IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STEPHEN WENDELL, et al.,

Plaintiffs,

v.

JOHNSON & JOHNSON, et al.,

Defendants.

/

No. C 09-4124 CW

ORDER GRANTING MOTION FOR SUMMARY JUDGMENT; DENYING MOTION FOR LEAVE TO FILE MOTION FOR RECONSIDERATION (Docket Nos. 257, 319, 355)

Plaintiffs Stephen and Lisa Wendell brought this action as successors-in-interest to their deceased son, Maxx Wendell. They asserted claims for negligence and strict liability against Defendants Johnson & Johnson, Centocor, Inc., Abbott Laboratories, Teva Pharmaceuticals USA, GlaxoSmithKline, and Par Pharmaceutical, Inc.[1] In January 2014, Defendants Johnson & Johnson, Centocor, Abbott Labs, and Teva moved jointly for summary judgment on all claims against them; however, shortly after the Court took this motion under submission, Plaintiffs reached a settlement in principle of their claims against Johnson & Johnson, Centocor, and Abbott Labs. The parties finalized their settlement agreements in June 2014. As a result, Teva is now the only Defendant remaining in this action and the only party still seeking summary judgment. Plaintiffs oppose Teva's motion for summary judgment. After considering the parties' submissions and oral argument, the Court grants the motion.

[1] Plaintiffs also initially brought suit against Gate Pharmaceuticals. However, because Gate is merely a division of Teva, rather than a separate entity, the Court construes the claims against Gate as claims against Teva.

## BACKGROUND

The following facts are undisputed except where otherwise noted.

Maxx Wendell was diagnosed with inflammatory bowel disease (IBD) in 1998 when he was twelve years old. Soon afterward, he began receiving treatment from Dr. Edward Rich, a pediatric gastroenterologist, at Kaiser Permanente in San Francisco, California.

In June 1999, Dr. Rich prescribed a six-mercaptopurine (6MP) drug to treat Maxx's IBD. The drug was manufactured by GlaxoSmithKline, then known as SmithKline Beecham, and marketed under the brand name Purinethol.

Three years later, in July 2002, while Maxx was still taking Purinethol, Dr. Rich prescribed him an anti-tumor necrosis factor (anti-TNF) drug called Remicade, which was manufactured, marketed, and distributed by Centocor.

In July 2003, GlaxoSmithKline sold its distribution rights for Purinethol to Teva and ceased distributing the drug. Maxx continued to take the Teva-distributed Purinethol until July 2004 when he switched to a generic 6MP drug distributed by Par Pharmaceutical, Inc. Maxx continued to take the generic 6MP drug until April 2007.

In May 2006, after Maxx's IBD symptoms had subsided, Dr. Rich directed Maxx to stop taking Remicade. In November 2006, however, after Maxx's symptoms returned, Dr. Rich prescribed him another anti-TNF drug called Humira. Maxx continued to take Humira, which is manufactured, marketed, and distributed by Abbott Labs, until June 2007.

One month later, in July 2007, Maxx was diagnosed with a rare, incurable, and aggressive form of cancer known as hepatosplenic T-cell lymphoma (HSTCL). He passed away in December 2007 at the age of twenty-one.

Plaintiffs initiated the present lawsuit in July 2009 and filed their fourth amended complaint (4AC) in April 2011. Docket No. 165, 4AC. In their 4AC, they alleged that Maxx had developed HSTCL as a result of taking the combination of drugs that he was prescribed between 2002 and 2007 -- specifically, the combination of 6MP and anti-TNF drugs. Plaintiffs further alleged that the manufacturers and distributors of those drugs failed to issue adequate warnings about the risks associated with taking 6MP drugs in combination with anti-TNF drugs. They asserted claims under California law for negligence and strict liability against Johnson & Johnson, Centocor, Abbott Labs, GlaxoSmithKline, Par, and Teva. 4AC ¶¶ 62-101.

In 2011, Defendants Abbott Labs, GlaxoSmithKline, Teva, and Par moved for summary judgment. The Court granted the motion in December 2011, finding that Plaintiffs had failed to produce sufficient evidence to support an inference that different warning labels would have changed Dr. Rich's decision to prescribe the specific combination of drugs at issue in this case. The Court based its decision, in part, on the undisputed evidence "that Dr. Rich was already aware of the risk of lymphomas associated with 6–MP, but still chose to prescribe the drug" to Maxx in combination with an anti-TNF drug. Docket No. 204, Dec. 2011 Summary Judgment Order, at 15.

Plaintiffs subsequently moved for reconsideration of the December 2011 ruling after they discovered new evidence suggesting that Dr. Rich may not have known about the risks associated with these drugs before prescribing them. Based on this new evidence, the Court granted Plaintiffs' motion for reconsideration and withdrew its December 2011 summary judgment order. In July 2012, after reviewing Plaintiffs' new evidence, the Court denied Teva's, Par's, and Abbott Labs' motions for summary judgment. The Court granted summary judgment to GlaxoSmithKline, however, because it found that Plaintiffs had presented "insufficient evidence for a reasonable jury to find that, before July 1, 2003 when [GlaxoSmithKline] discontinued distribution of Purinethol, it had a duty to warn of the risk of hepatosplenic T-cell lymphoma." Docket No. 232, July 2012 Summary Judgment Order, at 27. One year later, the Court granted Par's unopposed motion for summary judgment. Docket No. 293, May 2013 Summary Judgment Order, at 1.

In January 2014, the four remaining Defendants -- Johnson & Johnson, Centocor, Abbott Labs, and Teva -- filed the instant motion for summary judgment. As noted above, Plaintiffs subsequently settled their claims against all of these Defendants other than Teva.

## LEGAL STANDARD

Summary judgment is properly granted when no genuine and disputed issues of material fact remain, and when, viewing the evidence most favorably to the non-moving party, the movant is clearly entitled to prevail as a matter of law. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986);

Eisenberg v. Ins. Co. of N. Am., 815 F.2d 1285, 1288-89 (9th Cir. 1987).

The moving party bears the burden of showing that there is no material factual dispute. Therefore, the court must regard as true the opposing party's evidence, if supported by affidavits or other evidentiary material. Celotex, 477 U.S. at 324; Eisenberg, 815 F.2d at 1289. The court must draw all reasonable inferences in favor of the party against whom summary judgment is sought. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986); Intel Corp. v. Hartford Accident & Indem. Co., 952 F.2d 1551, 1558 (9th Cir. 1991).

Material facts which would preclude entry of summary judgment are those which, under applicable substantive law, may affect the outcome of the case. The substantive law will identify which facts are material. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Where the moving party does not bear the burden of proof on an issue at trial, the moving party may discharge its burden of production by either of two methods:

> The moving party may produce evidence negating an essential element of the nonmoving party's case, or, after suitable discovery, the moving party may show that the nonmoving party does not have enough evidence of an essential element of its claim or defense to carry its ultimate burden of persuasion at trial.

Nissan Fire & Marine Ins. Co., Ltd., v. Fritz Cos., Inc., 210 F.3d 1099, 1106 (9th Cir. 2000).

If the moving party discharges its burden by showing an absence of evidence to support an essential element of a claim or defense, it is not required to produce evidence showing the

absence of a material fact on such issues, or to support its motion with evidence negating the non-moving party's claim. Id.; see also Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 885 (1990); Bhan v. NME Hosps., Inc., 929 F.2d 1404, 1409 (9th Cir. 1991). If the moving party shows an absence of evidence to support the non-moving party's case, the burden then shifts to the non-moving party to produce "specific evidence, through affidavits or admissible discovery material, to show that the dispute exists." Bhan, 929 F.2d at 1409.

If the moving party discharges its burden by negating an essential element of the non-moving party's claim or defense, it must produce affirmative evidence of such negation. Nissan, 210 F.3d at 1105. If the moving party produces such evidence, the burden then shifts to the non-moving party to produce specific evidence to show that a dispute of material fact exists. Id.

If the moving party does not meet its initial burden of production by either method, the non-moving party is under no obligation to offer any evidence in support of its opposition. Id. This is true even though the non-moving party bears the ultimate burden of persuasion at trial. Id. at 1107.

DISCUSSION

As previously noted, Plaintiffs assert claims against Teva for negligence and strict liability. Teva contends that these claims must fail because Plaintiffs have failed to present sufficient evidence to support an inference that Purinethol, either alone or in combination with anti-TNF drugs, caused Maxx to develop HSTCL. Teva further contends that Plaintiffs lack sufficient evidence to support an inference that it had a duty to

warn about the risks associated with taking Purinethol. Each of these arguments is addressed separately below.

A. Causation

"An essential element in claims for product strict liability and negligence is causation." Cox v. Depuy Motech, Inc., 2000 WL 1160486, at *5 (S.D. Cal.). Thus, a plaintiff claiming that he or she was personally injured by a pharmaceutical product must "establish that the substance at issue was capable of causing the injury alleged (general causation), and that the substance caused, or was a substantial factor in causing, the specific plaintiff's injury (specific causation)." Avila v. Willits Envtl. Remediation Trust, 633 F.3d 828, 836 (9th Cir. 2011). Under California law, "'causation must be proven within a reasonable medical probability based upon competent expert testimony.'" Id. (citing Jones v. Ortho Pharmaceutical Corp., 163 Cal. App. 3d 396, 402 (1985)).

Here, Plaintiffs rely on the opinions of two experts to show causation: Drs. Dennis Weisenburger and Andrei Shustov.[2] Drs. Weisenburger and Shustov are both medical doctors who opined in their expert reports that the combination of 6MP drugs and anti-TNF drugs prescribed to Maxx increased his likelihood of developing HSTCL and, ultimately, caused his death. Because these opinions are not based on sufficiently reliable scientific data, they are not admissible under Federal Rule of Evidence 702 and do not support an inference of causation.

[2] Because Plaintiffs' third expert, Dr. David Ross, has not offered any opinions on causation, the Court does not discuss the admissibility of his opinions here. See Docket No. 337, Pls.' Opp. 24 ("Plaintiffs are not, however, offering Dr. Ross as a medical causation expert, but as an expert on the FDA's regulatory requirements.").

Rule 702 permits an expert to offer opinion testimony on a subject if

> (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. In short, expert opinion testimony is only admissible if the opinion the expert seeks to offer is both relevant and reliable. Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 589 (1993) (Daubert I); Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141 (1999). Although Teva does not dispute that the opinions of Drs. Weisenburger and Shustov are relevant here, it contends that they are not reliable.

To evaluate the reliability of expert opinion testimony, a court must consider the factors set out in Daubert I, which include "whether the theory or technique in question can be (and has been) tested, whether it has been subjected to peer review and publication, its known or potential error rate and the existence and maintenance of standards controlling its operation, and whether it has attracted widespread acceptance within a relevant scientific community." 509 U.S. at 593–94. The "test of reliability is 'flexible,' and Daubert's list of specific factors neither necessarily nor exclusively applies to all experts or in every case." Kumho Tire, 526 U.S. at 141 (citations omitted). The focus, in other words, "must be solely on principles and

methodology, not on the conclusions that they generate." Daubert I, 509 U.S. at 595.

The opinions of Drs. Weisenburger and Shustov do not meet this standard. First, neither doctor has ever conducted any independent research or published any studies on the specific relationship between 6MP and anti-TNF drugs and the development of HSTCL. Although both conclusorily stated during their depositions that their opinions on this subject were based on a reasonable degree of medical certainty, they also conceded that their opinions would not satisfy the standards required for publication in peer-reviewed medical journals. For instance, when Dr. Weisenburger was asked whether his opinions in this case would be publishable in a medical article, he replied that the standard for publication would "probably be more rigorous" than the standard he applied in forming his opinions. See Docket No. 320, Defs.' Ex. 4, Weisenburger Depo. 118:22-119:4. Similarly, Dr. Shustov testified that he would not be comfortable publishing his opinions in this case regarding the alleged causal link between 6MP and anti-TNF drugs and HSTCL. Defs.' Ex. 6, Shustov Depo. 74:4-75:9. The fact that both of Plaintiffs' causation experts are reluctant to publish their opinions -- and appear to have developed their opinions specifically for the purposes of this litigation -- casts doubt the reliability of their methodologies under Rule 702. See Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) (Daubert II) ("One very significant fact to be considered [under Rule 702] is whether the experts are proposing to testify about matters growing naturally and directly out of research they

have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.").

So, too, does their failure to identify any animal studies or epidemiological studies showing a causal link between HSTCL and the combination of 6MP and anti-TNF drugs prescribed to Maxx. Plaintiffs admit that they have not identified any such studies, arguing instead that such studies are impossible to conduct because HSTCL is an "exceedingly rare" disease. See Docket No. 349, March 13, 2014 Hrg. Tr. 16:18-:22 ("If it were possible to do the kind of epidemiological study that the Defendants insist is required here, that would have been done a long time ago. Nobody has done it."). The difficulty of conducting these studies, however, does not relieve Plaintiffs of their obligation to present evidence of causation. Indeed, the need for such evidence is especially important here in light of the fact that more than seventy percent of observed HSTCL cases are idiopathic, meaning that they have no known cause. Weisenburger Depo. 174:4-:15; Shustov Depo. 106:5-:24. Given this high rate of idiopathic cases, Plaintiffs cannot reasonably eliminate other potential causes of Maxx's HSTCL without some reliable evidence of a positive link between the drugs at issue and the disease. Daubert II, 43 F.3d at 1319 (finding expert testimony inadmissible under Rule 702 where expert offered "no tested or testable theory to explain how, from [] limited information, he was able to eliminate all other potential causes").

This is precisely why courts often exclude expert medical testimony under Rule 702 when the expert fails to cite any specific epidemiological studies suggesting that a given drug

caused a disease with a high rate of idiopathic cases. In Lopez v. Wyeth-Ayerst Labs., for instance, this Court excluded the testimony of a medical expert under Rule 702 because his testimony was not based on reliable epidemiological evidence and failed to "eliminate all other potential causes" of the plaintiff's condition. 1996 WL 784566, at *3 (N.D. Cal.), aff'd, 139 F.3d 905 (9th Cir. 1998). The Court found that the expert's failure to rule out other possible causes of the plaintiff's Guillain–Barre Syndrome (GBS) was "particularly troubling in light of [the expert]'s statement that 30 to 40% of the GBS cases have idiopathic or unknown causes." Id. The Court also specifically noted that the defendant's expert had presented "uncontroverted testimony that there has been no epidemiological study showing increased incidence of GBS in persons receiving a non-swine flu vaccine," like the one that the plaintiff alleged had caused him to develop GBS. Id. Plaintiffs have not distinguished the present case from Lopez nor from any of the other cases where courts have excluded expert medical evidence under Rule 702 for failing to eliminate potential alternative causes of the plaintiff's harm.[3] See, e.g., Henricksen v. ConocoPhillips Co., 605 F. Supp. 2d 1142, 1163 (E.D. Wash. 2009) ("[B]ecause [the expert]'s methodology employed fails to adequately account for the possibility that [plaintiff]'s AML was idiopathic, the court finds that his conclusion that prolonged exposure to benzene in gasoline was the cause of his AML is unreliable and therefore

[3] Plaintiffs failed to discuss Lopez in their briefs and, when asked to distinguish the case at the hearing, noted simply that Lopez was decided "a long time ago." March 13, 2014 Hrg. Tr. 35:3-:13. This is not a relevant distinction.

inadmissible."); Soldo v. Sandoz Pharm. Corp., 244 F. Supp. 2d 434, 567 (W.D. Pa. 2003) (excluding expert testimony under Rule 702 because it did not "reliably rule out reasonable alternative causes of [the plaintiff's condition] or idiopathic causes").

Although Plaintiffs cite a handful of studies and case reports discussing possible causes of HSTCL, none of these purports to show that the specific combination of drugs prescribed to Maxx actually causes HSTCL. Rather, the studies -- only some of which are actually cited in Plaintiffs' expert reports[4] -- contain statistics about the incidence of HSTCL among different patient populations, including patients with IBD. Plaintiffs contend that these statistics, viewed as a whole, show that patients exposed to a combination of 6MP and anti-TNF drugs are more likely to develop HSTCL than other patients. However, Plaintiffs have not shown that all of the observed differences in these incidence rates are statistically significant or that they account for plausible alternative causes of HSTCL, such as IBD itself. Indeed, Dr. Shustov himself acknowledged during his deposition that the studies he reviewed failed to control for IBD as a possible risk factor. Shustov Depo. 25:19-26:12. Although he and Dr. Weisenberger both stated that they do not believe IBD is a risk factor for HSTCL, they have not presented any scientific evidence to support that opinion. See Heller v. Shaw Indus., Inc., 167 F.3d 146, 156 (3d Cir. 1999) ("'[W]here a defendant points to a plausible alternative cause and the doctor offers no

[4] Neither Dr. Weisenberger nor Dr. Shustov appears to have cited the 2010 letter-to-the-editor written by David Kotlyar et al. or the 2013 article written by Prakkal Deepak et al.

explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable.'" (quoting In re Paoli Railroad Yard PCB Litig., 35 F.3d 717, 759 n.27 (3d Cir. 1994))); Casey v. Ohio Med. Products, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (explaining that "case reports are not reliable scientific evidence of causation, because they simply describe[] reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group" and "do not isolate and exclude potentially alternative causes").

In sum, the opinions of Drs. Weisenburger and Shustov do not provide sufficiently reliable evidence of causation and must be excluded under Rule 702. Plaintiffs have not presented any other admissible evidence sufficient to support an inference of "a reasonable causal connection" between the combination of Purinethol and anti-TNF drugs and the development of Maxx's HSTCL. Jones, 163 Cal. App. 3d at 399, 402 (recognizing that causation "must be proven within a reasonable medical probability based upon competent expert testimony" and that "[m]ere possibility alone is insufficient to establish a prima facie case"); see also Avila, 633 F.3d at 836 (quoting same). Accordingly, Teva is entitled to summary judgment on all of Plaintiffs' remaining claims against it for negligence and strict liability.

B. Duty to Warn

Plaintiffs' failure to produce any admissible evidence of causation is sufficient to preclude them from prevailing on any of their claims under a failure-to-warn theory. See Finn v. G. D. Searle & Co., 35 Cal. 3d 691, 701 (1984) ("The strength of the

causal link thus is relevant both to the issue of whether a warning should be given at all, and, if one is required, what form it should take."). But Teva is also entitled to summary judgment on Plaintiffs' claims under this theory for another, independent reason: specifically, because they have not adduced any evidence to suggest that Dr. Rich actually relied on Teva's warning labels before prescribing Purinethol to Maxx.

Dr. Rich testified during his deposition that he cannot recall reading the Purinethol label in making his decision to prescribe the drug and that it is "not [his] regular practice to look at drug labeling." Defs.' Ex. 1, Rich Depo. 192:6-:7; id. 283:13-:15 ("I don't remember specifically reading the label for Purinethol 6-MP or generic [sic] at any particular time."). Plaintiffs have not identified any evidence to contradict this testimony or otherwise suggest that Dr. Rich actually relied on the Purinethol warning label. Accordingly, they cannot prevail on their negligence claim under a failure-to-warn theory. Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 112 (2008) ("There can be no proximate cause where, as in this case, the prescribing physician did not read or rely upon the allegedly inadequate warnings promulgated by a defendant about a product."); Motus v. Pfizer Inc., 358 F.3d 659, 661 (9th Cir. 2004) ("Because the doctor testified that he did not read the warning label that accompanied Zoloft or rely on information provided by Pfizer's detail men before prescribing the drug to [plaintiff], the adequacy of Pfizer's warnings is irrelevant to the disposition of this case."). To the extent that Plaintiffs have asserted a claim against Teva for negligent misrepresentation, that claim fails for

the same reason. Apollo Capital Fund, LLC v. Roth Capital Partners, LLC, 158 Cal. App. 4th 226, 243 (2007) (recognizing that one of the "elements of negligent misrepresentation" is "justifiable reliance on the misrepresentation").[5] Teva is therefore entitled to summary judgment on all of Plaintiffs' claims based on a failure-to-warn theory.

## CONCLUSION

For the reasons set forth above, Teva's motion for summary judgment (Docket No. 319) is GRANTED. Plaintiffs' request to strike the supplemental declarations of Teva's experts, Drs. Robert Valuck and Andrew Place, is DENIED as moot as the Court did not rely on either of these supplemental declarations in reaching its decision.

In addition, Plaintiffs' motion for leave to file supplemental material (Docket No. 355) is DENIED. Plaintiffs have failed to establish that the March 2014 statements and documents issued by Health Canada and Teva Canada, neither of which is a party in this action, are admissible. Furthermore, even if the statements and documents were admissible, they would not alter the outcome of this case. A warning notice issued by a foreign government under an unidentified regulatory standard is not sufficient to support an inference of causation here, particularly when the warning notice only pertains to Purinethol, rather than the full combination of drugs at issue in this case.

[5] Plaintiffs conceded at the hearing that they cannot prevail on their strict liability claims against Teva under a failure-to-warn theory. March 13, 2014 Hrg. Tr. 50:24-:25 (Plaintiffs' Counsel: "What I agree is we can't hold Teva liable under strict liab[ility].").

Finally, Plaintiffs' motion for leave to file a motion for reconsideration of the Court's July 2012 order granting summary judgment to GlaxoSmithKline (Docket No. 257) is DENIED as moot. Plaintiffs cannot prevail on their claims against GlaxoSmithKline for the same reasons they cannot prevail on their claims against Teva: once again, they have not presented sufficient evidence to support an inference of (1) a causal link between the combination of 6MP and anti-TNF drugs and HSTCL; nor (2) actual reliance by Dr. Rich on the warning label for Purinethol. Maxx's untimely death was tragic but, without this evidence, Teva cannot be held liable as its cause.

The clerk shall close the file and the parties shall bear their own costs.

IT IS SO ORDERED.

Dated: 6/30/2014

CLAUDIA WILKEN
United States District Judge