UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

LOIS ILICH KOHO,

Plaintiff,

v.

FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC.,

Defendants.

Case No. C05-0667RSL

ORDER GRANTING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT

I. INTRODUCTION

This matter comes before the Court on plaintiff's "Motion for Partial Summary Judgment" (Dkt. #39) and "Motion to Supplement Summary Judgment Record" (Dkt. #55). Defendants respond with motions to strike a number of plaintiff's exhibits (Dkt. #48). Plaintiff has alleged products liability claims against defendants related to the 2002 death of her husband Ray Ilich. See Complaint (Dkt. #1) at 2-3. Plaintiff seeks summary judgment on two of defendants' affirmative defenses: preemption and the learned intermediary doctrine.

The Court has reviewed the parties' submissions and heard oral argument on the motion. For the reasons discussed below, the Court GRANTS in part and DENIES in part defendants' motions to strike,[1] GRANTS plaintiff's motion to supplement summary judgment record, and

[1] Defendants' request to hold the motion in abeyance in order to complete the deposition of Dr. Randall Gould is DENIED. "If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may: (1) defer considering the

GRANTS plaintiff's motion for partial summary judgment.

II. DISCUSSION

A. Background

Ray Ilich was prescribed the Selective Serotonin Reuptake Inhibitor (SSRI) Celexa by his physician, Dr. Randall Gould, in 2002 to treat situational depression. Motion (Dkt. #39) Ex. 16 at 2. Ilich returned to Dr. Gould a few days later reporting that his condition had deteriorated. Id. On August 13, seven days after being prescribed with Celexa, Ilich committed suicide. Id. Ilich was 48 years old. Id. Ex. 18 at 1.

The New Drug Application (NDA) for Celexa was submitted to the FDA on May 7, 1997. Response (Dkt. #48) at 12. The FDA approved Celexa on July 17, 1998, for the treatment of depression in adults. Id.

In 2002, the risk of suicide was referenced on the Celexa warning label as follows:

> The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for Celexa should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose.

Motion (Dkt. #39) Ex. 19 at 2. As the FDA gradually became more aware of the suicidality risks posed by SSRIs, the agency began mandating more stringent warnings. On March 19, 2004, the FDA required that the Celexa warning label be modified to add a new subsection entitled "Clinical Worsening and Suicide" which read:

> Patients with major depressive disorder, both adult and pediatric, can experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality), whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Although there has

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motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order." Fed. R. Civ. P. 56(d). To obtain relief under Rule 56(d) a party "must show: (1) it has set forth in affidavit form the specific facts it hopes to elicit from further discovery; (2) the facts sought exist; and (3) the sought-after facts are essential to oppose summary judgment." Family Home & Fin. Ctr., Inc. v. Fed. Home Loan Mortg. Corp., 525 F.3d 822, 827 (9th Cir. 2008). Defendants have not made a sufficient showing to merit additional discovery.

> been a long-standing concern that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients, a causal role for antidepressants in inducing such behaviors has not been established. **Nevertheless, patients being treated with antidepressants should be observed closely for clinical worsening and suicidality, especially at the beginning of a course of drug therapy, or at the time of dose changes, either increases or decreases** . . . **Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications should be alerted about the need to monitor patients for the emergence of agitation, irritability, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers.**

Konnerth Decl. (Dkt. #51) Ex. Y at 2 (emphasis in original). On May 1, 2007, the FDA continued to mandate the following language: "**All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.**" Id. Ex. MM at 3 (emphasis in original).[2]

Since approving the first SSRI, Prozac, in 1987, the FDA has received three citizen petitions requesting that approval be withdrawn based on claims that the drug caused suicidality. Response (Dkt. #48) at 12-15. These petitions, which were reviewed in 1990, 1991, and 1997, were rejected due to the FDA's conclusion that there was insufficient causal evidence to support an association between SSRIs and suicidality. Id. at 14. Over time, the FDA began mandating suicidality warnings concerning pediatric and young adult patients, but it has yet to find an increased risk of suicide in adults taking SSRIs. See id. at 16-19.

Plaintiff filed her complaint in the above-captioned case in April 2005. Complaint (Dkt. #1) at 1. The case was transferred to the Eastern District of Missouri in 2006 for consolidated pre-trial proceedings. See Transfer Order (Dkt. #26) at 1. While conducting the Multi-District Litigation, the court ruled that plaintiff's warnings expert, Dr. Michael Hamrell, was qualified to

[2] This is the latest version of the Celexa warning presented to this Court.

give expert testimony concerning the Celexa warning label. See In re Celexa and Lexapro Products Liab. Litig., MDL No. 1736, 2013 WL 791784, at *6 (E.D. Mo. March 4, 2013). On August 28, 2013, the case was remanded to this Court. Remand Order (Dkt. #28) at 1.

B. Motions to Strike

Defendants have moved to strike Exhibits 1, 2, 8, 16, 17, 18, 20, 22, 23, 25, 26, 27, 28, 29, and 30 in support of plaintiff's motion for partial summary judgment. Response (Dkt. #57) at 2. Plaintiff responds by moving to supplement the record with the Declaration of Arnold Vickery (Dkt. #55-1) and the deposition of Dr. Randall Gould. Motion (Dkt. #55) at 1-2. As many of the contested exhibits can be categorized based on their content, the Court will adjudicate defendants' motions by exhibit group.

1. Declaration of Arnold Vickery

Plaintiff moves to supplement the record with the Declaration of Arnold Vickery written by plaintiff's attorney. Motion (Dkt. #55) at 1. The declaration's purpose is solely to authenticate the exhibits submitted by plaintiff in support of her motion for partial summary judgment. Id. The Court therefore GRANTS plaintiff's motion to supplement the record with the Declaration of Arnold Vickery.

2. Exhibits 1, 2, 8, 29, and 30: Newspaper and Periodical Articles

Exhibits 1, 2, 8, 29, and 30 consist of various articles concerning the possible link between SSRIs and suicidality. See Motion (Dkt. #39) Ex. 1, 2, 8, 29, 30. Defendants contend that these exhibits are irrelevant and unauthenticated hearsay. Response (Dkt. #57) at 3. Fed. R. Evid. 902(6) allows "[p]rinted material purporting to be a newspaper or periodical" to be self-authenticating. Fed. R. Evid. 902(6). Plaintiff therefore does not need to authenticate the articles for them to be admissible.

"Evidence is relevant if: (a) it has any 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. 401. "The Rule's basic standard of relevance . . . is a liberal one." Daubert v.

Merrell Dow Pharm., Inc., 509 U.S. 579, 587 (1993). As the articles provide background information on the supposed link between suicidality and SSRIs, the Court finds that they pass the liberally construed relevance standard. Defendants' motions to strike Exhibits 1, 2, 8, 29, and 30 are therefore DENIED.

3. Exhibits 17 and 18: Medical Reports

Exhibits 17 and 18 are medical and autopsy reports concerning decedent Ilich. See Motion (Dkt. #39) Ex. 17, 18. Defendants contend that these records are both irrelevant and unauthenticated hearsay. Response (Dkt. #57) at 4. These exhibits are not properly authenticated by the Declaration of Arnold Vickery as Vickery lacks personal knowledge of the contents of the two reports. These documents could however be presented in a form admissible at trial. See Block v. City of Los Angeles, 253 F.3d 410, 418-19 (9th Cir. 2001) (At summary judgment stage, "a party does not necessarily have to produce evidence in a form that would be admissible at trial."). The Court also finds that these documents are relevant as they provide useful background information. Defendants' motions to strike Exhibits 17 and 18 are therefore DENIED.

4. Exhibits 20 and 22: Letters from Pharmaceutical Companies

Exhibits 20 and 22 are letters from pharmaceutical companies Wyeth and Glaxo SmithKline advising health care professionals of updated warning information for the SSRIs Effexor and Paxil. See Motion (Dkt. #39) Ex. 20, 22. The documents appear to have been discovered by plaintiff on the Internet. Vickery Decl. (Dkt. #55-1) at 3. Defendants assert that the exhibits have not been properly authenticated by a person with personal knowledge. Response (Dkt. #57) at 4. The Court agrees. As plaintiff's attorney, Vickery lacks personal knowledge of the information contained in the two letters. See Fed. R. Civ. P. 56(c)(4). The Court therefore GRANTS defendants' motion and strikes Exhibits 20 and 22.

5. Exhibits 23, 25, 26, and 27: Amicus Documents

Exhibits 23, 25, 26, and 27 pertain to an amicus brief submitted by the Department of

Justice in the Third Circuit Court of Appeals case Colacicco v Apotex Inc., 521 F.3d 253 (3rd Cir. 2008), vacated by Colacicco v. Apotex Inc., 566 U.S. 1101 (2009). See Motion (Dkt. #39) Ex. 23, 25, 26, 27. Exhibit 23 is the amicus brief in support of defendants. Id. Ex. 23. Exhibit 25 and 26 are letters from the Department of Justice concerning Colacicco. Id. Ex. 25, 26. Exhibit 27 is a Third Circuit Court of Appeals opinion remanding the matter to district court. Id. Ex. 27; see also Colacicco v. Apotex Inc., 2009 WL 9042591 (3rd Cir. April 28, 2009). Defendants contend that these documents are unauthenticated by plaintiff. Response (Dkt. #57) at 5. The Court agrees as to Exhibits 23, 25, and 26. As plaintiff's attorney, Vickery lacks personal knowledge of the information contained in the amicus brief and Department of Justice correspondence. See Fed. R. Civ. P. 56(c)(4). Further, the Court takes judicial notice of the Third Circuit court's decision, but will not admit the opinion for the purpose of establishing facts. See Wyatt v. Terhune, 315 F.3d 1108, 1114 (9th Cir. 2003) ("taking judicial notice of findings of fact from another case exceeds the limits of [Fed. R. Evid.] 201"). The Court therefore GRANTS defendants' motion with respect to Exhibits 23, 25, and 26.

6. Exhibit 28: FDA Interview

Exhibit 28 is an excerpt from an interview of two FDA doctors. See Motion (Dkt. #39) at 1. Defendants assert that the exhibit is unauthenticated hearsay. Response (Dkt. #57) at 6. The Court agrees. As plaintiff's attorney, Vickery lacks personal knowledge of the information contained in the interview. See Fed. R. Civ. P. 56(c)(4). The Court therefore GRANTS defendants' motion and strikes Exhibit 28.

7. Exhibit 16: Declaration of Randall K. Gould

Exhibit 16 contains the Declaration of Randall K. Gould, decedent Ilich's physician. See Motion (Dkt. #39) at 1. Defendants claim that Dr. Gould lacked personal knowledge and that the declaration is comprised primarily of speculation. Response (Dkt. #57) at 10. The Court will admit the Declaration of Randall K. Gould as the doctor merely discusses his professional judgment concerning what he would have done with different warnings. Further, although the

Declaration of Randall K. Gould should not be authenticated as an exhibit by the Declaration of Arnold Vickery, it can be presented in a form admissible at trial. See Block, 253 F.3d at 418-19. The Court therefore DENIES defendants' motion to strike Exhibit 16.[3]

8. Deposition of Randall K. Gould

Plaintiff moves to supplement the record with the deposition testimony of Dr. Gould. Motion (Dkt. #55) at 2. Defendants object to this supplementation but only submits argument against the Declaration of Randall K. Gould. See Response (Dkt. #57) at 6. The deposition contains relevant evidence concerning Dr. Gould's state-of-mind and procedure while treating decedent Ilich. The Court therefore GRANTS plaintiff's motion to supplement the summary judgment record with the deposition transcript.

C. Summary Judgment

The moving party is entitled to summary judgment under Fed. R. Civ. P. 56 ("Rule 56") "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). The moving party bears the initial burden of showing the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). If the moving party bears the burden of persuasion at trial, it must show that "the evidence is so powerful that no reasonable jury would be free to disbelieve it." Shakur v. Schriro, 514 F.3d 878, 890 (9th Cir. 2008) (internal quotation marks and citation omitted).

Where a nonmoving party will bear the ultimate burden of proof at trial, the moving party on motion for summary judgment bears both the initial burden of production and the ultimate

[3] Defendants also contend that they were not able to substantiate the contents of Dr. Gould's declaration during his deposition as they were not able to complete their questioning. Response (Dkt. #57) at 6. While the parties dispute which counsel is responsible for causing the termination of the deposition, this issue does not affect the admissibility of Dr. Gould's declaration.

burden of persuasion. Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Cos., Inc., 210 F.3d 1099, 1102 (9th Cir. 2000). To meet the burden of production, "the moving party must either produce evidence negating an essential element of the nonmoving party's claim . . . or show that the nonmoving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial." Id. Once the moving party meets its initial burden of persuasion, the nonmoving party must produce evidence to support its claim. Id. at 1103. If the nonmoving party fails to establish a genuine issue of material fact, the moving party is entitled to summary judgment. Id. All reasonable inferences supported by the evidence are to be drawn in favor of the nonmoving party. See Villiarimo v. Aloha Island Air, Inc., 281 F.3d 1054, 1061 (9th Cir. 2002).

Plaintiff moves for summary judgment on two of defendants' affirmative defenses: preemption and the learned intermediary doctrine.

1. Preemption

State law can be preempted by federal law under the Supremacy Clause, U.S. Const. Art. VI cl. 2, in three circumstances. English v. Gen. Elec. Co., 496 U.S. 72, 78 (1990). Express preemption occurs when "Congress . . . define[s] explicitly the extent to which its enactments pre-empt state law." Id. State law can also be preempted when the state "regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." Id. at 79. Finally, implied conflict preemption may be found if there would be "an 'actual[] conflict []' between state and federal law." Gilstrap v. United Air Lines, Inc., 709 F.3d 995, 1008 (9th Cir. 2013) (quoting Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992)). Implied conflict preemption can manifest in two forms: "where it is impossible for a private party to comply with both state and federal requirements [and] where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" English, 496 U.S. at 79 (internal citations omitted). Here, defendants assert that it was impossible to comply with both the FDA requirements for warning labels and state tort law. See Response (Dkt. #48) at 21.

The FDA's approval of an NDA is conditioned upon the manufacturer's use of an

approved warning label. 21 C.F.R. § 314.105(b). The majority of label changes require prior approval from the FDA. See 21 C.F.R § 314.70(b). Under the changes-being-effected (CBE) provision however, a manufacturer may issue certain changes in labeling prior to FDA approval. See 21 C.F.R. § 314.70(c). This provision permits changes to reflect newly acquired information

> (A) [t]o add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter; (B) [t]o add or strengthen a statement about drug abuse, dependence, psychological effect, or overdose; (C) [t]o add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product; (D) [t]o delete false, misleading, or unsupported indications for use or claims of effectiveness; or (E) [when a]ny labeling change normally requiring a supplemental submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.

21 C.F.R § 314.70(c)(6)(iii). "The ability to make CBE labeling changes underscores a central premise of federal drug regulation: A 'manufacturer bears responsibility for the content of its label at all times.'" Mason v. SmithKline Beecham Corp., 596 F.3d 387, 392 (7th Cir. 2010) (quoting Wyeth v. Levine, 555 U.S. 555, 570-71 (2009)).

The Supreme Court has directly addressed "whether the FDA's drug labeling judgments preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." Levine, 555 U.S. at 563 (internal quotation marks and citation omitted). In Levine, the plaintiff was injured as the result of an IV-push injection of Phenergan. Id. at 559. The plaintiff developed gangrene, leading to the amputation of her right forearm. Id. Wyeth, the manufacturer of Phenergan, argued that Levine's state law failure-to-warn claims were preempted because it was impossible to comply with both state law and the FDA's labeling requirements. Id. at 568.

The Court held that a manufacturer "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." Id. at 571. Wyeth could comply with both federal and state law as "the CBE regulation permitted it to provide such a warning before receiving the FDA's approval." Id. To prevail on an impossibility

conflict preemption claim, a defendant must provide clear evidence that the FDA would not have approved a change of the label. Levine, 555 U.S. at 571. Although "[t]he Supreme Court . . . did not clarify what constitutes 'clear evidence,'" Mason, 596 F.3d at 394, "[i]mpossibility pre-emption is a demanding defense," Levine, 555 U.S. at 573. "[L]ower courts are left to determine what satisfies this 'clear evidence' standard in each case." Dobbs v. Wyeth Pharm., 797 F.Supp.2d 1264, 1270 (W.D. Okla. 2011) (quoting Schilf v. Eli Lily & Co., No. CIV 07-4015, 2010 WL 3909909, at *4 (D.S.D. Sept. 30, 2010)).

Defendants' preemption argument rests on the premise that "the scientific substantiation to support the warning plaintiff advocates does not exist." Response (Dkt. #48) at 21. They contend that the FDA's past conclusions that there is no causal link between SSRIs and suicidality in adults constitute "clear evidence" under Levine. Id. Defendants, however, misconstrue plaintiff's failure-to-warn claim. Plaintiff argues Defendants "should have added a warning of increased risk of suicidal thoughts and behaviors early in treatment, including an emphasis on the importance of communicating the risk to family members who would be the first to observe any telltale changes in behavior." Reply (Dkt. #54) at 4. Defendants are correct that they had no authority to add a "black box warning" to the Celexa label. See Response (Dkt. #48) at 11. These are, however, not the type of warnings plaintiff contends should have been in effect. Neither is plaintiff asking for a specific warning that Celexa increases the likelihood of suicide among adult patients.

The lack of "clear evidence that the FDA would not have approved a change" is apparent when reviewing the updated warning labels supplied by defendants. The 2007 version includes the phrase "[**a**]**ll patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for** . . . **suicidality**." Konnerth Decl. (Dkt. #51) Ex. MM at 3 (emphasis in original). This language clearly includes decedent Ilich among those who should be closely observed during the initial treatment phase. The 2004 version states that "[**f**]**amilies and caregivers of patients being treated with antidepressants for major**

depressive disorder or other indications should be alerted about the need to monitor patients for the . . . emergence of suicidality, and to report such symptoms immediately to health care providers." Id. Ex. Y at 2 (emphasis in original). The inclusive "patient" categorization, utilized since the 2004 FDA mandated label change, makes it highly unlikely that the agency would not have approved a similar change two years earlier.

Defendants assert that the three citizen petitions rejected by the FDA during the 1990's constitute "clear evidence" that the agency would not have approved the labeling change. See Response (Dkt. #48) at 12-14. The final petition was rejected in 1997, five years before decedent Ilich was prescribed Celexa. Id. at 14. This Court joins several other district courts in finding that these petitions do not constitute "clear evidence." See Mason, 596 F.3d at 395 (noting temporal gap between petitions and suicide as well as fact that petitions involved different SSRIs); Dorsett v. Sandoz, Inc., 699 F.Supp.2d 1142, 1157 (C.D. Cal. 2010) (noting that "the FDA's rejection of those petitions constituted determinations that the warnings should not be *mandated*; they were not determinations that manufacturers could not choose to add warnings that they believed were scientifically substantiated."); see also Dobbs, 797 F.Supp.2d at 1277 ("This court agrees with Mason that the FDA rejection of the citizen petitions is not, without more, sufficient because Mr. Dobb's suicide, like that of Mr. Mason, occurred several years after 1997, and additional studies were conducted in the interim."). In light of the evolving nature of the data regarding the effects of prescription drugs, the temporal gap between the latest rejection of a citizen petition in 1997 and Ilich's death in 2002 is significant.

Plaintiff's warnings expert Dr. Michael Hamrell provides additional evidence that the FDA would not have rejected the alteration. Dr. Hamrell opined that "[t]he Lexapro and Celexa labels were inadequate at all times prior to 2005 and by June 30, 2001, Forest should have enhanced the warnings for suicidality." In re Celexa, 2013 WL 791784, at *5. Dr. Hamrell suggested the following language: "Patients of all ages who are started on Lexapro therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or

unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber." Id. This language is markedly similar to that approved by the FDA for subsequent Celexa warning labels. The MDL court concluded that "[i]n reaching this conclusion, Dr. Hamrell used the same type of methodology or analysis that he used while at the FDA." Id. at *6. Thus, Dr. Hamrell's opinion weighs against a finding of conflict preemption.

Defendants rely on Dobbs v. Wyeth Pharmaceuticals, the only district court decision that has found preemption in the context of failure to warn cases involving the suicidal risks of SSRIs since Wyeth.[4] In Dobbs, the plaintiff brought state law tort claims against the manufacturer of Effexor, an SSRI, to recover damages resulting from the suicide of her 53-year-old husband after taking Effexor for several days. 797 F.Supp.2d at 1266-67. The court found clear evidence that the FDA would have rejected a broader warning of the risks of suicidality in adults in Mr. Dobbs' age group prior to his suicide in 2002, and therefore, the plaintiff's state tort claims were preempted. Id. at 1277. In finding preemption, the court acknowledged that five other courts applying the Levine standard in a failure to warn case involving SSRIs have held that the manufacturer's evidence was inadequate to support preemption. Id. at 1277-80. The court, emphasizing the fact specific nature of the clear evidence standard, found these cases unpersuasive or distinguishable on their facts. Id. at 1270, 1280.

This court agrees with the Dobbs court that the clear evidence standard is a fact based

[4] Since the Supreme Court announced the clear evidence rule in Levine, five courts, including the Seventh Circuit Court of Appeals, have found that state tort claims in cases regarding insufficient warnings of the risk of suicidality of SSRIs are not preempted by federal law. Mason, 596 F.3d at 396; Baumgardner v. Wyeth Pharm., Nos. 06-2518, 06-2519, 06-2520, 06-2521, 06-2522, 06-2523, 06-2524, -06-2525, 06-2526, 06-2527, 2010 WL 3431671, at *1 (W.D. Pa. Aug. 31, 2010); Dorsett, 699 F.Supp.2d at 1164; Aaron v. Wyeth, No. 2:0vcv927, 2010 WL 653984 (W.D. Pa. Feb. 19, 2010); Forst v. Smithkline Beecham Corp., 639 F.Supp.2d 948, 955 (E.D. Wis. July 29, 2009). Beyond Dobbs, the Court has not located any case that has applied Levine in the context of failure to warn cases involving SSRIs and found preemption.

inquiry that depends on the express type of warning at issue and the particular facts of each case. Id. at 1266, 1270, 1280. As explained above, unlike the plaintiff in Dobbs, plaintiff here does not argue that Celexa should have contained an enhanced, general warning of suicidality for adults in Ilich's age group. Rather, the precise warning at issue in this case involves the increased risk of suicidal thoughts and behaviors during the initial phase of drug treatment and the recommendation that family members and caregivers monitor behavior early in treatment. Reply (Dkt. #54) at 4. In addition, unlike Dobbs, there is no evidence here that defendants proposed any enhanced warning regarding a risk of increased suicidality prior to or near the time of Ilich's death. It is undisputed that defendants did not propose any modifications to Celexa's label prior to Ilich's death in 2002.

In response to plaintiff's motion, defendants do provide evidence that the FDA would not have allowed it to deviate from the class labels regarding suicidality risks of SSRIs after March 2004, Laughren Decl. (Dkt. #49) at 6, and evidence that the FDA did in fact reject defendants' proposed label changes after 2004, Konnerth Decl. (Dkt. #51) Ex. GG. However, the FDA's rejection based on its 2004 decision to maintain consistent labels regarding suicidality risks associated with SSRIs as a class does not suggest that before 2002, the FDA would have prohibited a stronger, general warning regarding the need for close supervision of patients when they begin taking Celexa. See Forst, 639 F.Supp.2d at 954. On the contrary, the FDA continued to note that "sponsors have the authority to make changes [similar to those proposed by Wyeth] that are perceived to strengthen labeling from the standpoint of safety, without prior approval by FDA." Motion (Dkt. # 39) Ex. 24. Furthermore, the FDA's acceptance of Wyeth's enhanced warning regarding suicidality and increased hostility in children taking Effexor suggests that the FDA would not have rejected the particular warning at issue in this case. See Mason, 699 F.Supp.2d at 1159 ("A mere possibility that the FDA might not have allowed an enhanced suicidality warning for Prozac, despite allowing it for Effexor and Paxil, is not enough to warrant preemption."). In light of this evidence, defendants' speculation regarding how the FDA

would have viewed such a warning does not constitute clear evidence that the FDA would have rejected the particular warning at issue in this case. See Dorsett, 699 F.Supp.2d at 1159 (theoretical assumptions regarding what FDA may have done is not enough to warrant preemption).

As the Supreme Court noted, "[i]mpossibility pre-emption is a demanding defense." Levine, 555 U.S. at 573. Considering the particular facts and warning of this case, the Court finds that defendants have failed to demonstrate a genuine issue of material fact concerning whether there is "clear evidence that the FDA would not have approved a change." See id. at 571. The Court, therefore, GRANTS plaintiff's motion for summary judgment on defendants' affirmative preemption defense.

2. Learned Intermediary Doctrine

Plaintiff also moves for summary judgment on defendants' learned intermediary affirmative defense. Motion (Dkt. #39) at 21. "Washington follows the learned intermediary doctrine, so the manufacturer's duty is satisfied if the product is properly labeled and the prescribing physician has adequate warning as to any possible dangers." Luttrell v. Novartis Pharm. Corp., 894 F.Supp.2d 1324, 1342 (E.D. Wash. 2012); see Terhune v A. H. Robins Co., 90 Wn.2d 9, 14 (1978) ("the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient."). The Court of Appeals of Washington has stated that

> [t]o determine whether a warning is adequate requires an analysis of the warnings as a whole and the language used in the package insert. The court must examine the meaning and context of the language and the manner of expression to determine if the warning is accurate, clear and consistent and whether the warning portrays the risks involved in taking the prescription drug.

Estate of LaMontagne v. Bristol-Myers Squibb, 127 Wn. App. 335, 344 (2005). Further, "the Court must consider whether a 'different increased warning' would have persuaded the plaintiff, or under the learned intermediary doctrine, his physician, 'to take a different course of action.'"

Luttrell, 894 F.Supp.2d at 1344 (internal citation omitted).

When decedent Ilich was prescribed Celexa, the warning label only cautioned that suicide was inherent in depression itself, and did not discuss the possibility that the initiation of drug treatment may increase the risk of suicidality. See Motion (Dkt. #39) Ex. 19 at 2. Dr. Gould, the prescribing physician, has testified that "if I had known of this risk but had started him on the medication – which I doubt I would have done – I would have specifically discussed this risk with Ray and his wife Lois." Id. Ex. 16 at 3. Dr. Gould also mentioned that "[i]f I had been warned . . . I might not have started treatment with Celexa, and absolutely would have stopped it when his symptoms worsened." Id. As discussed above, the FDA began mandating inclusive "patient" language in the 2004 version of the Celexa warning label concerning suicidality. See Konnerth Decl. (Dkt. #51) Ex. Y at 2. The 2002 warning label did not inform Dr. Gould of this risk and his declaration makes clear that he would have acted differently had the risk been known to him.

In opposition to summary judgment defendants attack Dr. Gould's deposition as being inconsistent with his earlier declaration. Response (Dkt. #48) at 23. While his deposition testimony is more uncertain, Dr. Gould nevertheless states that "I would have been a lot more careful about prescribing it . . . [i]f I had been warned." Gould Depo. (Dkt. #54-1) at 42. Defendants focus on Dr. Gould's statements that Forest never withheld any information from him. Response (Dkt. #48) at 24. This is, however, irrelevant to the present inquiry. As Dr. Gould states in both his declaration and deposition, he would have taken different steps with a different warning. That is sufficient to satisfy the causation prong of the learned intermediary doctrine.

The Court therefore GRANTS plaintiff's motion for summary judgment on the learned intermediary affirmative defense as defendants fail to raise a genuine issue of material fact concerning the elements of that defense under Washington law.

III. CONCLUSION

For all the foregoing reasons, the Court GRANTS in part and DENIES in part defendants'

motions to strike (Dkt. #48), GRANTS plaintiff's motion to supplement summary judgment record (Dkt. #55), and GRANTS plaintiff's motion for partial summary judgment (Dkt. #39). The Clerk of the Court is directed to strike Exhibits 20, 22, 23, 25, 26, and 28 to plaintiff's motion for partial summary judgment.

DATED this 30th day of April, 2014.

Robert S. Lasnik
United States District Judge