within *Wyeth's* ruling is that

evidence of a drug manufacturer's decision to revise the packaging label for its drug as marketed is *always* relevant to a jury's determination of whether a drug manufacturer should be held liable for its decision to market the drug in a way which harmed a consumer like petitioner.

Just as relevant under *Daubert*, *Wyeth* and Rule 401 is petitioner's proof that prior to 2005 respondents were on notice of sufficient facts giving rise to an association between Lupron and thyroid damage and severe bone density loss, enough to cause them to include a warning about it in their packaging labels before 2005; and yet in 2005 respondents decided *not* to include a warning about these known risks, warnings which they had thought necessary to provide in prior years. Under the rationale of both *Daubert* and *Wyeth* as well as Fed. R. Evid. 401, this evidence was relevant, admissible and competent proof of respondents' *notice* of certain dangers associated with the use of Lupron before they sold the drug to petitioner without warnings in 2005 and the jury should have heard this proof in assessing their liability.

This Court's later ruling in *Matrixx Initiatives, Inc. v. Siracusano*, ___U.S. ___; 131 S.Ct. 1309 (2011) reinforces this conclusion. In determining that investors in a pharmaceutical company were entitled to know about a statistically significant number of adverse event reports showing a reliable causal link between the company's cold remedy and a loss of smell for purposes of alleging securities fraud, the Court ruled that a reasonable investor would have viewed these adverse event reports as a "material fact" in his decision to invest. *Id.* at ___; *Id.* at 1319-1323.

In so ruling, however, the Court made the point that even though adverse event reports may not be statistically significant, it does not make them unreliable. *Id.* at ___; *Id.* at 1319-1320. A "prominent degree of suspicion" is a sufficient basis for revising a packaging label; and adverse event reports are always material to any consideration of whether a drug manufacturer was on notice of certain hazards associated with its drug and the possibility, even if not statistically significant, of a causal link. *Id.* at ___; Id. at 1321-1323.

The Court's decisions in *Daubert*, *Wyeth*, and *Matrixx Initiatives, Inc.* therefore support without question the admissibility of petitioner's proof of respondents' packaging labels for the exact same formulation of Lupron prior to 2005, all of which contained warnings about thyroid damage and severe bone density loss; Medwatch and other adverse event reports prior to 2005----of which respondents had notice---which showed that many other woman besides petitioner suffered thyroid damage and severe bone density loss after using this exact same formulation of Lupron; and PDRs prior to 2005----which respondents helped compile----which showed an association between this same formulation of Lupron and the harm which befell petitioner.

All of this evidence would have permitted the jury to find that respondents were on notice of the hazards associated with their drug before 2005 and sold it to petitioner in 2005 without warnings anyway. The trial court's rulings denying the admissibility of this crucial proof and the court of appeals' ratification of those rulings denied petitioner her right to adduce for

the jury the most relevant, probative evidence of respondents' liability for their failure to warn her of known risks. The decision below undermines the fundamental notions of relevance under the Federal Rules of Evidence and usurps the decisional law of this Court which encourages the admissibility of such evidence to show respondents' notice or knowledge in order for a jury fairly to assess their liability.

Inferior federal courts and state courts agree that earlier versions of drug packaging labels are admissible, relevant evidence to show the adequacy or inadequacy of the warnings at issue. See *Higgins v. E.I. DuPont de Nemours & Co.*, 863 F.2d 1162, 1165-1167 & nn. 5; 12 (4th Cir. 1988); *Tucker v. Smithkline Beecham Corp.*, 596 F. Supp. 2d 1225, 1228-1230 (S.D. Ind. 2008); *Shatz v. TEC Technical Adhesives*, 415 A.2d 1188, 1191-1192 (N.J. Super. 1980). *Blasing v. P.R.L. Hardenbergh Co.*, 226 N.W.2d 110, 115 (Minn. 1975). See also Weinstein & Berger, *Weinstein's Evidence* at 801(c) at 801-70 to 801-71 (proof showing respondents' state of mind is admissible under Fed. R. Evid. 803(3) and does not constitute hearsay).

Similarly, adverse event reports such as Medwatch reports are admissible evidence with any confusion about the proof subject to clarification by cross examination and limiting instructions, with the jury being free to give whatever weight to this evidence it deems sufficient. See *Benedi v. McNeil-P.P.C.*, 66 F.3d 1378,1385-1386 (4th Cir.1995); *Kehm v. Proctor & Gamble Mfg. Co.*, 724 F.2d 613, 625-626 (8th Cir. 1983). *Smith v. Wyeth-Ayerst Laboratories*, 278 F. Supp. 2d 684, 703-704 (W.D.N.C. 2003). Moreover, PDRs are admissible proof of which the trial court can

take judicial notice in assessing the adequacy of the warnings given. See *Coleman v. State Supreme Court*, 697 F. Supp. 2d 493, 513-514 (S.D.N.Y. 2010).

Finally, it must be reemphasized that the court of appeals' decision is fundamentally wrong on two critical points:

(1) petitioner's proof of respondents' warnings on their earlier packaging labels did *not* implicate "different formulations of Lupron," as the court of appeals surmised (App. 2). All of her proof in this regard showed that respondents before 2005 had issued warnings about thyroid damage and severe bone density loss *with the exact same formulation of Lupron* which they sold to petitioner in 2005 without those warnings. The district judge never made such a finding that the formulations were not the same; there was no such evidence adduced in this regard; and the record in this case establishes that every formulation of Lupron was the same formulation which respondents sold to petitioner and which caused her harm;

(2) for the reasons already identified, the court of appeals was wrong to conclude that the adverse event reports were unreliable and therefore inadmissible because they lacked "information relevant to causation" (App. 2). As made clear by both *Wyeth* and *Matrixx Initiatives, Inc.*, such reports do *not* have to show causation in order to be admissible. Instead, such reports are probative proof that respondents were on notice that there was reasonable evidence of a serious hazard with its drug, enough to prompt revising its label to include a warning to consumers about it. That respondents warned users of Lupron prior to 2005 of

the drug's association with thyroid damage and severe bone density loss is proof positive that they were on notice of these risks when they sold Lupron to petitioner in 2005 without these warnings. The jury should have known this crucial fact in order to assess fairly respondents' culpability.

2. Petitioner Was Denied A Fair Trial When The Trial Judge Excluded From Evidence Respondents' Prior Labeling Of Lupron And Its Awareness Of Medwatch And Other Adverse Event Reports All Showing That Respondents Knew In 2005 Of A Nexus Between Lupron And The Thyroid Disorders And Severe Bone Density Loss Which Petitioner Sustained.

The deferential abuse of discretion standard of review is especially necessary in assessing the admissibility of evidence at trial for the reasons identified by the Court in *General Electric Co. v. Joiner*, 522 U.S.136,147-150 (1997) (Breyer, J., concurring), i.e., a stricter standard such as *de novo* review has the potential to undo the sound decisions of the trial judge upon appellate factfinding having no special worth except as a "second guess" in the aftermath of trial; it undercuts the bias of the Federal Rules of Evidence favoring the admissibility of evidence; and it denigrates without reason the crucial "gatekeeping" function of the trial court. *Id.* Most important, it "help[s] secure the basic objectives of the Federal Rules of Evidence, which are...the ascertainment of truth and the just determination of proceedings." *Id.* at 150.

In *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), the Court reinforced the notion that the trial judge be given wide latitude by the appellate court in making his decision to admit or exclude proffered evidence and that an abuse of discretion standard of review furthers this goal because "the Rules seek to avoid 'unjustifiable expense and delay' as part of their search for "truth" and the "jus[t] determin[ation]" of proceedings. Fed. R. Evid. 102. *Id.* at 152-153.

But just as "[t]here are constitutional limitations upon the power of courts, even in aid of their own valid processes, to dismiss an action without affording a party the opportunity for a hearing on the merits of his case," *Societe Internationale Pour Participations Industrielles et Commerciales S.A. v. Rogers*, 357 U.S. 197, 209 (1958), the discretion possessed by district judges in administering the Federal Rules of Evidence must be employed so that the proceedings are conducted "fairly" within the meaning of Rule 102, a concept which surely accommodates fundamental notions of due process.

By denying petitioner her right to adduce the relevant, probative evidence that respondents prior to 2005 had used different packaging labels with warnings that exactly the same formulation of Lupron which it sold to petitioner has an association with substantial thyroid damage and severe bone density loss, the very injuries petitioner sustained after she used the drug without being so warned, is not only at odds with Fed. R. Evid. 401 and 803(3), but also contravenes fundamental notions of due process. This evidence together with her proof about respondents' notice of the PDFs' warnings and the Medwatch and other

adverse event reports all would have permitted a jury to find more probably than not that respondents were aware of the connection between Lupron and the injuries sustained by petitioner but failed to warn her of these risks in 2005 thereby causing her the harm which ensued.

Where the federal trial system with its component rules of procedure and evidence provides a framework for disposing of litigation within its system, those remedies must comport with the demands of the due process clause of the federal constitution. *Evitts v. Lucey*, 469 U.S. 387, 393 (1985). *Griffin v. Illinois*, 351 U.S. 12, 13-14 (1956). See *Ortwein v. Schwab*, 410 U.S. 656, 660 (1973). Petitioner's cause of action and her right to have her claims fairly heard and decided by a jury is a valuable property right entitled to due process protection. *Board of Regents v. Roth*, 408 U.S. 564, 571-572 (1972). See *Cleveland Board of Education v. Loudermill*, 470 U.S. 532, 538;541 (1985) ("The point is straightforward: the Due Process Clause provides that certain substantive rights—life, liberty, and property—cannot be deprived except pursuant to constitutionally adequate procedures"); *Gibbes v. Zimmerman*, 290 U.S. 326, 332 (1933); *Fidelity & Deposit Co. v. Arenz*, 290 U.S. 66, 68 (1933). See also *Boddie v. Connecticut*, 401 U.S. 371, 374-375 (1971).

Once the due process clause applies to the proceedings below, "the question remains what process is due." *Loudermill*, 470 U.S. at 541. *Mathews v. Eldridge*, 424 U.S. 319, 334-335 (1976). At a minimum, it consists of a reasonable opportunity to be heard, *to marshal the relevant evidence in support of her cause* and to have a fair hearing on the proof adduced.

Armstrong v. Manzo, 380 U.S. 545, 551-552 (1965).*Grannis v. Ordean*, 234 U.S. 385, 394 (1914). Judge Hunt's preemptive exclusion of petitioner's relevant evidence founded upon his distorted and legally wrong view of the relevancy of petitioner's proof under Fed. R. Evid. 401, 403 and 803(3)-----a ruling ratified by the court of appeals as an exercise of his "discretion"----is a denial of the process due petitioner under the federal constitution, the federal trial system and the Federal Rules of Evidence.

These rulings by both courts below also denied petitioner her right to substantive due process, i.e., her right to be free from the arbitrary action of government, regardless of the superficial fairness of the procedures employed to implement that action. *Collins v. Harker Heights*, 503 U.S. 115, 125 (1992). *Daniels v. Williams*, 474 U.S. 327, 331 (1986) citing *Dent v. West Virginia*, 129 U.S. 114, 123 (1889). The concept of substantive due process serves to prevent governmental power from being "used for purposes of oppression." *Daniels*, 474 U.S. at 331-332 (1986) quoting *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 277 (1856). The denial of petitioner's right to adduce the earlier drug labels containing the same formulation of Lupron or the PDFs' warnings or the MedWatch and other adverse event reports----all showing that respondents were on notice of the connection between their drug and the harm which befell petitioner----violates her right to substantive due process.

These evidentiary rulings also denied petitioner a jury trial. The seventh amendment to the federal constitution provides that in suits at common law, "the

right of trial by jury shall be preserved...." As the Court observed in *Blakely v. Washington*, 542 U.S.296, 305-306 (2004), the right to a jury trial in civil cases is not a procedural formality but a fundamental "reservation of power in our constitutional structure," assuring the people's ultimate control of the judiciary. *Id.* citing 2 *The Complete Anti-Federalist* 315, 320 (H. Storing ed.1981). This guaranty of a jury trial in the Constitution and the common law traditions it entrenches was nullified by the evidentiary rulings of the trial court and the court of appeals' decision ratifying their propriety.

Without petitioner's crucial, relevant evidence that respondents had notice and knowledge of the risks attendant to Lupron's use prior to August of 2005 when they sold the drug to petitioner, and without proof that in their prior labels respondents warned of the very risks omitted from the 2005 Lupron label, the very adverse events petitioner sustained, and without proof of the Medwatch and other adverse event reports giving respondents the same notice, the jury was left without the most probative proof by which to measure the sufficiency of the respondents' warnings on this particular medication sold to petitioner in 2005 or to assess the credibility of respondents' expert witnesses who testified that the warnings were sufficient. With petitioner's proof stripped of all of its probative force, it was a jury trial in name only.

Finally, petitioner's claim that the trial judge's evidentiary rulings together with his other conduct during the trial exhibited a disqualifying bias against her is firmly anchored in the record. He ruled against petitioner on virtually all her motions *in limine* while

granting almost all of respondents' motion *in limine*; and whenever petitioner sought to introduce evidence showing respondents' notice or knowledge of an association between Lupron and the unwarned-of adverse events which petitioner suffered, respondents' objections were sustained or the trial court *sua sponte* denied petitioner a fair opportunity to present to the jury the elements of her failure-to-warn case.

In addition, on repeated occasions, the trial judge *sua sponte* made objections to evidence to petitioner's detriment; suggested answers for respondents' witnesses when cross examined by petitioner's counsel; criticized petitioner's counsel in front of the jury; made comments on the evidence, even arguing the case for respondents; unfairly limited petitioner's cross examination of respondents' FDA expert; commented on testimony of petitioner's FDA expert and *sua sponte* attempted to discredit him, even cross examining and then arguing with him; and refused to allow petitioner's cross examination of respondents' expert by reference to scientific journals. All this conduct at trial, including his evidentiary rulings and even the favorable treatment respondents received by his earlier discovery rulings, tied petitioner's hands and stymied the presentation of her case to the jury. What little evidence petitioner was allowed to adduce was indelibly colored by Judge Hunt's pejorative remarks and characterizations which left the jury with the firm impression that her evidence was not to be believed.

As the Court's majority in *Caperton v. A. T. Massey Coal Co.*, 556 U.S. 868, 876 (2009), made clear, due process requires a neutral and detached judge both

at the trial and appellate level. 556 U.S. at 876. See *Hamdi v. Rumsfeld*, 542 U.S. 507, 533 (2004) quoting *Ward v. Vill. of Monroeville*, 409 U.S. 57, 61-62 (1972). *Withrow v. Larkin*, 421 U.S. 35, 46-47 (1975). *In re Murchison*, 349 U.S. 133, 136 (1955). Trial judges are more than mere umpires; they are the governors of the proceedings before them----and they cannot become an advocate or otherwise use their judicial powers to advantage or disadvantage a party. *Quercia v. United States*, 289 U.S. 466, 470(1933). Nor "should [they] give vent to personal spleen or respond to a personal grievance." *Offutt v. United States*, 348 U.S. 11,14 (1954).

The Court in *Caperton* established that the due process clause provides a constitutional floor in analyzing when recusal of a judge is required, i.e., "when the probability of actual bias on the part of the judge or decision-maker is too high to be constitutionally tolerable"----when, that is, there is a "serious, objective risk of actual bias." 556 U.S. at 883-886. The objective due process standards do not require proof of actual bias but instead ask if "under a realistic appraisal of psychological tendencies and human weakness," the interest "poses such a risk of actual bias or prejudgment that the practice must be forbidden if the guarantee of due process is to be adequately implemented." *Id.* at 885 quoting *Withrow*, 427 U.S. at 47.

Such is the case here. The trial judge's serial evidentiary rulings to petitioner's detriment, his oppressive conduct during trial, including his statements in front of the jury to the detriment of petitioner and her counsel, and his clear message to the

jury that petitioner's proof was not to be believed, deprived petitioner of a fair and impartial trial before a neutral and detached judge as guaranteed under the fifth amendment.

CONCLUSION

For all of these reasons identified herein, a writ of certiorari should issue to review the judgment of the United States Court of Appeals for the Ninth Circuit 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, Las Vegas Division, with directions that this matter be reassigned to another district court judge in this (or another) judicial district so that "a new judge...[may] take a fresh look at the issues," all consistent with this Court's decision in *Liljeberg Health Servs. Acquisition, Corp.*, 486 U.S. 847, 863-864;868 (1988); that petitioner be granted renewed discovery and a new trial on her claims against respondents; or grant petitioner such other relief which is justified by the circumstances of this case.

Respectfully submitted,

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Filed May 17, 2013

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

No. 11-17250

D.C. No. 2:08-cv-00681 -RLH-RJJ

MEMORANDUM*

KARIN KLEIN,

Plaintiff - Appellant,

v.

TAP PHARMACEUTICAL PRODUCTS, INC.; ABBOTT LABORATORIES,

Defendants - Appellees.

Appeal from the United States District Court
for the District of Nevada
Roger L. Hunt, Senior District Judge, Presiding

Submitted May 14, 2013**
San Francisco, California

Before: CLIFTON and BEA, Circuit Judges, and

* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

** The panel unanimously concludes this case is suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

DUFFY, District Judge.***

Karin Klein claimed that TAP Pharmaceuticals and Abbott Laboratories[1] failed to warn her adequately of the severe side effects she experienced after taking Lupron Depot 3.75 mg. The case was tried to a jury, and Klein lost. She now argues that the district court abused its discretion in several evidentiary and discovery rulings and that the district court was unfairly biased. We have jurisdiction pursuant to 28 U.S.C. § 1291, and we affirm.

Klein challenges the district court's exclusion of several Lupron labels, adverse event reports, scientific articles, and supplemental expert reports. The district court did not abuse its discretion in excluding the challenged Lupron labels 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. *See* Fed. R. Evid. 403. Similarly, the district court did not err in excluding the adverse event reports. They were hearsay reports of uncertain reliability, lacking information relevant to causation. We also affirm the district court's rulings excluding the scientific articles on hearsay grounds because Klein failed to establish that any exception applied. *See* Fed. R. Evid. 803. Finally, the district court appropriately deemed the supplemental expert reports untimely because Klein submitted the reports two years after

*** The Honorable Kevin Thomas Duffy, U.S. District Judge for the Southern District of New York, sitting by designation.

[1] Defendant-Appellee Takeda Chemical Industries, Ltd. has been removed from the caption because it was never served, did not make an appearance, and is not a party to this action.

the deadline for expert reports and within one month of the start of trial. *See* Fed, R. Civ. P. 26(e) (parties must supplement materially incomplete or incorrect information in a "timely manner").

Klein also challenges the district court's supervision of discovery. The district court acted within its discretion in granting Klein's narrowed motion to compel and requiring Klein to bear the cost of reproducing documents that had already been produced. The district court's denial of Klein's motion to extend discovery was also reasonable because the motion was filed too close to the discovery deadline. D. Nev. Local R. 26-4.

Finally, Klein has not even remotely established that the district court exhibited "such a high degree of favoritism or antagonism as to make fair judgment impossible." *Liteky* v. *United States*, 510 U.S. 540, 555 (1994). Judicial bias cannot be demonstrated simply by pointing to rulings that disfavored the complaining party.

AFFIRMED.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA
CASE NO. 2.-08-CV-00681 -RLH-RJJ

KARIN KLEIN,

Plaintiff,

vs.

TAP PHARMACEUTICAL PRODUCTS. INC.; ABBOTT LABORATORIES; TAKEDA CHEMICAL INDUSTRIES, LTD., and DOES I - V, inclusive.

Defendants.
_____/

PLAINTIFF'S MOTION IN LIMINE No. 16 Re; ADMITTING EVIDENCE IN THE FORM OF FORMER UNITED STATES LUPRON LABELS,

FOREIGN LUPRON LABELS AND WARNINGS CONTAINED IN PDR's

Plaintiff, Karin Klein, by and through her attorney of record and pursuant to Federal Rules of Evidence, hereby submits Plaintiffs Motion in Limine No. 16 Re: Admitting Evidence in the Form of Former United States Lupron Labels, Foreign Lupron Labels and Physician Desk References C'PDR's). Plaintiff requests this Court grant this motion *in limine* ruling that labels of Lupron used within the United States, the Danish label and all PDRs containing warnings for LUPRON DEPOT 3.75 mg. (including those for the years 1995, 1996) the children's label and, the men's label from 1990 and 2010, be pre-admitted in this action and that Plaintiff shall be allowed to refer to these labels in Opening Statement. This Motion is supported by a memorandum which is filed in support hereof. For the reasons set forth in the memorandum, this Court should fully grant this Motion in Limine.

Respectfully submitted this 12th day of June, 2011.

HUGGINS & MAXWELL
/s/ J. Huggins

_____

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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA
LAS VEGAS DIVISION
CASE NO: 2:08-CV-681-RLH-RJJ
CIVIL
Las Vegas, Nevada
Friday, July 15, 2011
(11:38 a.m. to 12:50 p.m.)

KARIN KLEIN,)
)
Plaintiff,)
)
vs.)
)
TAP PHARMACEUTICAL PRODUCTS,)
INC, ET AL,)
)
Defendants .)

CALENDAR CALL

BEFORE THE HONORABLE ROGER L. HUNT,
UNITED STATES DISTRICT CHIEF JUDGE

Appearances:See next page

Court Reporter:Denise Saavedra; FTR

Courtroom Administrator: Kandy Capozzi

Transcribed by:Exceptional Reporting Services, Inc.
P.O. Box 18668
Corpus Christi, TX 78480-8668
61 949-2988

Las Vegas, Nevada; Friday, July 15, 2011; 11:38 a.m.

(Call to Order)

THE CLERK: This is the time set for calendar call for *Klein versus TAP Pharmaceutical Products* set for trial to commence on August 1st, Civil 08-681-RLH-RJJ.

Counsel, please note your appearances for the record.

MR. HUGGINS: Joe Huggins for Karin Klein.

MS. MAXWELL: Kristine Maxwell for Ms. Klein also.

MR. NEMEROFF: Good morning. Rick Nemeroff for Ms. Klein as well.

MR. REIDY: Good morning, your Honor. Dan Reidy on behalf of the Defendants.

MR. COLE: Good morning, your Honor. Jeremy Cole on behalf of the Defendants.

MR. ALLEN: Good morning. West Allen on behalf of the Defendants.

THE COURT: This is the calendar call. There are before the Court 32 motions in limine plus some additional motions that have been filed since then and the Court intends to rule on those motions. I do not intend to take argument. So, I will do that first and then we'll address the other details of the calendar call

if you will.

I'll go through the plaintiff's motions first by number.

Plaintiff's Number 1 and for the record I'll give you and to give his opinions about his examination and treatment of her that the argument would be strongly in the other direction. A treating physician has to make a diagnosis and a prognosis and his treatment and observations are pertinent and they are certainly relevant to this case. And so the motion to forbid Dr. Wright, her treating physician, from testifying about his opinions about her, as well as statements that she may have made and references that she may have made in the court will -- that are against her interests -- the Court will permit as an exception to the hearsay rule.

Number 16 and this is Document 175. I'm probably not giving you all the document numbers, but this asks the Court to admit the form or former United States Lupron labels, foreign Lupron labels, and warnings in the PDR and reference to that in the opening argument; this motion is denied.

Again, I'm not going to permit any exhibits, even those stipulated to, to be used in opening argument because it should be an opening statement and the Court expects it to be brief. The opening statement is not a place for counsel to try to prove their case to the jury so that they don't have to do it during trial, and I'm not going to permit the exhibits to be used without the jury being able to hear foundational testimony about what they are and their significance. They should not rely on plaintiff's representations with respect to that in the opening statement.

This request involves Lupron labels that are not at issue in this case. They're different formulations. They are irrelevant. It involves the men's formulation

of the 7.5 versus the 3.5 formulation of this. The men's formulation was for a different purpose, a different treatment, or a different problem. The dosage was different; the length of dosage was different. It was prescribed by different doctors for different reasons and the Court believes that any information with respect to any other label, particularly of products that were not used by the plaintiff to be totally irrelevant to this case and would be highly prejudicial and very confusing to the jury.

Post-dated labels are irrelevant and I think would discourage parties from, if they find something that, needs to be corrected, from correcting them if we -- if they were faced with making any corrections and then having that thrown back in their face for doing it.

The issue here is whether or not the warnings on this medication were sufficient. The medication is only deficient, only dangerous, if the warnings are inadequate in this Court's view, and we will limit this trial to that issue and to this particular medication and not to warnings, or actions, or reports that involve other renditions of even Lupron Depot and certainly not of other kinds of medications.

But furthermore, things that she did not see, in the Court's view, are irrelevant. Things that her doctor did not consider for her are irrelevant.

The Danish labels. The Court does not know what the law is. I think it involves different formulations. I'm not sure that the side effects are relevant here. At any rate, the motion is denied.

Number 17 is to reference to and use evidence which has been preadmitted or stipulated to in opening argument. So Number 17, Document 176, I think I've already addressed this; it's denied.

There appears to be a misunderstanding about

what an opening statement is and I reiterate it's not an argument and exhibits will not be used.

I think I need to say at this point, in case I don't say it later on, the fact that in the pretrial order that one party or the other has identified exhibits and they have not been objected to does not mean that exhibit is admitted into evidence. Even if the parties stipulate to exhibits that they will be introduced into evidence and I strongly encourage both sides to make a good faith effort to do this as much as possible, but even if you stipulate to them they are not admitted into evidence until you move for admission based upon the stipulation during the trial. And so don't assume that because you've stipulated that that's now in evidence and just ignore it until your closing argument because unless you move

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

THE HONORABLE ROGER L. HUNT, CHIEF JUDGE PRESIDING
CASE NO.:
2:08-cv-681-RLH-RJJ
Testimony of John L. Gueriguian, M.D.

KARIN KLEIN,
Plaintiff,
vs.
TAP PHARMACEUTICAL PRODUCTS, INC., ET AL.,
Defendants,

REPORTER'S PARTIAL TRANSCRIPT OF JURY TRIAL DAY ONE

Monday, August 1, 2011

APPEARANCES:

See Page 2
HEATHER K. NEWMAN, CCR 774
Official Federal Reporter

MR. REIDY: Your Honor, again, I make the same objection. I think this is what's been ruled on.

MR. NEMEROFF: With respect, Your Honor, the ruling was the specific reports themselves will not be preadmitted, that was the rule.

MR. REIDY: Your Honor, I object to the speaking answer.

MR. NEMEROFF: Well, then I object to the fact that he keeps making motions.

THE COURT: Counsel, both of you be quiet and come to sidebar.

(Thereupon, a discussion was had at sidebar out of the hearing of the jury.)

MR. REIDY: Your Honor, I believe that this area of getting into the adverse event reports and what they mean has been ruled upon by the Court. I think, you know, some general description of it, which we've had, was okay. Now I think getting any more precise about it and now we have the suggestion, you know, that the Court has ruled that there are adverse event reports which we're not talking about, that, you know, the theme of, you know, it was In the press about things being kept from the jury has me concerned, that's why I objected a second time.

THE COURT: I understand.

I'm concerned about that as well, counsel, and I'm concerned about you continually pushing it.

I don't have any problem with the fact that there

are med reports, that the FDA keeps them, and that the manufacturers -- that they were reported to the manufacturers or they observe them and, you know, depending on how significant they may seem to be, he has testified that the FDA and maybe four or five times that he was involved with out of a hundred, that they pursued them to see if something more should be done. I think when you start going beyond that and then you start asking how many times do you have to have a report before gets into the issue of whether or not how much credibility they give to specific reports.

MR. NEMEROFF: The --- I apologize. Is the Court finished?

THE COURT: Yes.

MR. NEMEROFF: Your Honor, the transcript of the hearing that the Court had on this issue was premised on a Motion in Limine to preadmit adverse drug events. The Court denied our request, that was the only request, was to preadmit them. Everything else, there was no request that they be stricken, there was no corresponding motion that they not be discussed. I'm laying the foundation to make my offer of proof as to the need and validity of relying upon adverse drug events reported through MedWatch that, Your Honor —

THE COURT: Is it your position that the evidence will show that they didn't read MedWatch reports?

MR. NEMEROFF: Quite the opposite, Your Honor. What I'm -- what the evidence, I think, is going

to show, if the Court will permit, is that there was a number of MedWatch events for many of the illnesses and injuries that Miss Klein complains of that went unresponded to by the manufacturers in this case.

THE COURT: Were they raised by the FDA?

MR. NEMEROFF: They don't have to be raised by the FDA.

THE COURT: That's an argument, counsel.

MR. REIDY: Judge --

THE COURT: I'm sorry, just a minute, counsel. You don't need to go any further.

MR. REIDY: Yes, sir.

THE COURT: I don't need to be reminded of what my ruling was. My ruling was with respect to your specific motion.

MR. NEMEROFF: Correct.

THE COURT: My ruling on this is not based upon my ruling then, it's based upon the reason for my ruling then is we're not going to get into these specific reports, the number of specific reports, the source of the specific reports or the validity of the specific reports. We don't have the time and it isn't important.

MR. NEMEROFF; If that's the Court's —

THE CLERK: You're a little loud. Wait till the

music starts again.

MR. NEMEROFF: Sorry. I have never had to wait for the music to start before I start making my argument.

THE COURT: We like an accompaniment.

MR. NEMEROFF: If that's the Court's ruling, which I now have on the record, that I am precluded from discussing the impact of adverse drug events as it relates to this drug, then I can move on.

THE COURT: No, that's not what I — you have done that.

MR. NEMEROFF: But I haven't. I haven't been able to talk about the significance of adverse drug events as they would relate to how many you need and why they're important.

THE COURT: And that's why I'm not going to get into it because how many they need may depend on the type they are and then we get into the whole ball of wax which is not, in my opinion, relevant to this case. So this objection is sustained.

MR. NEMEROFF: That's what I needed. Thank you, Your Honor.

THE COURT: I hope you understand --

MR. NEMEROFF: I do.

THE COURT: — because I don't want to have

to keep

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

THE HONORABLE ROGER L. HUNT, CHIEF JUDGE PRESIDING
CASE NO.:
2:08-cv-681-RLH-RJJ
Testimony of
John L. Gueriguian, M.D.

KARIN KLEIN,
)
Plaintiff,
)
vs.
)
TAP PHARMACEUTICAL PRODUCTS, INC., ET AL.,
)
Defendants,
)

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REPORTER'S PARTIAL TRANSCRIPT OF JURY TRIAL DAY ONE

Monday, August 1, 2011

APPEARANCES:

See Page 2

theory is, the label changes are inconsistent with their own documents and inconsistent among themselves. That's always been our theory.

MR. REIDY: Here, Judge.

We understand that he may want to criticize which study was chosen to put in the label in 2005, the only label that's relevant to this woman, and he can -- we understand he may go into these studies and his report does contain reference to the studies. It does not contains an analysis of one label versus the other label. There's nothing --

MS. GHEZZI: Right.

THE COURT REPORTER: Wait. One at a time.

MR. REIDY: So if he's in the label, I mean, if he's in the studies, and wants to talk about the study, we expect him to say they should have used this number in their label instead of that from the studies. I mean, obviously we disagree, but that's a fair comment. But he doesn't say a thing about this label versus that label in his report.

MS. GHEZZI: Right.

MR. REIDY: And that was the subject of our Motion in Limine.

THE COURT: I understand.

MS. GHEZZI: Exactly.

THE COURT: And my ruling on the Motion in Limine stands.

UNITED STATES DISTRICT COURT
DISTRICT OF _____
Case Number: 2:08-CV-0681 RLH-RJJ

Karen Klein

Plaintiff,

V.

TAP Pharmaceutical Products Inc et al

Defendants.

JUDGMENT IN A CIVIL CASE

☐ **Jury Verdict.** This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

☐ **Decision by Court.** This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

☐ **Notice of Acceptance with Offer of Judgment.** A notice of acceptance with offer of judgment has been filed in this case.
IT IS ORDERED AND ADJUDGED

Judgment is entered for Defendants and against Plaintiff.

August 25, 2011_____
/s/ Lance S. Wilson_____

Date
Clerk

/s/ Eileen Sterba_____
(By) Deputy Clerk

Filed July 30, 2013

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

No. 11-17250
D.C. No. 2:08 -cv-00681 -RLH-R J J
District of Nevada,
Las Vegas

KARIN KLEIN,

Plaintiff - Appellant,

v.

TAP PHARMACEUTICAL PRODUCTS, INC.; ABBOTT LABORATORIES; TAKEDA CHEMICAL INDUSTRIES, LTD.,

Defendants - Appellees.

ORDER

Before: CLIFTON and BEA, Circuit Judges, and DUFFY, District Judge.*

The panel voted to deny the petition for rehearing. Judges Clifton and Bea voted to deny the petition for rehearing en banc, and Judge Duffy so

* The Honorable Kevin Thomas Duffy, U.S. District Judge for the Southern District of New York, sitting by designation.

recommends.

The full court has been advised of the petition for rehearing en banc and no judge of the court has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing and petition for rehearing en banc, filed on June 24, 2013, are denied.