UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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JOHN FLOWERS, Plaintiff,	3:14-cv-0094-LRH-VPC
v.	ORDER
ELI LILLY AND COMPANY, Defendant.	

Before the Court is Defendant Eli Lilly's ("Eli Lilly") Motion for Summary Judgment. Doc. #55.[1] Plaintiff John Flowers ("Flowers") filed an Opposition (Doc. #59), to which Eli Lilly replied (Doc. #60).

I. Facts and Procedural Background

Flowers is a pro se plaintiff who is currently in custody with the Nevada Department of Corrections ("NDOC"). Flowers has been prescribed Zyprexa since the beginning of his incarceration in 1997, although his initial prescription was discontinued in 2003. Flowers was re-prescribed Zyprexa in 2009, and this prescription has continued to the present. Zyprexa is a antipsychotic drug manufactured by Eli Lilly that has been approved by the Food and Drug Administration ("FDA") for treatment of schizophrenia and bipolar disorder. Flowers alleges that Zyprexa led to the onset of his type II diabetes, which was diagnosed in November 2012. At that time, Flowers requested that he be taken off Zyprexa. The request was denied, and Flowers says he was forced to continue taking the drug. Flowers alleges that he has been prescribed three times the suggested daily dose of Zyprexa due to the severity of his illness. Flowers alleges further that Dr. Jakob Camp ("Camp") contacted Eli Lilly in 2002 to inquire whether it was safe

[1] Refers to the Court's docket number.

to prescribe Flowers three times the suggested dose. Representatives of Eli Lilly allegedly responded that it was safe for Flowers to take such a large daily dose, and never suggested that Dr. Camp monitor weight, blood sugar, or other vitals that would have indicated the onset of diabetes.

In 2003, the FDA announced that it would require certain antipsychotic drugs, including Zyprexa, to include warnings about the risks of hyperglycemia and diabetes from taking these drugs. On September 16, 2003, Eli Lilly added the required language to the Zyprexa label and issued a press release about the new language. On March 1, 2004, Eli Lilly sent a letter to physicians in the United States informing them of the label change. In July 2007, Eli Lilly amended the Zyprexa label, and this language remained in the warning section of the label when Flowers was re-prescribed Zyprexa in 2009. This warning stated in part: "Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued." Doc. #55, Ex. A at 8. In 2009, the labeling was revised to include similar language regarding hyperglycemia, and a new warning regarding weight gain: "Potential consequences of weight gain should be considered prior to starting olanzapine. Patients receiving olanzapine should receive regular monitoring of weight." *Id.*, Ex. B at 7, 9.

Flowers filed his complaint against Eli Lilly on January 30, 2014. Flowers filed another complaint under 42 U.S.C. § 1983 against the Northern Nevada Correctional Center ("NNCC") on September 29, 2014. *Flowers v. Baca*, No. 14-cv-0366-RCJ-WGC.[2] On November 7, 2014, the Court granted Eli Lilly's Motion for Partial Dismissal, but Flowers' claim for negligence based on failure to warn remains. Doc. #43. Eli Lilly filed the present Motion for Summary Judgment on March 30, 2015. Doc. #55.

II. Legal Standard

Summary judgment is appropriate only when "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 judgment as a matter

[2] On September 29, 2014, Judge Robert C. Jones dismissed Flowers' Complaint against the NNCC. Flowers filed a Notice of Appeal on October 7, 2014.

of law." Fed. R. Civ. P. 56(c). In assessing a motion for summary judgment, the evidence, together with all inferences that can reasonably be drawn therefrom, must be read in the light most favorable to the party opposing the motion. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587 (1986); *Cnty. of Tuolumne v. Sonora Cmty. Hosp.,* 236 F.3d 1148, 1154 (9th Cir. 2001).

The moving party bears the burden of informing the court of the basis for its motion, along with evidence showing the absence of any genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). On those issues for which it bears the burden of proof, the moving party must make a showing that is "sufficient for the court to hold that no reasonable trier of fact could find other than for the moving party." *Calderone v. United States*, 799 F.2d 254, 259 (6th Cir. 1986); *see also Kerwin v. Remittance Assistance Corp.*, 559 F. Supp. 2d 1117, 1121 (D. Nev. 2008).

To successfully rebut a motion for summary judgment, the non-moving party must point to facts supported by the record which demonstrate a genuine issue of material fact. *Reese v. Jefferson Sch. Dist. No. 14J,* 208 F.3d 736 (9th Cir. 2000). A "material fact" is a fact "that might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Where reasonable minds could differ on the material facts at issue, summary judgment is not appropriate. *See v. Durang*, 711 F.2d 141, 143 (9th Cir. 1983). A dispute regarding a material fact is considered genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Liberty Lobby*, 477 U.S. at 248. The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient to establish a genuine dispute; there must be evidence on which the jury could reasonably find for the plaintiff. *See id.* at 252.

III. Discussion

Eli Lilly argues that the Court should grant summary judgment on Flowers' failure to warn claim because the company's warnings to doctors regarding the potential Zyprexa side effects were adequate as a matter of law, and regardless, Flowers cannot establish proximate

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causation of his injuries. Flowers argues that Eli Lilly continually attempted to hide the truth about Zyprexa, and never informed individuals taking the drug about its potential side effects.

Under Nevada law, a plaintiff asserting product liability claims must prove: "1) the product had a defect which rendered it unreasonably dangerous, 2) the defect existed at the time the product left the manufacturer, and 3) the defect caused the plaintiff's injury." *Fyssakis v. Knight Equip. Corp.*, 826 P.2d 570, 571 (Nev. 1992). "A failure to warn may constitute a product defect." *Heredia v. Johnson*, 827 F. Supp. 1522, 1525 (D. Nev. 1993); *see Allison v. Merck and Co., Inc.*, 878 P.2d 948, 956 n.12 (Nev. 1994) (discussing standards for failure to warn in the product defect context). The Nevada Supreme Court has adopted the "learned intermediary rule" in the context of personal injury claims against pharmacists. *Klasch v. Walgreen Co.,* 264 P.3d 1155, 1157-58 (Nev. 2011). "Under the learned-intermediary doctrine, a drug manufacturer is immune from liability to a patient taking the manufacturer's drug so long as the manufacturer has provided the patient's doctor with all relevant safety information for that drug." *Id.* at 1158.[3] "It is then up to the patient's doctor—who has the benefit of knowing the patient's specific situation—to convey to the patient any information that the doctor deems relevant." *Id.*; *see Phillips v. C.R. Bard, Inc.*, No. 3:12-cv-0344, 2014 WL 7177256, at *9 (D. Nev. Dec. 16, 2014) (finding that the defendant manufacturer was "entitled to summary judgment as to liability for failing to warn Plaintiff of any risks for which they in fact warned Plaintiff's physician").

The Court considers Eli Lilly's Motion first based on Flowers' prescription after 2004—when Eli Lilly informed doctors of its altered label—and second based on his prescription before 2004.

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[3] The Nevada Supreme Court has not expressly applied the learned intermediate doctrine in prescription medicine product liability cases. "In the absence of controlling precedent from the Nevada Supreme Court, this Court must use its own best judgement to predict how the state court would decide the relevant substantive issues." *Rio Props., Inc. v. Stewart Annoyances, Ltd*., 420 F. Supp. 2d 1127, 1131 (D. Nev. 2006) (citing *Dimidowich v. Bell & Howell*, 803 F.2d 1473, 1482 (9th Cir. 1986)). In the absence of case law to the contrary, the Court believes that the Nevada Supreme Court would apply the learned intermediary doctrine to prescription medicine product liability cases. *See Klasch,* 264 P.3d at 1157-58.

A. Prescription After 2004

Zyprexa began including warnings about hyperglycemia and diabetes on its labeling in 2003, and in that same year issued a press release about this label change. On March 1, 2004, Eli Lilly wrote a letter to doctors in the United States informing them of this label change.[4] Amended versions of these warnings were on the label when Flowers was re-prescribed Zyprexa in 2009. Moreover, the record indicates that at all times relevant to this litigation, each doctor or nurse responsible for Flowers' medication was aware of the potential side effects of Zyprexa, and made a knowing determination that these risks were outweighed by the risks of discontinuing Flowers' Zyprexa prescription, which had been more effective than other drugs in treating Flowers' psychotic symptoms. Dr. Ronald Centric ("Centric") treated Flowers from 2009 to 2011. Dr. John Harris ("Harris") treated Flowers from 2011 to 2013. Dr. Stephen Frye ("Frye") treated Flowers from 2013 to 2014. Nurse Teodoro Manalang ("Manalang") has treated Flowers from 2014 to the present. Each of these individuals stated in their depositions that they were aware of the side effects associated with Zyprexa—including weight gain and increased blood sugar—but continued to prescribe the drug because it was effective in treating Flowers' psychotic symptoms, and these benefits outweighed the risks. *See* Doc. #56, Ex. H (Centric Depo.) at 113:4-23; Doc. #55, Ex. J (Harris Depo.) at 26:5-27:11; Doc. #56, Ex. G (Frye Depo.) at 25:8-11, 53:12-54:5;[5] Doc. #55, Ex. K (Manalang Depo.) at 43:2-18.

Based on the foregoing, the Court finds that Eli Lilly met its burden—under the failure to warn and learned intermediary standards—to communicate the potential for Zyprexa to lead to

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[4] The warnings included in the Zyprexa labels, attached to Eli Lilly's Motion (Doc. #55, Ex. A, Ex. B), are adequate under the guidelines established by the Nevada Supreme Court. *See Lewis v. Sea Ray Boats, Inc.*, 65 P.3d 245, 250 (Nev. 2003) (finding that warnings "must be (1) designed to reasonably catch the consumer's attention, (2) that the language be comprehensible and give a fair indication of the specific risks attendant to use of the product, and (3) that warnings be of sufficient intensity justified by the magnitude of the risk").

[5] Flowers argues that Frye acknowledged in his deposition that he could not recall being informed about metabolic risks associated with second-generation antipsychotics. Doc. #59 at 4. However, this portion of Frye's testimony referred only to black box warnings, and regardless, Frye stated clearly that he was aware of the metabolic risks associated with Zyprexa, and that he still determined that the drug's psychological benefits outweighed these risks. *See* Doc. #56, Ex. G at 53:12-23.

weight gain and diabetes to Flowers' physicians after 2004. This finding is consistent with the findings of the Second Circuit Court of Appeals in *Shepherd v. Eli Lilly & Company*, which the Court finds to be persuasive. Referring to Eli Lilly's March 1, 2004, "Dear Doctor" letter, the court found that "the District Court was correct to conclude that Eli Lilly could not be liable under a failure-to-warn theory after that date." *Shepherd v. Eli Lilly & Co.*, 497 Fed. Appx. 143, 145 (2d Cir. 2012). As in *Shepherd*, the Court finds that Eli Lilly's "Dear Doctor" letter, in addition to the stated knowledge of Centric, Harris, Frye, and Manalang regarding Zyprexa's potential side effects, establishes that Eli Lilly fulfilled its obligation to warn doctors under the learned intermediary doctrine. Accordingly, the Court grants Eli Lilly's Motion for Summary Judgment as to any failure to warn after 2004 because as a matter of law, Eli Lilly cannot be liable under a failure to warn theory based on Flowers' post-2004 prescription.

Even if the learned intermediary doctrine did not apply, the Court would find as a matter of law that Flowers could not establish proximate causation. As discussed above, each doctor or nurse who prescribed Flowers Zyprexa after 2004 did so with knowledge of its metabolic risks, and based on a judgment that those risks were outweighed by the benefits to Flowers' treatment. The Court agrees with the large number of district courts that have determined in similar situations that the plaintiff could not establish proximate cause. *See, e.g.*, *Young v. Eli Lilly & Co.*, No. 11-cv-3555, 2012 WL 2374644, at *9 (E.D.N.Y. June 22, 2012) (applying Maryland law and granting summary judgment because plaintiff's physician testified that he knew Zyprexa's side effects included weight gain and diabetes, but determined that the benefits outweighed the risks); *Greaves v. Eli Lilly & Co.*, 277 F.R.D. 243, 250-51 (E.D.N.Y. 2011) (applying Rhode Island law and granting summary judgment because there was no evidence that the doctor "would have altered his prescription had the warning that accompanied Zyprexa been different"); *Neal v. Eli Lilly & Co.*, No. 06-cv-2782, 2009 WL 1852001, at *14-15 (E.D.N.Y. June 22, 2009) (applying California law and granting summary judgment partially because there was "no evidence that any of plaintiff's treating psychiatrists would have altered their decision to prescribe Zyprexa to plaintiff had a different warning been provided by Lilly").

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B. Prescription Before 2004

Eli Lilly's Motion is nearly devoid of discussion regarding Flowers' prescription prior to Eli Lilly's heightened warnings in 2004. The Motion does acknowledge that "Flowers was treated with Zyprexa for slightly more than a year in 2002 and 2003, initiated by psychiatrist Dr. Jakob Camp and continued by psychiatrist Dr. Ole Thienhaus." Doc. #55 at 9 n.6. Drs. Camp and Thienhaus have since moved out of state, and therefore have not been deposed by Eli Lilly. Moreover, there is no evidence on the record that Eli Lilly warned doctors about the potential side effects of Zyprexa prior to 2003. In fact, Flowers alleges that Camp requested information about the drug from Eli Lilly in 2002, and he was not warned about the potential metabolic side effects. Accordingly, Eli Lilly has not met its burden to establish that the learned intermediary doctrine would bar Flowers' claim regarding his prescription prior to 2004.

In *Shepherd*, the Second Circuit also considered a plaintiff's failure to warn claim against Eli Lilly for Zyprexa that was first prescribed before 2004. After finding that Eli Lilly's "Dear Doctor" letter insulated Eli Lilly from liability for failure to warn after 2004, the Court found that the plaintiff's claim that his injuries "were caused by residual effects of his Zyprexa usage before 2004" failed because plaintiff's own causation expert "concluded that his diabetes was caused by the Zyprexa he took from 2006 to 2009." 497 Fed. Appx. at 145. Here, the parties have not yet conducted expert discovery regarding causation. In its Motion, Eli Lilly states that it "denies that Zyprexa was a substantial factor in causing Flowers' claimed diabetes injury, but the issue is not ripe for dispositive motion given that expert discovery has yet to occur." Doc. #55 at 2 n.1. Without this causation testimony, Eli Lilly has not met its burden to resolve the disputed questions of material fact regarding whether Flowers' Zyprexa prescription before 2004 contributed to the subsequent diabetes diagnosis. *See Celotex Corp.*, 477 U.S. at 323 (finding that the party moving for summary judgment has the burden to establish the absence of genuine disputes of material fact). Accordingly, the Court denies Eli Lilly's Motion for Summary Judgment as to Flowers' Zyprexa prescription prior to 2004.

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IV. Conclusion

IT IS THEREFORE ORDERED that Eli Lilly's Motion for Summary Judgment (Doc. #55) is GRANTED in part and DENIED in part.

IT IS FURTHER ORDERED that the parties shall file a joint pre-trial order with the Court pursuant to Local Rules 16-3 and 16-4 within forty-five (45) days of this Order.

IT IS SO ORDERED.

DATED this 10th day of July, 2015.

LARRY R. HICKS
UNITED STATES DISTRICT JUDGE