**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLORADO**
**Chief Judge Marcia S. Krieger**

**Civil Action No. 13-cv-02070-MSK-CBS**

**JENNIFER HEINEMAN; and**
**ERIC ALLEN HEINEMAN,**

**Plaintiffs,**

**v.**

**AMERICAN HOME PRODUCTS CORPORATION;**
**WYETH-AYERST PHARMACEUTICALS, INC;**
**WYETH-AYERST INTERNATIONAL, INC.; and**
**WYETH-AYERST LABORATORIES DIVISION OF AMERICAN HOME PRODUCTS CORPORATION,**

**Defendants.**

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**OPINION AND ORDER DENYING MOTIONS FOR SUMMARY JUDGMENT**

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**THIS MATTER** is before the Court on the Defendants' (collectively, "Wyeth") Motion For Summary Judgment Re: Plaintiff's Claim for Compensatory Damages **(# 29)**, the Plaintiffs' response **(# 40)**, and Wyeth's reply **(# 42)**; and Wyeth's Motion for Summary Judgment Re: Plaintiff's Claims for Punitive Damages **(# 30)**, the Plaintiffs' response **(# 41)**, and Wyeth's reply **(# 43)**.

## FACTS

The Court briefly summarizes the pertinent facts herein, and elaborates as necessary in its analysis. In 1996, Plaintiff Jennifer Heineman, then 24 years old, prevailed upon her physician parents, Dr. Joan Scott ("Dr. Joan") and Dr. John Scott ("Dr. John"), to issue her a prescription for the drug Pondimin, a brand-name variant of the weight-loss drug fenfluramine manufactured by Wyeth. Dr. John apparently signed one or more blank prescription forms, and Dr. Joan

apparently filled in the relevant information, allowing Ms. Heineman to obtain the drug. Ms. Heineman took Pondimin from approximately March 1996 to May 1997.

In November 2010, Ms. Heineman was diagnosed was pulmonary arterial hypertension ("PAH," sometimes also known as "primary pulmonary hypertension"), a progressive and potentially fatal lung disease. Mr. Heineman attributes her contracting of PAH to having taken Pondimin.

In or about April 2012, Ms. Heineman commenced this action in the Pennsylvania Court of Common Pleas (site of ongoing mass-plaintiff litigation against manufacturers and distributors of fenfluramine products, known as the *In re: Phen-Fen* litigation). Ms. Heineman's suit incorporated by reference certain claims found in a "Master Complaint" in use in the *In re: Phen-Fen* litigation, specifically asserting the following claims: (i) negligence, in that Wyeth "failed to use due care in the designing, testing, and manufacturing of . . . fenfluramine" and "failed to accompany their product with proper warnings regarding all possible adverse side effects," among others; (ii) strict products liability, in that the fenfluramine products were "unreasonably dangerous"; (iii) strict liability failure to warn; (iv) breach of implied warranty; (v) breach of express warranty, in that Wyeth made certain "written and verbal assurances of safety and efficacy" and "false and misleading written information . . . published in the Physicians Desk Reference on an annual basis"; (vi) fraud, in that Wyeth's "advertising program, by affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of fenfluramine . . . was safe for human use"; (vii) loss of consortium, asserted by Eric Heineman, Jennifer's husband; and (viii) a "claim" for compensatory and punitive damages.

Citing to the federal subject-matter jurisdiction premised on diversity of citizenship, 28 U.S.C. § 1332, Wyeth removed the action to the United States District Court for the Eastern District of Pennsylvania, where a multi-district litigation case entitled *In re Diet Drugs*, 990 F.Supp. 834 (J.P.M.L. 1997), was pending. Although Ms. Heineman's case was joined into that MDL proceeding, in or about May 2013, Wyeth sought a transfer of venue of this case to the District of Colorado, noting that Ms. Heineman and her parents were all citizens of Colorado throughout the time periods at issue here, and that Ms. Heineman's injuries were sustained in Colorado. In June 2013, the court granted that motion, transferring the case to this Court.

Wyeth now seeks summary judgment on all of the Plaintiffs' claims through motions curiously-titled[1] "Motion for Summary Judgment re: Plantiffs' Claim for Compensatory Damages" **(# 29)** and "Motion for Summary Judgment re: Plaintiffs' Claim for Punitive Damages" **(# 30)**. In short, Wyeth argues: (i) all of the Plaintiffs' claims are simply variants of their failure to warn claim; (ii) the failure to warn claim fails because Dr. John testified that he did not review any warnings about Pondimin before prescribing it, and thus, a more comprehensive warning would not have prevented Ms. Heineman's injury; (iii) the Plaintiffs cannot rely on the fact that Dr. Joan may have considered the content of Pondimin's warnings, insofar as only Dr. John, as a matter of law, the duty to warn runs only to the prescribing physician.

## ANALYSIS

### A. Standard of review

Rule 56 of the Federal Rules of Civil Procedure facilitates the entry of a judgment only if no trial is necessary. *See White v. York Intern. Corp.*, 45 F.3d 357, 360 (10th Cir. 1995).

[1] It is axiomatic that remedies (such as damages of any kind) follow from claims. Thus, "judgment," summary or otherwise, is directed at claims, not damages.

Summary adjudication is authorized when there is no genuine dispute as to any material fact and a party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Substantive law governs what facts are material and what issues must be determined. It also specifies the elements that must be proved for a given claim or defense, sets the standard of proof and identifies the party with the burden of proof. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Kaiser-Francis Oil Co. v. Producer's Gas Co.*, 870 F.2d 563, 565 (10th Cir. 1989). A factual dispute is "genuine" and summary judgment is precluded if the evidence presented in support of and opposition to the motion is so contradictory that, if presented at trial, a judgment could enter for either party. *See Anderson*, 477 U.S. at 248. When considering a summary judgment motion, a court views all evidence in the light most favorable to the non-moving party, thereby favoring the right to a trial. *See Garrett v. Hewlett Packard Co.*, 305 F.3d 1210, 1213 (10th Cir. 2002).

If the movant has the burden of proof on a claim or defense, the movant must establish every element of its claim or defense by sufficient, competent evidence. *See* Fed. R. Civ. P. 56(c)(1)(A). Once the moving party has met its burden, to avoid summary judgment the responding party must present sufficient, competent, contradictory evidence to establish a genuine factual dispute. *See Bacchus Indus., Inc. v. Arvin Indus., Inc.*, 939 F.2d 887, 891 (10th Cir. 1991); *Perry v. Woodward*, 199 F.3d 1126, 1131 (10th Cir. 1999). If there is a genuine dispute as to a material fact, a trial is required. If there is no genuine dispute as to any material fact, no trial is required. The court then applies the law to the undisputed facts and enters judgment.

If the moving party does not have the burden of proof at trial, it must point to an absence of sufficient evidence to establish the claim or defense that the non-movant is obligated to prove.

If the respondent comes forward with sufficient competent evidence to establish a *prima facie* claim or defense, a trial is required. If the respondent fails to produce sufficient competent evidence to establish its claim or defense, then the movant is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

**B. Choice of law**

The parties agree that Pennsylvania's choice of law rules apply to determine which jurisdiction – Pennsylvania or Colorado – provides the substantive law that governs the Plaintiffs' claims. Both sides agree that, at least with regard to the failure to warn claim and its necessary element of causation, both Pennsylvania and Colorado law are the same. Thus, no choice of law determination need be made as to this issue, and both parties have relied on both Colorado and Pennsylvania law. As to the issue of punitive damages, the standards permitting such damages are different between the two jurisdictions, but as discussed below, the Court need not address the availability of punitive damages at this time.

**C. Failure to warn claim**

The parties agree that an essential element of a failure to warn claim, whether it sounds in negligence or strict products liability, is that the failure to give an adequate warning proximately caused the claimed damages. For purposes of this motion, Wyeth concedes the possibility that its warnings on Pondimin, as of 1996 or early 1997, were inadequate. However, it argues that any defects in Pondimin's labeling or supplementary warning material notwithstanding, the Plaintiffs cannot demonstrate that the defect caused Ms. Heineman's injuries because Dr. John did not consider those warnings when deciding to honor Ms. Heineman's request for a prescription.

Dr. John testified that, when providing care to his children like Ms. Heineman, "I would sign prescriptions" because "I happened to have a prescription pad at home, [and] I don't believe [Dr. Joan] did." Thus, Dr. John stated that he and Dr. Joan would discuss Ms. Heineman's requests for prescriptions, "[Dr. Joan] would make the decisions, and I would sign the prescription." Dr. John clarified that "the prescriptions I signed were blank, so my wife would fill them in." At the time Dr. John signed the prescriptions that Ms. Heineman ultimately used to obtain Pondimin, Dr. John acknowledged that he did not consult any written materials for information about the drug, did not review the Physician's Desk Reference ("PDR") entry for the drug, and did not discuss the drug with any colleagues. Indeed, he testified that Pondimn was "a drug that, frankly, I had never heard of at that point." Dr. John's failure to consider any information about Pondimin prior to prescribing it for Ms. Heineman is the core of Wyeth's argument that the Plaintiff's cannot demonstrate that the allegedly defective warning was not the proximate cause of Ms. Heineman's injuries.

This requires the Court to pause for a moment and address a potential dispute of fact. The Plaintiffs contend that Dr. Joan – who testified that she <u>had</u> considered the allegedly incomplete warning information in the PDR about Pondimin before allowing Ms. Heineman to have it – may have also written one or more prescriptions for Ms. Heineman. This contention is based on a passing comment made by Dr. Joan during her deposition. Asked whether she "actually sign[ed] the prescription for Pondimin for Ms. Heineman," Dr. Joan testified "Apparently, I did. The prescriptions that you listed here."[2] Her answer continued, "I think at the time I was not – I think Fitzsimmons [where Dr. Joan had been working] had closed and I was

[2] From other portions of the deposition, it appears that Dr. Joan is referring to a deposition exhibit that lists certain prescriptions that Dr. Joan wrote for Ms. Heineman that were filled by Walgreens after 2002, many years after Ms. Heineman stopped taking Pondimin.

between jobs and I might have gotten my husband to sign it." Counsel then inquired whether "you still could have signed the prescription," despite Dr. Joan's office having been closed, to which she responded "No. . . . the prescription pads were specifically for [Fitzsimmons Hospital]. . . I guess I could have signed one of my husband's and put my number down." Later, when asked "Did you simply ask your husband to issue a prescription that Ms. Heineman could fill," Dr. Joan responded "I think so."

Wyeth contends that Dr. Joan's answer that "apparently, I did" write Pondimin prescriptions for Ms. Heineman was simply Dr. Joan thinking out loud, and that the remainder of her answer (and subsequent answers) reveals her reasoning that, despite her initial answer, she does not actually believe that she wrote any such prescriptions. The Court agrees that Dr. Joan's testimony fails to raise a genuine dispute of fact as to whether she also wrote Pondimin prescriptions for Ms. Heineman. The record as a whole reveals that Dr. Joan has no specific personal memory of having done so; at best, her testimony reflects her acknowledging the possibility that she might also have written a prescription, but she concedes that her own recollection is that she "simply ask[ed Dr. John]" to issue the prescriptions. In that sense, the Court agrees that Dr. Joan's "apparently, I did" comment is merely Dr. Joan thinking out loud, before correcting herself, concluding that Dr. John wrote all of the prescriptions in question. Notably, the Plaintiffs do not point to any additional testimony by Dr. Joan that clearly expresses a specific recollection of having written one or more Pondimin prescriptions. Accordingly, the Court concludes, for purposes of this motion, that Dr. John, and only Dr. John, was responsible for signing the prescriptions for Pondimin for Ms. Heineman.

Thus, the question presented is whether Dr. John's failure to research or read Wyeth's warnings before prescribing the Pondimin means, as a matter of law, that the Plaintiffs cannot

prove the necessary element of causation. Wyeth's reasoning is that if Dr. John read no warnings, any defect in the warnings published by Wyeth regarding Pondimin is irrelevant – indeed, even a warning that accurately and comprehensively addressed Pondimin's dangers (or, hypothetically, even one that over-compensated, warning that any ingestion of the drug would lead to certain death) would not have dissuaded Dr. John from prescribing it for Ms. Heineman, as Dr. John never bothered to read any warnings.

Wyeth points out that both Colorado and Pennsylvania law provide that a drug manufacturer's duty to warn runs only to the prescribing physician, not to the patient or any other person. *Citing O'Connell v. Biomet, Inc.*, 250 P.3d 1278, 1281 (Colo.App. 2010) (" where prescription drugs are concerned, the manufacturer's duty to warn has been limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use"); *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971) ("Since the drug was available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor"). Known as the "learned intermediary" doctrine, this principle assumes that the prescribing doctor assumes the responsibility of ascertaining the drug's dangers and evaluating whether its risks outweigh its benefits.

Wyeth points to *Wollam v. Wright Medical Group, Inc.*, 2012 WL 4510695 (D.Colo. Sept. 30, 2012), a recent decision by Judge Ebel. There, the plaintiff sued the manufacturer of an allegedly defective hip implant, alleging (among other things) claims of failure to warn. Judge Ebel granted summary judgment to the manufacturer, first explaining the "learned intermediary" doctrine, then finding that "Wright Medical is entitled to summary judgment on this claim because Plaintiffs have not submitted any evidence suggesting that any failure to warn or inadequacy of the warnings Wright Medical gave was the proximate cause of Wollam's harm."

Finding that the plaintiff's physician "testified in his deposition that he never read the warnings or instructions Wright Medical included with [the device]," Judge Ebel concluded that "Plaintiffs failed to submit evidence indicating that additional or different warnings would have made any difference."

The Plaintiffs argue that, in these circumstances, Wyeth's duty to warn ran not only to Dr. John as the physician technically prescribing Pondimin for Ms. Heineman, but also to Dr. Joan, as the physician ostensibly "treating" Ms. Heineman and consulting with Dr. John on the suitability of Pondimin. In support of this contention, they rely on *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 142 (3d Cir. 1973). In *Hoffman*, the plaintiff's treating physician successively referred the patient to two specialists to deal with a facial rash. Despite knowledge of the potential risks, the specialists prescribed a drug that posed a risk of permanent eye damage, and the plaintiff did ultimately suffer such damage. The plaintiff's suit against the drug manufacturer proceeded to trial on, among other things, a duty to warn claim, and the trial court instructed the jury that "[s]ince this was a prescription drug, notice directly to the user was virtually impossible and the notice to the prescribing physicians and treating physicians who knew plaintiff was taking the drug was the most practical . . . [A]ny warning you find should be given, . . .should be given not only to the prescribing physicians . . . but also to the treating physician." *Id.* The jury returned a verdict in favor of the plaintiff, and the drug manufacturer appealed, arguing that "the trial judge improperly instructed the jury that they had a duty to warn both the prescribing and the treating physicians, and that this was prejudicial because the prescribing physician . . . was already aware of the danger to the eye." *Id.* at 141.

Acknowledging the Pennsylvania Supreme Court's adoption of the "learned intermediary" doctrine in *Incollingo*, the Circuit Court distinguished that ruling, finding that

"there was no treating physician in *Incollingo*, and the plaintiff's doctors in that case were both prescribing physicians." *Id.* at 142. The *Hoffman* court declined to construe the "learned intermediary" doctrine as "establish[ing] a class of doctors to whom a warning must be given," and instead understood it to "establish the most effective means by which a warning could reach the patient." *Id.* *Hoffman* explains that "Pennsylvania law would view it as insignificant whether the doctor is a prescribing or treating physician, the important consideration being that the warning best reach the patient." *Id.* Finding that "in the case at bar, a warning given to . . . the treating physician might have avoided the tragedy which occurred." *Id.*

In reply, Wyeth argues that *Hoffman* reflects only an "*Erie* [doctrine] guess" by the Third Circuit as to how Pennsylvania state courts would extend state law, as embodied by the then-recent *Incollingo* decision, to other factual scenarios. Wyeth contends that *Hoffman*'s guess was wrong, and that Pennsylvania state courts have consistently held that the "learned intermediary" doctrine extends the manufacturer's duty to warn only to the prescribing physician. *Citing, e.g., White v. Wiener*, 562 A.2d 378, 384-85 (Pa. Super. 1989); *Rosci v. AcroMed*, 669 A.2d 959, 969 (Pa. Super. 1995).

The Court finds Wyeth's argument to be incomplete at this point, thus preventing the entry of summary judgment in its favor. Assuming, without necessarily finding, that Wyeth's argument correctly assesses the current state of the "learned intermediary" doctrine in Pennsylvania and/or Colorado, the Court finds that this argument elides the question of how the phrase "prescribing physician" should be understood in the unusual factual scenario presented here. The record reflects that Dr. John did nothing more than sign a blank prescription form and turn it over to someone else, apparently abdicating any and all professional responsibilities that

accompany the act of prescribing medicine.[3] Those responsibilities were performed, if at all, by Dr. Joan, who allegedly considered the suitability of Pondimin for Ms. Heineman, presumably selected the appropriate dosage, and filled out the body of the prescription. Neither party has pointed this Court to authority (presumably under Colorado law, where Drs. Joan and John practiced) that would define which physician (if either, or both) would be considered the "prescribing physician" (whether for purposes of applying the "learned intermediary" doctrine or otherwise) in such unusual circumstances. Wyeth may be correct that the question is answered slavishly, based solely on the signature on the bottom of the prescription, regardless of how that prescription came to be.

Or it may be that the answer to that question is animated by the purposes of the "learned intermediary" doctrine, which assumes that the "prescribing physician" has discharged his or her "duty . . . to be fully aware of the characteristics of the drug he is prescribing, the amount of the drug that can be asfely administered, and the different medications the patient is taking . . . ." *Mazur v. Merck & Co.*, 964 F.2d 1348, 1356 (3d Cir. 1992). Indeed, *Mazur* is particularly elucidating on this question. There, a city required that all schoolchildren be vaccinated against certain diseases. The specific vaccine to be administered was selected by a doctor with the city's health department, but school nurses were charged with making individualized determinations as to whether particular children would be administered the vaccine. A student receiving the vaccine claimed injuries resulting from it and brought suit against the vaccine manufacturer, asserting failure to warn claims. The manufacturer invoked the "learned intermediary" rule, pointing out that the doctor with the city's health department had been fully advised of the

[3] The record does not reflect what disciplinary action(s) were or will be taken or sought against Dr. John in this regard. Nor do the parties address the extent to which Dr. John's conduct exposes him to a claim by Wyeth for contribution.

vaccine's risks. The trial court rejected the notion that the doctor was an appropriate intermediary (or, in the parlance used by the parties here, the "prescribing physician"), as he "did not perform the necessary individualized balancing required of a learned intermediary." *Mazur v. Merck & Co.*, 742 F.Supp. 239, 253 (E.D.Pa. 1990). The trial court contemplated the possibility that the nurses involved in screening students might be an appropriate intermediary, but left that question open for further development of a factual record. *Id.* at 254-55. Later, the trial court concluded that the nurse in question lacked the qualifications to be an appropriate intermediary, and, on appeal, the Third Circuit agreed (essentially finding no "learned intermediary" existed). 964 F.2d at 1356-58. "At bottom," the Circuit Court explained, "it is the physician who is required to make the individualized medical judgment of what treatment to administer in a given instance, and it is the physician who is ultimately held accountable for that decision." *Id.* at 1358. Thus, a case like *Mazur* suggests that the "prescribing physician" (a/k/a the "learned intermediary") is necessarily the person who makes the individualized medical judgment about what drugs should be administered. In the circumstances presented here, that person is almost certainly Dr. Joan.[4]

Thus, even if the Court assumes that the causation question is determined by whatever consideration was given to product warnings by the "prescribing physician," the parties have failed to adequately address the means by which the Court can identify this person (or perhaps

[4] Perhaps anticipating the possibility that Dr. Joan would be deemed the "prescribing physician," Wyeth proceeds to argue that Dr. Joan did not consider her own knowledge of Pondimin's risks when deciding to prescribe it to Ms. Heineman, and instead decided to prescribe the drug out of a mother's concern for her daughter. A reasonable juror could conclude that the cited excerpts of Dr. Joan's testimony establish merely that Dr. Joan may have allowed her familial love for Ms. Heineman to influence the risk/benefit analysis that a learned intermediary is expected to undertake. However, when asked whether she would have nevertheless prescribed Pondimin if she had known of the actual risks that Wyeth had failed to disclose, she stated "probably not," suggesting that such information might have tipped even a sympathy-skewed risk/benefit analysis in the opposite direction.

persons) in the peculiar circumstances of this case. Accordingly, the Court cannot grant summary judgment to Wyeth on the failure to warn claims on the theory presented in its motion.

Because the Court does not grant Wyeth's motion with regard to the failure to warn claims, it need not reach Wyeth's further argument that the remaining claims are merely restatements of the failure to warn claim, such that summary judgment on all claims is warranted.

**D. Punitive damages**

The Court then turns to Wyeth's motion directed at the Plaintiffs' "claim" for punitive damages. Wyeth argues that the choice of law question presented here should result in the Court applying Colorado substantive law. Further, it argues that, under such law, the Plaintiffs cannot establish that Wyeth engaged in "willful and wanton conduct" as is required by C.R.S. § 13-21-102(1) before punitive damages may be awarded, much less show that fact "beyond a reasonable doubt" as required by C.R.S. § 13-25-127(2).

In response, the Plaintiffs make only a perfunctory argument that Pennsylvania law should apply (contending merely that "Pennsylvania also has a strong interest and connection to Plaintiffs' claims," in that Wyeth is headquartered in Pennsylvania and made certain decisions concerning the labeling of Pondimin there). They concede that, under Colorado law, punitive damages may only be awarded on a showing of "willful and wanton conduct," proven beyond a reasonable doubt.

Both parties acknowledge the recognition that it is this Court's general practice to defer questions of the sufficiency of evidence to support a demand (*c.f.* claim) for punitive damages until the time of the charging conference, and the Court has every intention of adhering to that practice here. Moreover, Court rejects Wyeth's contention that the Plaintiffs' proffered evidence

of Wyeth officials seeking to "neutralize" efforts by physicians and researchers to highlight a connection between Pondimin and PAH is conduct that "has no connection to this case." The evidence is arguably germane to the question of whether a stronger warning for Pondimin was warranted, and, as discussed above, there is some evidence in the record to suggest that Dr. Joan gave due weight to the existing warnings about Pondimin before deciding to prescribe it for Ms. Heineman. The Court also rejects Wyeth's argument that the U.S. Supreme Court's decision in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) precludes the Plaintiffs from offering evidence in support of a demand for punitive damages. *Buckman* stands for the proposition that federal law governing FDA proceedings precludes state-law claims sounding in fraud on the FDA, but that case neither expressly or impliedly precludes a party from asserting that, as matter of fact, such fraud is evidence of a defendant's malicious or wanton state of mind.

Accordingly, Wyeth's motion for summary judgment on the issue of punitive damages is denied.

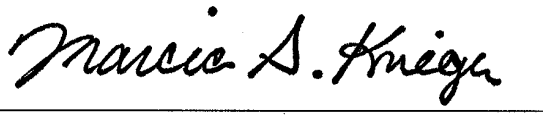
## CONCLUSION

For the foregoing reasons, Wyeth's Motions for Summary Judgment **(# 29, 30)** are **DENIED**. The record **(# 25)** reflects that discovery in this action was to have been completed by October 1, 2013, with only limited discovery reserved for completion thereafter. It appearing that the only remaining pretrial matters in this case concern hearings regarding the admissibility of certain expert testimony under Fed. R. Evid. 702, the Court directs that the parties jointly

contact chambers within 30 days to schedule a Pretrial Conference and request the issuance of a Trial Preparation Order to govern the completion of the parties' joint Proposed Pretrial Order.

Dated this 8th day of September, 2014.

**BY THE COURT:**



Marcia S. Krieger
Chief United States District Judge