UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

INA ANN RODMAN,

Plaintiff,

v.

OTSUKA AMERICA PHARMACEUTICAL, INC.,

Defendant.

Case No. 18-cv-03732-WHO

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Re: Dkt. No. 65, 66, 67, 68

In this product liability suit, plaintiff Ina Rodman alleges that she suffers from a movement disorder known as Tardive Dyskinesia ("TD") as a result of ingesting the prescription antipsychotic medication Abilify. She brings failure to warn and design defect claims against defendant Otsuka America Pharmaceutical, Inc. ("Otsuka"). Before me are cross-motions for summary judgment on the failure to warn claim, along with Otsuka's motion for summary judgment on the design defect claim. Both parties also move to exclude portions of expert testimony.

Rodman's case founders on a lack of proof. For the reasons set forth below, I GRANT summary judgment in favor of Otsuka on all three theories of Rodman's failure to warn claim, as well as her design default claim. Along the way, I GRANT Otsuka's motion to exclude Dr. Laura M. Plunkett's expert testimony on label inadequacy and DENY the remainder of its motion as moot. And I DENY Rodman's motion for partial summary judgment on her failure to warn claim and DENY as moot her motion to exclude portions of Dr. Sara J. Polfliet's and Dr. Christoph U. Correll's expert testimony.

BACKGROUND

Abilify is an "atypical" or "second-generation" antipsychotic prescription medication that

was first approved by the United States Food and Drug Administration ("FDA") for the treatment of schizophrenia. See Corrected Declaration of Matthew M. Saxon in Support of Defendant's Motion for Summary Judgment ("Saxon Decl. ISO MSJ") [Dkt. No. 73-2] ¶ 3 & Ex. B (2002 Abilify Label). It has since been approved by the FDA to treat several other mental health conditions, including bipolar disorder and Major Depressive Disorder ("MDD"). See id. ¶ 4 & Ex. C (2009 Abilify Label at 1). Since the medication was first marketed, the Abilify label has included the following warning about the risks of TD:

> **5.4 Tardive Dyskinesia**
>
> A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.
>
> The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.
>
> There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and, thereby, may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.
>
> Given these considerations, ABILIFY should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness

> that (1) is known to respond to antipsychotic drugs and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.
>
> If signs and symptoms of tardive dyskinesia appear in a patient on ABILIFY, drug discontinuation should be considered. However, some patients may require treatment with ABILIFY despite the presence of the syndrome.

Id., Ex. B (2002 Abilify Label at 8-9); see also Ex. C (2009 Abilify Label at 17-18).

In 2010, Rodman's prescribing physician and psychiatrist, Dr. John Hawkins, diagnosed Rodman with MDD and prescribed her Abilify. Id., Ex. A, (Hawkins Dep. at 157:3-24) and Ex. H, (Rodman Medical Records at 28, 32). In June 2015, after a change in medical insurance, Rodman emailed Dr. Hawkins explaining that Abilify has become "quite expensive" and asking for instructions about how best to discontinue the medication. Id., Ex. H (Rodman Medical Records at 334). Dr. Hawkins replied with instructions for weaning her off Abilify and told her to monitor her mood as she did. Id. He also instructed her to "be sure to follow-up with a new psychiatrist under you[r] new medical coverage." Id.

On March 30, 2016, a doctor at the University of Florida diagnosed Rodman with "dyskinesia of the tongue." Id., Ex. J (Rodman Dental Records at 9). On May 19, 2016, she began seeing a neurologist, Dr. Anette Nieves, who treated her TD symptoms. Id., Ex. F (Nieves Dep. at 47:11-48:23).

In the First Amended Complaint ("FAC") [Dkt. No. 28], Rodman alleges three theories with regard to failure to warn: (i) the Abilify label "did not accurately reflect the incidence and risk of developed [TD]" with the use of Abilify (FAC ¶¶ 26, 30); (ii) the Abilify label "failed to specifically discuss the fact that [TD] had been reported in patients taking Abilify, including those taking lower doses for depression" (FAC ¶ 25); and (iii) the label failed to "provide[] a discussion or instruction regarding specific methods for screening patient for [TD], such as AIMS (Abnormal Involuntary Movement Scale)" (FAC ¶ 29). The FAC also asserts a claim for defective design.

FAC ¶¶ 34-35.[1]

On March 2, 2020, Rodman filed a motion for partial summary judgment on the failure to warn claim and motion to exclude or limit the expert reports of Dr. Polfliet and Dr. Correll. See Plaintiff's Motion for Partial Summary Judgment ("Rodman Partial SJ") [Dkt. No. 66]; Plaintiff's Motion to Exclude Duplicative Expert Testimony and Motion to Exclude Inadmissible Expert Testimony ("Rodman Mot. Exclude") [Dkt. No. 65]. On the same day, Otsuka filed its motion for summary judgment on both the failure to warn and design defect claims and a motion to exclude the expert report of Dr. Plunkett. See Defendant's Motion for Summary Judgment ("Otsuka MSJ") [Dkt. No. 67]; Defendant's Motion to Exclude Testimony of Laura M. Plunkett ("Otsuka Mot. Exclude") [Dkt. No. 68].[2] On May 6, 2020, I heard argument from the parties.

LEGAL STANDARD

I. MOTION FOR SUMMARY JUDGMENT

Summary judgment on a claim or defense is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In order to prevail, a party moving for summary judgment must show the absence of a genuine issue of material fact with respect to an essential element of the non-moving party's claim, or to a defense on which the non-moving party will bear the burden of persuasion at trial. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the movant has made this showing, the burden then shifts to the party opposing summary judgment to identify "specific facts showing there is a genuine issue for trial." Id. The party opposing summary judgment must present affirmative evidence from which a jury could return a verdict in that party's favor. Anderson v. Liberty Lobby, 477 U.S. 242, 257 (1986).

On summary judgment, the court draws all reasonable factual inferences in favor of the

[1] On November 6, 2018, I denied Otsuka's motion to dismiss the FAC on grounds that it is barred by California's two-year statute of limitations. See Order Denying Motion to Dismiss [Dkt. No. 37].

[2] On March 30, 2020, Otsuka filed errata for both of its motions due to clerical errors and errors in compiling exhibits. See Defendant's Corrected Motion for Summary Judgment [Dkt. No. 73-1]; Defendant's Corrected Motion to Exclude Testimony of Laura M. Plunkett [Dkt. No. 74-1].

non-movant. Id. at 255. In deciding the motion, "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." Id. However, conclusory and speculative testimony does not raise genuine issues of fact and is insufficient to defeat summary judgment. See *Thornhill Publ'g Co., Inc. v. GTE Corp.*, 594 F.2d 730, 738 (9th Cir. 1979).

II. MOTION TO EXCLUDE EXPERT TESTIMONY

Federal Rule of Evidence 702 allows a qualified expert to testify "in the form of an opinion or otherwise" where:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

To be admissible under Rule 702 expert testimony must be relevant and reliable. See Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (1993). "[R]elevance means that the evidence will assist the trier of fact to understand or determine a fact in issue." Cooper v. Brown, 510 F.3d 870, 942 (9th Cir. 2007); see also Primiano v. Cook, 598 F.3d 558, 564 (9th Cir. 2010) ("The requirement that the opinion testimony assist the trier of fact goes primarily to relevance.") (internal quotation marks omitted).

Under the reliability requirement, the expert testimony must "have] a reliable basis in the knowledge and experience of the relevant discipline." Primiano, 598 F.3d at 565. To ensure reliability, the court must "assess the [expert's] reasoning or methodology, using as appropriate such criteria as testability, publication in peer reviewed literature, and general acceptance." Id. These factors are "helpful, not definitive," and a court has discretion to decide how to test reliability "based on the particular circumstances of the particular case." Id. (internal quotations marks and footnotes omitted). "When evaluating specialized or technical expert opinion testimony, the relevant reliability concerns may focus upon personal knowledge or experience." United States v. Sandoval-Mendoza, 472 F.3d 645, 655 (9th Cir. 2006).

DISCUSSION

I. MOTIONS TO EXCLUDE EXPERT TESTIMONY

A. Motion to Exclude Expert Testimony of Dr. Plunkett

Rodman retained Dr. Plunkett, a pharmacologist, toxicologist, and FDA regulatory specialist, to support her failure to warn claim. See Corrected Declaration of Matthew M. Saxon in Support of Defendant's Motion to Exclude Expert Testimony ("Saxon Decl. ISO Mot. Exclude") [Dkt. No. 74-2] Ex. B (Plunkett Rep.). Otsuka moves to exclude Dr. Plunkett's testimony on two grounds: (i) she is not qualified to offer label inadequacy opinions and her opinions are not reliable nor based on sufficient facts or data; (ii) she is not qualified to offer a specific causation opinion. Otsuka Mot. Exclude 1.

1. Dr. Plunkett's Opinion on Label Inadequacy

Otsuka attacks Dr. Plunkett's opinions supporting Rodman's three failure to warn theories that the Abilify label:

- "failed to adequately describe the risk of [TD] associated with use of the drug" because "the scientific literature [] contained discussion of the fact that the occurrence rate for [TD] was much higher than 0.1 to 1%, the 'infrequent' standard that was mentioned in the initial Abilify labeling." Plunkett Rep. ¶ 33.
- "failed to specifically discuss the fact that [TD] had been reported in patients taking Abilify, including those taking lower doses for depression." Plunkett Rep. ¶ 33.
- "never provided a discussion or instruction regarding specific methods for screening patients for [TD], such as AIMS (Abnormal Involuntary Movement Scale)." Plunkett Rep. ¶ 36.

In this section, I focus on whether Dr. Plunkett is qualified to render the first opinion and if it is based both on reliable facts or data and is the product of reliable principles or methods. As I explain later in Sections II.A.2-3, I deny Otsuka's motion to exclude Dr. Plunkett's second and third opinions as moot because I am granting Otsuka's motion for summary judgment on the second and third failure to warn theories since Dr. Hawkins unequivocally testified that a label that

added these points would not have changed his prescribing decision.

Otsuka argues that Dr. Plunkett lacks the qualifications to opine on the adequacy of the Abilify label because she has no special knowledge of antipsychotics like Abilify, she cannot prescribe them, and she has not published articles about them. Otsuka Mot. Exclude 7. While she cannot prescribe Abilify or diagnose TD, those skills are not necessary prerequisites to testifying about the adequacy of Abilify's label. Dr. Plunkett's experience and expertise as a toxicologist and pharmacologist qualify her to opine on Otsuka's labeling practices and the adequacy of its Abilify label. See In re Xarelto (Rivaroxaban) Prod. Liab. Litig., No. MDL 2592, 2017 WL 1352860, at *2 (E.D. La. Apr. 13, 2017) (denying motion to exclude Dr. Plunkett in case bringing multiple product liability claims, including failure to warn, and finding that she is "qualified to testify about drug pharmacology, general causation, regulatory matters and the adequacy of labels for both prescription and non-prescription drugs").

That said, the method she employed here is problematic. Dr. Plunkett primarily relies on a survey of scientific published literature to conclude that the Abilify label "failed to adequately describe the risk of [TD] associated with use of the drug." Plunkett Rep. ¶ 33. She describes this survey of scientific literature in paragraph 21 of her report.

It was initially reported that the risk of TD was greater with older antipsychotics compared to new agents, like Abilify, but Dr. Plunkett explains that published literature starting as early as 2006 found that may not be the case. Id. ¶ 21 (string cite of articles). She draws attention to two sources in particular. The first source is a 2011 study that calculated a 3.4% "estimate of the rate of occurrence of [TD] in a clinic population." Plunkett Rep. ¶¶ 21, 34; see Saxon Decl. ISO Mot. Exclude, Ex. I (Peña, M.S., et al. 2011, Tardive dyskinesia and other movement disorders secondary to aripiprazole. Mov. Disord. 26:147-152) (hereinafter "Peña study"). The second source is a listing of events found in the FDA Adverse Event Reporting System known as "FAERS". TD was the second most frequent reported adverse event among Abilify users and Dr. Plunkett finds that this "reporting rate (5%) was similar to the rate reported by Peña in 2011 in clinic experience (3.4%)." Plunkett Rep. ¶ 34. She compares these figures to those provided on the Abilify label. TD was listed on the Abilify label as an "infrequent" adverse reaction that was

observed outside of clinic studies with Abilify; infrequent was defined as an occurrence of greater than 0.1% but less than 1%. Plunkett Rep. ¶ 31.[3]

From all of this she concludes that "consideration of the body of studies related to [TD] and Abilify use show that [TD] is not a rare event (i.e., less than 0.1%) or even an infrequent event (less than 1%) but instead may be considered a common adverse event (greater than 1%)." Id. ¶ 21. Her concluding paragraph reads: "Therefore, it is my opinion that the Abilify labeling on the drug prescribed by Dr. Hawkins and used by Ms. Rodman failed to adequately describe the risk of [TD] associated with use of the drug. Moreover, removal of the mention of [TD] from the Adverse Reactions section of the label in 2014 was inconsistent with the fact that the reporting of [TD] in the published literature has risen significantly and that physicians were reporting higher rates of [TD] than 1% (see paragraph 21 above). Failure to provide physicians with accurate and up to date information on the occurrence of [TD] put patients at risk." Id. ¶ 33.

Otsuka's motion focuses on the inaccuracies of comparing data collected from Dr. Plunkett's cited sources to data reflected on the Abilify label. The "infrequent" figure of 0.1 to 1% that Dr. Plunkett identifies in the Abilify label was a calculated incidence rate of TD among Abilify users; the 5% (from FAERS) and 3.4% (from Peña study) figures she compares it with were not true incidence rates. A true incidence rate is one that looks at a pool of Abilify users to identify how many patients developed TD. The studies Dr. Plunkett cites looked at a pool of those with TD and identified how many of them used Abilify, which does not result in a true incidence

[3] Dr. Plunkett also points out that this specific "infrequent" warning was located on the Abilify label when it was first approved by the FDA in 2002. Abilify continued to carry it in 2007, when it was approved for use in MDD. Plunkett Rep. ¶ 31. But in December 2014, the specific mention of "infrequent" occurrence of TD was dropped from that particular "Adverse Reaction" section of the label. Id. She finds it "difficult to understand why the term was removed altogether from this section" given that "by 2014 there were numerous reports of [TD] in the published medical literature (see discussion in above paragraph 21)." Id. ¶ 33.

As Otsuka points out, the December 2014 label still mentioned TD under the "Adverse Reaction" section by cross-referencing the reader to the "Warnings and Precautions" section of the label, which contained the warning reproduced in the Background section of this Order. What Dr. Plunkett referred to was the removal of information about the frequency of the TD from a particular portion of the "Adverse Reaction" section of the label. See Declaration of Matthew M. Saxon in Support of Defendant's Reply in Support of its Motion to Exclude Expert Testimony [Dkt. No. 81-1] ¶ 6 & Ex. E (2014 Abilify Label at ECF page numbers 417, 428, 444).

rate.

Both the FAERS and Peña study cautioned that their sources cannot be used to calculate an incidence rate. In the cover letter accompanying the FAERS data, which Rodman's counsel obtained via Freedom of Information Act ("FOIA") request and on which Dr. Plunkett relied, the FDA expressly stated that the FAERS data cannot be used to calculate an incidence rate. See Saxon Decl. ISO Mot. Exclude, Ex. F (FOIA Request and Response at 5) ("The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.") (emphasis added). The Peña study had a similar disclaimer. See id., Ex. I (Peña study at 150) ("[T]he true prevalence and incidence of TD and other drug-induced movement disorders associated with TGAs, such as aripiprazole [Abilify], are not known."). Dr. Plunkett also conceded in her deposition that the FAERS data and the Peña study did not give her an incidence rate of TD. See id., Ex. C (Plunkett Dep. at 126:12-15); id., Ex. H (copy of Dr. Plunkett Dep. in Crochet v. Bristol-Myers Squibb Co., Case No. 3:16-cv-00036 (M.D. La.), at 56:3-6; 324:11-19; 284:4-23).

Dr. Plunkett may not "analyze[] data that was not [her] own and reinterpret[] it in a manner inconsistent with the conclusions of those who originally generated it." Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc., 55 F. Supp. 2d 1024, 1040 (N.D. Cal. 1999); In re Accutane Prod. Liab., No. 804-MD-2523-T-30TBM, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009), *aff'*d, 378 F. App'x 929 (11th Cir. 2010) ("[W]hen an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study."). Indeed, "experts are properly disqualified if the studies on which they rely merely suggest, without definitely concluding, the truth of a particular assertion." *Haynes ex rel. Haynes v. Nat'l R.R. Passenger Corp.*, 319 F. App'x 541, 543 (9th Cir. 2009) (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136, 144–47 (1997)).

Notably, Dr. Plunkett's testimony has been previously excluded in another drug product liability case on analogous grounds. The court in In re Mirena Ius Levonorgestrel-Related Prod. Liab. Litig. (No. II), 341 F. Supp. 3d 213, 260 (S.D.N.Y. 2018) concluded "there [was] too great an analytic gap between the available data and the conclusion" that Dr. Plunkett drew. In that case, Dr. Plunkett opined on the causality between a prescription drug and idiopathic intracranial

hypertension. In making her conclusion, she found that the temporality factor was satisfied based on her reliance on "three studies which, she stated, had 'addressed' temporality (by Valenzuela, Rai, and Alder) and on three case reports drawn from the Bayer database." Id. at 255. "Beyond identifying these materials, however, Dr. Plunkett [did] not address their contents. The Valenzuela authors, for instance, specifically noted in their publication that they lacked temporal data." Id. The court found that "Dr. Plunkett's handling of the Valenzuela study is [] problematic" and ultimately excluded her proposed testimony because it was "beset by methodological deficiencies." Id. at 261, 263

Similarly, in this case Dr. Plunkett exceeds the boundaries of the sources she relies on by going beyond what the sources concluded. Without explanation, she compares figures that authors explicitly cautioned are not true incidence rates with the true incidence rate provided in Abilify's label. Rodman argues that only Otsuka has the capability to calculate the true incidence rates, but this assertion is rebutted by Otsuka's expert, Dr. Correll, who was able to conduct a true incidence rate study of Abilify (which Rodman does not seek to exclude).[4]

Dr. Plunkett does not explain why it makes sense to compare different data sets and how that necessarily leads to her conclusion that the Abilify label was inadequate. For example, she does not address the contents of the Peña study that gave her the supposedly comparative figure of 3.4%. The Peña study was an analysis of TD patients over the span of eight years at a movement disorders clinic in Houston, Texas. The review found that for 8 out of the clinic's 236 patients being treated for TD, their symptoms were either "definite[ly]" or "probabl[y]" associated with Abilify. See Saxon Decl. ISO Mot. Exclude, Ex. I (Peña study at 150).[5] Importantly, the study analyzed a pool of TD patients and tracked whether they had taken Abilify in the past, not a pool

[4] As discussed in Section I.B. of this Order, Rodman's motion to exclude other portions of Dr. Correll's expert testimony is DENIED as moot.

[5] A patient was categorized as "definite" Abilify-associated TD if Abilify was the only neuroleptic used prior to the onset of the movement disorder; a patient was categorized as "probable" if the patient was exposed to multiple neuroleptics, but [Abilify] was the last one before the movement disorder emerged. See Saxon Decl. ISO Mot. Exclude, Ex. I (Peña study at 150). Out of the eight patients identified in the study, five patients were categorized as "definite" and three were categorized as "probable". Id.

of Abilify users to track whether they contracted TD, which would have led to a true incidence rate. In addition to cautioning that the study did not provide a true incidence rate, the authors recognized that although patients classified as "definite" were "only those patients taking [Abilify] alone before the developments of TD, we cannot exclude the possibility that they were also taking other neuroleptics as medication history was obtained only from the patient interview." Id. at 151.

In her opposition, Rodman attempts to characterize Dr. Plunkett's report in a different way. She claims that even though the data and studies Dr. Plunkett relies upon cannot establish incidence rates, they "should have alerted Otsuka to investigate and change the Abilify label." Plaintiffs' Memorandum of Points and Authorities in Opposition to Defendant's Motion to Exclude Testimony of Dr. Laura M. Plunkett [Dkt. No. 75] 13. But the concluding paragraph in question here, on which Rodman primarily relies for her failure to warn claim, reflects a different conclusion:

> During this time, the scientific literature also contained discussion of the fact that the occurrence rate for tardive dyskinesia was much higher than 0.1 to 1%, the "infrequent" standard that was mentioned in the initial Abilify labeling and in the labeling in 2010 through December 2014 as well. Therefore, it is my opinion that the Abilify labeling on the drug product prescribed by Dr. Hawkins and used by Ms. Rodman failed to adequately describe the risk of tardive dyskinesia associated with use of the drug.

Plunkett Rep. ¶ 33.

Rodman also argues that Dr. Plunkett's report would be helpful to the jury because her expertise in FDA regulation is necessary to explain how Otsuka should have used the information at its disposal to label its product correctly. But Dr. Plunkett's report does not opine on whether Otsuka met the FDA guidelines; she testifies about whether the Abilify label adequately warns doctors about use of this prescription drug.[6]

Because Dr. Plunkett extrapolated conclusions beyond the scope of her sources, I find that

[6] Even if I take Rodman's re-characterization of Dr. Plunkett's report at face value, Dr. Plunkett does not explain how a failure to investigate informs her failure to warn claim. See, e.g., Latiolais v. Merck & Co., Inc., 2007 WL 5861354, at *3 n.1 (C.D. Cal. 2007) (finding a failure-to-act theory, based on pharmaceutical negligent testing of medication, "is subsumed by the manufacturer's duty to warn and it does not change the premise of Plaintiff's claims, which is that [the pharmaceutical company's] failure to warn of any product defects or dangers—tested or not—ultimately caused" the injury).

her opinion on label inadequacy is not the product of reliable principles or methods. Otsuka's motion to exclude Dr. Plunkett's opinion on label inadequacy is GRANTED and its motion to exclude other opinions by Dr. Plunkett, namely on specific causation, is DENIED as moot. As explained below, this is ultimately fatal to Rodman's failure to warn claim on the theory that the Abilify label underreported the risk of contracting TD.

B. Motion to Exclude Expert Testimony of Dr. Polfliet and Dr. Correll

Rodman moves to exclude Dr. Polfliet's expert testimony on grounds that it is duplicative with testimony from Otsuka's other expert, Dr. Correll, and to exclude certain portions of Dr. Polfliet's and Dr. Correll's opinions because they "improperly offer legal conclusions" regarding Dr. Hawkins' testimony and speculate as to his state of mind. Rodman Mot. Exclude 3-4, 9-11. Given my ruling on the other motions, Rodman's motion to exclude is DENIED as moot.

II. MOTIONS FOR SUMMARY JUDGMENT

A. Failure to Warn

A manufacturer of a prescription drug is obligated warn physicians, not patients, of potential side effects associated with its pharmaceutical products. Motus v. Pfizer Inc., 196 F. Supp. 2d 984, 990 (C.D. Cal. 2001) ("Motus I"), *aff'd sub nom.* Motus v. Pfizer Inc. (Roerig Div.), 358 F.3d 659 (9th Cir. 2004) ("Motus II"). Known as the "learned intermediary" doctrine, the duty to warn the physician—rather than the patient—applies in the case of prescription drugs and implants, where "the physician stands in the shoes of the 'ordinary user' because it is through the physician that a patient learns of the properties and proper use of the drug or implant." Valentine v. Baxter Healthcare Corp., 68 Cal. App. 4th 1467, 1483 (1999). A manufacturer discharges its duty to warn if it provides adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient. Motus I, 196 F. Supp. 2d, at 991 (citation omitted).

"A plaintiff asserting causes of action based on a failure to warn must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury." Motus I, 196 F. Supp. 2d at 991. Whether a warning is adequate depends on "how a prescribing doctor would understand the label." Hexum v. Eli Lilly

& Co., 2015 WL 5008263 at *7 (C.D. Cal. 2015). There can be no genuine dispute about the adequacy of a warning that "directly warns in plain and explicit terms of the specific risk that has caused injury to the plaintiff." Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 673-74 (S.D.N.Y. 2017) (applying California law), *aff'd sub nom. Gibbons v. Bristol*-Myers Squibb Co., 919 F.3d 699 (2d Cir. 2019).

Otsuka moves for summary judgment on the failure to warn claim on grounds that Rodman has failed to adduce any evidence that the Abilify label was inadequate or that an additional warning would have changed how Dr. Hawkins treated her. Otsuka MSJ 10. Rodman cross-moves for partial summary judgment on grounds that there is no genuine dispute that the Abilify label was inadequate under all three of her failure to warn theories. Rodman Partial SJ 2. While she does not explicitly say so in her motion, she appears to argue that there is no genuine dispute on the proximate causation element of her failure to warn claim as well. Id. at 10.

1. Rodman's First Theory: the label understated the incidence and risk of developing TD with use of Abilify

Rodman concedes that the Abilify label mentions TD as a risk; instead, she contends that Otsuka "failed to disclose the actual risk of contracting [TD] adequately, that was known or knowable in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution." Rodman Partial SJ 1. She relies on Dr. Plunkett's expert report to argue that she has met the first element (label inadequacy) of her failure to warn claim under this theory. Id. at 6-7; see also id. at 8 ("Dr. Plunkett concluded her report and testimony by confirming that defendant failed to properly identify the incidence rate of tardive dyskinesia.")

Because I exclude Dr. Plunkett's opinion on this point and that opinion is essential to the first element of Rodman's failure to warn theory, summary judgment is GRANTED to Otsuka. See, e.g., Carlucci v. CNH America LLC, No. 10–12205–DPW, 2012 WL 4094347, at *1, *10 (D. Mass. Sept.14, 2012) (noting that "[a]fter determining to grant [the defendant's] motion to exclude [the plaintiffs' defective design and warnings expert's] testimony, [the court] conclude[s][it] should grant [the defendant's] motion for summary judgment" since "[a]s to their negligence and

breach of implied warranty claims for design defects . . . the [plaintiffs'] lack of expert testimony is fatal").[7]

2. Rodman's Second Theory: the label failed to specifically discuss the fact that TD has been reported in patients taking Abilify, including those taking lower doses

"[I]nadequacy of the warning and causation are separate elements of Plaintiffs' affirmative burden." Tucker v. Wright Med. Tech., Inc., No. 11-CV-03086-YGR, 2013 WL 1149717, at *16 (N.D. Cal. Mar. 19, 2013). Therefore, even if a warning was inadequate, "a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." Motus II, 358 F.3d at 661. In other words, a defendant may prevail on summary judgment "by showing that Plaintiff lacks evidence establishing that an adequate warning would have affected [the doctor's] decision to prescribe [the medication]." Motus I, 196 F. Supp. 2d at 992. A defendant "need not produce its own evidence; pointing to an absence of evidence on the Plaintiff's part is sufficient." Id. (citation omitted).

Rodman argues that the label warning failed to specifically discuss the fact that TD has been reported in patients taking Abilify, including those taking lower doses for depression. Otsuka responds that the label already included a warning to physicians that patients taking low doses of Abilify could develop TD. See Saxon Decl. ISO MSJ, Ex. B (2002 Abilify Label at 8-9) (stating that TD "can develop, although much less commonly, after relatively brief treatment periods at low doses"); id., Ex. C (2009 Abilify Label at 17-18) (same); Declaration of Matthew M. Saxon in Support of Defendant's Reply in Support of its Motion to Exclude Expert Testimony [Dkt. No. 81-1] ¶ 6 & Ex. E (2014 Abilify Label at ECF page number 417).

Even assuming that the label did not include an adequate warning about TD risks at low doses, Rodman's argument fails. Dr. Hawkins confirmed that he was aware that Abilify could cause TD even in patients taking lower doses. See Saxon Decl. ISO MSJ, Ex. A (Hawkins Dep. at

[7] At the hearing, Rodman argued that she has met the second element of her failure to warn claim under this theory because Dr. Hawkins testified that if the incidence rate of TD was higher than depicted on the Abilify label, then it would have impacted his prescribing decision. Even if Rodman has met the second element, the point here is that she has failed to establish a genuine issue of material fact regarding the first element of her claim.

263:18-264:2) (statement that "syndrome can develop . . . after relatively brief periods at low doses" was "consistent with [his] understanding while [he was] treating Ms. Rodman"). He repeatedly testified that he "knew when [he was] prescribing Ms. Rodman Abilify that [TD] was one of the risks of the medication," and that "[TD] was a possibility" with the use of Abilify. See id. at 121:20-122:15, 118:18-25; see also id. at 102:10-14 (admitting that "when [he] began prescribing Ms. Rodman Abilify, at that time [he] understood that [TD] was one of the risks associated with the use of Abilify"). He also testified that he understood that one of the risks "related to discontinuing use of Abilify" was that "there can be symptoms of [TD] when an antipsychotic is discontinued." Id. at 294:14-19. Even if the label had included the warning desired by Rodman, Dr. Hawkins unequivocally testified that it would not have impacted his prescribing decision.

Otsuka's motion for summary judgment on this failure to warn theory is GRANTED.

3. Rodman's Third Theory: the label failed to provide instruction regarding specific methods for screening patients for TD, such as the AIMS test

Rodman argues that the Abilify label failed to provide a discussion or instruction regarding specific methods for screening patients for TD, such as the AIMS test. But Dr. Hawkins testified that he knew how to monitor for TD symptoms, including using the AIMS test, and monitored Rodman while she was in his care. See Saxon Decl. ISO MSJ, Ex. A (Hawkins Dep. at 124:21-24, 126:25-127:15, 270:10-271:13 (Dr. Hawkins testified that he was "familiar with the AIMS test" at the time he was prescribing Abilify to Rodman, that he has been familiar with the test "for a long time" having learned about it during medical school or residency training, and that he "didn't need a drug company at the time to tell [him] about the AIMS test"). A change in the label would not have impacted Dr. Hawkins's prescribing decision because he already understood ways to monitor Rodman for TD symptoms, including the AIMS test. Accordingly, Otsuka's motion for summary judgment on this failure to warn theory is GRANTED.

In sum, summary judgment is GRANTED to Otsuka on all three theories of Rodman's failure to warn claim.

B. Design Defect

California does not recognize strict liability for design defects in prescription drugs. See Brown v. Super. Ct., 44 Cal.3d 1049, 1061 (1988) ("[A] drug manufacturer's liability for a defectively designed drug shall not be measured by the standards of strict liability."). A plaintiff alleging a design defect claim under a negligence theory must prove "that the defect in the product was due to negligence of the defendant." Tucker, 2013 WL 1149717, at *7 (N.D. Cal. Mar. 19, 2013) (quoting Chavez v. Glock, Inc., 207 Cal.App.4th 1283, 1305 (2012)). As with a general negligence claim, the plaintiff must show breach of duty, causation, and damages. Id. (citation omitted). Concerning the standard of care for negligence, a "[designer/manufacturer/etc.] is negligent if [it] fails to use the amount of care in [designing/manufacturing/etc.] the product that a reasonably careful [designer/manufacturer/etc.] would use in similar circumstances to avoid exposing others to a foreseeable risk of harm. Id. (citation omitted, alteration in original).

Generally, "the test of negligent design involves a balancing of the likelihood of harm to be expected from a [product] with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm." Tucker, 2013 WL 1149717, at * 7 (quoting Merrill v. Navegar, Inc., 26 Cal. 4th 465, 479 (2001)). Even if a manufacturer has done all it reasonably could have done to warn about a risk or hazard related to a product's design, a reasonable person could conclude that the magnitude of the reasonably foreseeable harm as designed outweighed the utility of the product as designed. Id. (citation omitted). "In evaluating the adequacy of a product's design under the risk-benefit test, 'a jury may consider, among other relevant factors, the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design.'" Tucker, 2013 WL 1149717, at * 8 (citation omitted).

In opposing Otsuka's summary judgment motion on this claim, Rodman argues that she "has no obligation" to offer evidence at this point because she is "not required to divulge the testimony of medical witnesses designated to testify at trial." Plaintiff's Opposition to

Defendant's Motion for Summary Judgment ("Oppo. Otsuka MSJ") [Dkt. No. 77] 15-16. This is not the law. As the non-moving party with the burden of proof, Rodman "must set forth by affidavit or other admissible evidence, specific facts demonstrating the existence of an actual issue for trial"; she "may not merely state that [she] will discredit the moving party's evidence at trial and proceed in the hope that something can be developed at trial in the way of evidence to support [her] claim." *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n,* 809 F.2d 626, 630 (9th Cir. 1987); see also Richardson v. CBS Studios Inc., No. CV 12-7925 ABC (SHX), 2013 WL 12120265, at *7 (C.D. Cal. Sept. 25, 2013) ("[s]ummary judgment is warranted because Plaintiffs, the non-moving parties, have failed to produce enough evidence to create a genuine issue" and cannot wait until trial to present that evidence); Codding v. Pearson Educ., Inc., No. 18-CV-00817-LB, 2019 WL 5864579, at *10 (N.D. Cal. Nov. 8, 2019) (granting summary judgement after rejecting argument that plaintiff "has no obligation to offer affirmative evidence on [] issue until trial").

The limited evidence Rodman does identify comes short of creating a genuine dispute on the design defect claim. She cites the deposition of Dr. Anette Nieves, the neurologist who diagnosed her with TD, who testified that she does not prescribe Abilify to her patients and that she may prescribe clonazepam and quetiapine when "a patient would come off of an antipsychotic medication." See Declaration of Perry R. Staub, Jr. in Support of Opposition to Defendant's Motion for Summary Judgment ("Staub Decl."), Ex. 2 (Nieves Dep. at 38:3-10). Dr. Nieves never suggested that these two medications were safer alternatives to Abilify, just that she would recommend patients take these medications when "com[ing] off an antipsychotic medication," like Abilify. Id. at 38:5.

Rodman also cites testimony from Dr. Hawkins that if he had been aware that the rate of TD was higher than that reported in the label, he might have considered other alternative medications. Oppo. Otsuka MSJ 15. But this testimony does not address whether there were any safer alternative medications to Abilify.

Next, she relies on two portions of Dr. Plunkett's expert report that discuss the different pharmacological profile of Abilify versus other atypical antipsychotic drugs. Oppo. Otsuka MSJ

16. In the first portion, Dr. Plunkett merely describes "[o]ther drugs that have been or are used today in the treatment of psychotic disorders," not that any of these are necessarily safer alternatives than Abilify. Staub Decl., Ex. 3 (Plunkett Rep. ¶ 15). In the other portion, Dr. Plunkett finds that "like other anti-psychotic drugs, the risk of adverse events such as [TD] would be biologically plausible"; Rodman does not explain how this shows existence of a safe alternative design. Id. at ¶ 20. Rodman fails to show how any of Dr. Plunkett's concluding paragraphs relate to her design defect claim. Id. ¶¶ 33-38.

Even if the testimony she points to could somehow create a genuine despite on the existence of a safe alternative design, Rodman fails to address any other elements of a design defect claim. For example, she does not point to evidence that goes to the relative costs and benefits of Abilify as compared with similar drugs on the market. Nor does she provide any evidence that Otsuka failed to design Abilify with the amount of care that a reasonably careful designer or manufacturer would have used in similar circumstances and "presents no admissible evidence regarding what a reasonably careful designer or manufacturer would have done with respect to the design." Mariscal v. Graco, Inc., 52 F. Supp. 3d 973, 991 (N.D. Cal. 2014) (granting summary judgment to defendant where plaintiff "produced no other admissible evidence from which a jury could deduce the appropriate standard of care, which is fatal to [plaintiff's] negligent design defect claim"). Instead, she incorrectly argues that she "has no obligation to divulge the planned trial testimony of treating medical physicians disclosed as testifying experts at trial." Oppo. Otsuka MSJ 16.

For these reasons, Otsuka's motion for summary judgment on the design defect claim is GRANTED.

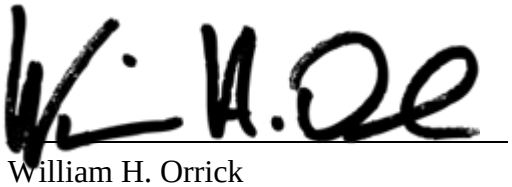
CONCLUSION

Accordingly, Otsuka's motion for summary judgment on all three theories of Rodman's failure to warn claim and design defect claim is GRANTED. Its motion to exclude Dr. Plunkett's expert testimony on label inadequacy is GRANTED and the rest of its motion is DENIED as moot. Rodman's motion for partial summary judgment on her failure to warn claim is DENIED

and her motion to exclude Dr. Polfliet's and Dr. Correll's expert testimony is DENIED as moot.

IT IS SO ORDERED.

Dated: May 18, 2020



William H. Orrick
United States District Judge

United States District Court
Northern District of California