United States District Court
Northern District of California

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 DENYING MOTION FOR RECONSIDERATION

Re: Dkt. No. 91

Plaintiff Ina Rodman asks that I reconsider the grant of summary judgment to defendant Otsuka America Pharmaceutical, Inc. ("Otsuka"). She seeks reconsideration of the portion of my order dismissing one of her failure to warn theories based on the allegation that the label on the prescription antipsychotic medication Abilify did not accurately reflect the incidence and risk of developing a movement disorder known as Tardive Dyskinesia ("TD"). Because she either rehashes old arguments and theories raised in the summary judgment briefing or raises evidence and argument for the first time that could reasonably have been raised earlier, her motion for reconsideration is DENIED.

BACKGROUND

Rodman filed this product liability suit for defective design and failure to warn, alleging that she suffers from TD as a result of ingesting Abilify. First Amended Complaint ("FAC") [Dkt. No. 28]. She alleged three theories with regard to failure to warn: (i) the Abilify label "did not accurately reflect the incidence and risk of developing [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).

On March 2, 2020, both parties filed cross-motions for summary judgment on the failure to warn claim, and Otsuka filed a motion for summary judgment on the design defect claim. Both parties also moved to exclude portions of expert testimony. Otsuka moved to exclude Dr. Laura M. Plunkett's expert opinion on the adequacy of Abilify's label. Rodman moved to exclude Dr. Sara J. Polfliet's expert testimony on grounds that it is duplicative with testimony from Otsuka's other expert, Dr. Christoph U. Correll, and to exclude certain portions of Dr. Polfliet's and Dr. Correll's opinions because they "improperly offer[ed] legal conclusions" regarding the testimony of Dr. John Hawkins, Rodman's doctor, and speculated as to his state of mind.

On May 18, 2020, I granted summary judgment in favor of Otsuka as to both the defective design and failure to warn claims. Order Granting Defendant's Motion for Summary Judgment ("MSJ Order") [Dkt. No. 87]. As to Rodman's failure to warn claim, I dismissed her first theory because the lack of expert testimony to support the first element (label adequacy) was fatal. I dismissed her second and third theory because even if the label had included the warning she desired, she did not have enough to support the second element (causation). Dr. Hawkins unequivocally testified that an improved or different label would not have impacted his prescribing decision. He confirmed that he was aware that Abilify could cause TD even in patients taking lower doses and testified that he knew how to monitor for TD symptoms, including using the AIMS test, and monitored Rodman while she was in his care. MSJ Order 14–15.

On June 15, 2020, Rodman moved to reconsider the portion of my order dismissing her first failure to warn theory. Plaintiff's Motion for Reconsideration ("Mot.") [Dkt. No. 91]. She does not seek reconsideration of my dismissal of her other two failure to warn theories or her design defect claim.

LEGAL STANDARD

Federal Rule of Civil Procedure 59(e) permits a district court to reconsider and amend a previous order under certain circumstances. A motion for reconsideration is appropriate if the court: "(1) is presented with newly discovered evidence, (2) committed clear error or the initial decision was manifestly unjust, or (3) if there is an intervening change in controlling law." *Sch.*

Dist. No. 1J, Multnomah Cnty., Or. v. ACandS Inc., 5 F.3d 1255, 1263 (9th Cir. 1993); *accord Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co.*, 571 F.3d 873, 880 (9th Cir. 2009); *Kona Enterprises, Inc. v. Estate of Bishop*, 229 F.3d 877, 890 (9th Cir. 2000). Reconsideration "offers an extraordinary remedy, to be used sparingly in the interests of finality and conservation of judicial resources." *Carroll v. Nakatani*, 342 F.3d 934, 945 (9th Cir. 2003) (internal quotation marks omitted). Accordingly, a motion for reconsideration may not be used to raise evidence or argument for the first time that "could reasonably have been raised earlier in the litigation." *Marlyn*, 571 F.3d at 880 (internal quotation marks omitted); *see also Bhatnagar v. Surrendra Overseas Ltd.*, 52 F.3d 1220, 1231 (3d Cir. 1995) ("[R]eargument should not be used as a means to argue new facts or issues that inexcusably were not presented to the court in the matter previously decided.") (internal quotation marks omitted).

DISCUSSION

I. EXCLUSION OF DR. PLUNKETT'S EXPERT TESTIMONY AND DISMISSAL OF THE FIRST FAILURE TO WARN THEORY

Rodman seeks reconsideration of my decision to exclude Dr. Plunkett's expert testimony on grounds that Dr. Plunkett properly used the FAERS data and case studies to offer her expert opinion. Mot. 6. She simply restates the same argument she made in her opposition to both Otsuka's motion for summary judgment and its motion to exclude Dr. Plunkett's testimony, which I have already considered and rejected. *See F.T.C. v. Neovi, Inc.*, No. 06-CV-1952-JLS JMA, 2009 WL 56130, at *2 (S.D. Cal. Jan. 7, 2009), *aff'd*, 604 F.3d 1150 (9th Cir. 2010) ("A motion for reconsideration is not an opportunity to renew arguments considered and rejected by the court, nor is it an opportunity for a party to re-argue a motion because it is dissatisfied with the original outcome.").

Rodman insists that "[w]hile these sources do not provide exact incidence rates for TD among Abilify users, they provide signals that Otsuka should have investigated in order to change its label." Mot. 9. This is exactly what she argued in her opposition to Otsuka's motion to exclude Dr. Plunkett's testimony. Plaintiff's Memorandum of Point and Authorities In Opposition To Defendant's Motion To Exclude Testimony Of Dr. Laura M. Plunkett [Dkt. No. 75] 14

("Plunkett offers an opinion on Otsuka's failure to act upon this information."). I considered this argument and found her attempt to re-characterize Dr. Plunkett's report in a different way was unconvincing. MSJ Order 11 (finding that the "concluding paragraph in question here, on which Rodman primarily relies for her failure to warn claim, reflects a different conclusion"). Further, even if I considered Rodman's re-characterization, I found that she failed to explain "how a failure to investigate informs her failure to warn claim." *Id.* at 11 n.6. Her explanation was inadequate then and her attempt to bolster that explanation now does not show that a clear error was made. Nor is it appropriate for her to bolster her explanation in ways that "could reasonably have been raised earlier in the litigation." *Marlyn*, 571 F.3d at 880 (internal quotation marks omitted).[1]

Her argument that I should reconsider dismissing her failure to warn claim fails for the same reasons. Mot. 12. As I made clear in my order, she relies on Dr. Plunkett's expert report to argue that she has met the first element (label inadequacy) of her first failure to warn theory. MSJ Order 13. Because I excluded Dr. Plunkett's opinion for extrapolating conclusions beyond the scope of her sources, and that opinion was essential to the first element of Rodman's failure to warn theory, summary judgment was ultimately granted to Otsuka. *Id.* In other words, Rodman's lack of expert testimony to support the first element of her failure to warn claim was fatal.

She also asks that I reconsider granting summary judgment because there is a genuine dispute as to whether Dr. Hawkins would have changed his treatment of Rodman had he known that the occurrence of TD was many times higher than reported on the Abilify label. Mot. 12. Here, she challenges the conclusions I made on page 15 of the MSJ Order. But those conclusions

[1] Rodman also argues that the parties "did not have the opportunity to argue the merits of their respective motions to exclude expert opinions" at the May 6, 2020 hearing and claims that "the opportunity to discuss Dr. Plunkett's methodology and findings would be helpful to the Court in determining the admissibility of her testimony." Mot. 6. Not true. At the outset of the hearing I told the parties that "I'm inclined to strike Dr. Plunkett's opinion regarding the failure to describe the risk of [TD], because she didn't look at the inciden[ce] rate," and "misrepresented the articles regarding current use." Transcript of Proceedings Held on May 6, 2020 ("Transcript") [Dkt. No. 90] 3:25–4:4. I also noted that Rodman "didn't review the Abilify trials, nor challenge Dr. Correll's review," so "the theory that the label understated the incidence and risk of developing TD fails." *Id.* at 4:4–4:7. Rodman's counsel had ample opportunity to respond to my tentative and address the merits of the motions to exclude expert opinion. I issued my written order after considering both the extensive summary judgment briefing and oral argument. Rodman cannot seek reconsideration for something I have already considered simply because she is not satisfied with the result.

were about the other two failure to warn theories (label did not warn about TD risks even at lower doses and label did not provide instructions on how to monitor TD symptoms), not the first failure to warn theory for which she is seeking reconsideration (label understated the incidence and risk of developing TD). I dismissed the first theory because the lack of expert testimony to support the first element (label adequacy) was fatal. Accordingly, I did not reach the second element of her first theory (*i.e.*, whether Dr. Hawking testified that a label that adequately reflected the incidence and risk of developing TD would have altered his prescribing decision). Rodman cannot ask for reconsideration on something that was not reached in the first place.

II. CHALLENGE TO DR. CORRELL'S EXPERT TESTIMONY

Rodman seeks reconsideration of my supposed "finding that Dr. Correll's 2018 study on the rates of [TD] among users of antipsychotic medications established a true incidence rate of TD among Abilify patients" and my dismissal of "her failure to warn claim even though the findings in Dr. Correll's 2018 study are further evidence that TD occurs more commonly in Abilify patients than stated in the Abilify label." Mot. 1. Rodman's challenge is both misguided and belated.

First, she claims that I did not consider the actual findings of Dr. Correll's study on the rate of TD among Abilify users in relation to Dr. Plunkett's testimony. Mot. 4. But the reliability of Dr. Plunkett's expert report was at issue, not Dr. Correll's study. I excluded Dr. Plunkett's expert opinion because she "exceed[ed] the boundaries of the sources she relie[d] on by going beyond what the sources concluded" in forming her label adequacy opinion. MSJ Order 10. The two studies Dr. Plunkett relied upon—the Peña Study and the FAERS data—both "cautioned that their sources cannot be used to calculate an incidence rate." *Id.* at 9. Yet Dr. Plunkett still "compare[d] figures that authors explicitly cautioned are not true incidence rates with the true incidence rate provided in Abilify's label." *Id.* at 10. I found Rodman's rebuttal that "only Otsuka has the capability to calculate the true incidence rates" unconvincing because Otsuka's expert, Dr. Correll, claimed that he was able to conduct such a study. *Id.* I never found that Dr. Correll's study actually established a true incidence rate of TD among Abilify patients. Dr. Plunkett's expert report was excluded not because Dr. Correll's study was "better" but because Dr. Plunkett

"extrapolated conclusions beyond the scope of her sources," leading me to conclude that "her opinion on label inadequacy is not the product of reliable principles or methods." MSJ Order 11–12. The purported comparison between Dr. Correll's and Dr. Plunkett's report was never made.

Second, her belated challenge that Dr. Correll's study did not establish a true incidence rate is improper. As I noted both at the hearing and in my written order, Rodman did not seek to exclude the portion of Dr. Correll's expert opinion in which he discussed his study. MSJ Order 10 (Dr. Correll claims he "was able to conduct a true incidence rate study of Abilify" which "Rodman does not seek to exclude"); Transcript 4:4–5 ("[P]laintiffs didn't review the Abilify trials, nor challenge Dr. Correll's review.").[2] She cannot challenge it now on reconsideration. *Alvarez v. NBTY, Inc.*, No. 17-CV-00567-BAS-BGS, 2020 WL 42767, at *2 (S.D. Cal. Jan. 3, 2020) (citation omitted) ("A Rule 59(e) motion may not be used to raise arguments or present evidence for the first time when they could reasonably have been raised earlier in the litigation.").

Rodman contends that, even if Dr. Correll's study established a true incidence rate, his study actually supports her theory that there was a higher risk of TD among Abilify users than stated in the label. Mot. 4. She offers a new declaration from Dr. Plunkett who claims, for the first time, that the Correll Study is "yet another indicator that the occurrence of [TD] among Abilify patients is greater than the figures that have been stated in the label prior to 2014." Declaration of Dr. Laura M. Plunkett [Dkt. No. 91-1] ¶ 6. Rodman also submits a new exhibit summarizing public payments from Otsuka to Dr. Correll to challenge the objectiveness of Dr. Correll's study. Declaration of Perry R. Staub, Jr. [Dkt. No. 91-2]. But "[a] Rule 59(e) motion may *not* be used to raise arguments or present evidence for the first time when they could reasonably have been raised earlier in the litigation." *Kona Enterprises*, 229 F.3d at 890; *see also Phillips v. City of Fairfield*, No. CIVS040377FCD PAN, 2006 WL 335472, at *2 (E.D. Cal. Feb. 10, 2006) (supplemental declaration by expert was based upon facts known to plaintiff at the time

[2] She only moved to exclude Dr. Polfliet's expert testimony on grounds that it is duplicative with testimony of Dr. Correll, and to exclude certain portions of Dr. Polfliet's and Dr. Correll's opinions because they "improperly offer[ed] legal conclusions" regarding Dr. Hawkins' testimony and speculated as to his state of mind. MSJ Order 12. I denied these motions as moot given my ruling on the other motions.

of the summary judgment motion, so it was "new" evidence but "not truly newly-discovered"). Therefore, this new argument regarding Dr. Correll's study, which could have been raised before, is improper.

In order to survive summary judgment, it was Rodman's burden to present affirmative evidence from which a jury could return a verdict in her favor. *See Anderson v. Liberty Lobby*, 477 U.S. 242, 257 (1986). Because she failed to do that, summary judgment was granted to Otsuka. Reconsideration of a final judgment is only granted in "highly unusual circumstances." *Carroll v. Nakatani*, 342 F.3d 934, 945 (9th Cir. 2003). Reiterating arguments already made and considered or presenting new arguments she could have made earlier are not grounds for reconsideration.

CONCLUSION

For the foregoing reasons, Rodman's motion for reconsideration is DENIED.

IT IS SO ORDERED.

Dated: July 22, 2020

William H. Orrick
United States District Judge

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