UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION

As to All Related and Member Cases

Case No.: 13-md-2452-AJB-MDD

OMNIBUS ORDER:

(1) GRANTING DEFENDANTS' JOINT MOTION FOR SUMMARY JUDGMENT BASED ON PREEMPTION (Doc. No. 3594);

(2) GRANTING DEFENDANTS' JOINT MOTION TO EXCLUDE DRS. MADIGAN, WELLS, BROWN, AND GALE (Doc. No. 3586);

(3) GRANTING DEFENDANTS' JOINT MOTION TO EXCLUDE DRS. LANDOLPH, WOOLF, AND TAYLOR (Doc. No. 3521);

(4) DENYING AS MOOT PLAINTIFFS' MOTION TO EXCLUDE DRS. THAYER, WANG, AND SCHARFSTEIN (Doc. No. 3613);

(5) GRANTING DEFENDANT MERCK'S MOTION FOR SUMMARY JUDGMENT BASED ON CAUSATION (Doc. No. 3524);

(6) GRANTING DEFENDANTS AMYLIN AND LILLY'S MOTION FOR SUMMARY JUDGMENT BASED ON CAUSATION (Doc. No. 3525); and

(7) GRANTING DEFENDANT NOVO'S MOTION FOR SUMMARY JUDGMENT BASED ON CAUSATION (Doc. No. 3585).

I. INTRODUCTION

Pancreatic cancer is an unrelenting disease, occurring at a rate of more than 50,000 cases a year. It is a leading cause of cancer-related death in the United States and has caused, and continues to cause, much suffering to tens of thousands of Americans each year. This multidistrict litigation involves claims that Defendants failed to warn that four prescription brand-name drugs used to treat type 2 diabetes cause, or increase the risk of, pancreatic cancer. Plaintiffs are individuals diagnosed with type 2 diabetes who were prescribed and consumed one or more of the following prescription drugs: Byetta, Januvia, Janumet, and Victoza. Defendants are the pharmaceutical companies that manufacture and market the drugs: Amylin Pharmaceuticals, LLC ("Amylin"), Eli Lilly and Company ("Lilly"), Merck Sharp & Dohme Corp. ("Merck"), and Novo Nordisk Inc. ("Novo") (collectively, "Defendants").

The drugs are sometimes referred to by their active ingredients.[1] Exenatide is the active ingredient in Amylin and Lilly's Byetta. Sitagliptin is the active ingredient in

[1] For purposes of this Order, the Court will use the drug's brand name and its active ingredient interchangeably.

Merck's Januvia and Janumet. Liraglutide is the active ingredient in Novo's Victoza. The therapies involve incretin hormones, which operate in the body to lower blood sugar by stimulating or sustaining production of insulin. Exenatide and liraglutide are glucagon-like peptide-1 ("GLP-1") receptor agonists ("GLP-1 RAs"). Sitagliptin is a dipeptidyl peptidase-4 ("DPP-4") inhibitor ("DPP-4i"). Although the therapies are different classes of drugs, the FDA has generally reviewed and recognized them under the broader terms of incretin mimetics or incretin-based therapies. Up until now, the parties did too, focusing their arguments on incretin-based drugs collectively. Now, their arguments also discuss the drugs separately and with respect to their classification as either a GLP-1 RA or DPP-4i.

Through the enactment of the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 et seq. ("FDCA"), Congress delegated authority to the Food and Drug Administration ("FDA") to regulate pharmaceutical manufacturers and their products. With subsequent amendments, Congress enlarged this authority, charging the FDA with the power to protect the public health, and to assure the safety, effectiveness, and reliability of drugs. In discharging its regulatory duties, the FDA oversees the introduction of new drugs into the market, regulates the content of drug labeling, and ensures manufacturers comply with post-marketing requirements. Despite the FDA's broad regulatory duties, a drug manufacturer remains primarily responsible for maintaining the adequacy of product labeling. State tort law is therefore generally viewed as a complimentary form of drug regulation, providing additional protections and recourse for injured consumers. Yet, when state tort law imposes a duty impossible to meet in light of FDA regulations, federal law will preempt state law.

II. BACKGROUND

On November 9, 2015, this Court granted Defendants' motion for summary judgment based on preemption. (Doc. No. 1539.) On appeal, the Ninth Circuit did not reach the preemption question, and instead, remanded the case for the Court to permit certain discovery, consider the materiality of Plaintiffs' asserted new safety information, and

reinstate the opinion of Plaintiffs' expert, Dr. Fleming. *In re Incretin-Based Therapies Prod. Liab. Litig.*, 721 F. App'x 580, 581–82, 584 (9th Cir. 2017).

Several years later, and upon completion of supplemental discovery, Defendants renewed their joint motion for summary judgment based on preemption. (Doc. No. 3594.) In addition, Defendants each filed a motion for summary judgment based on lack of general causation as to their respective drugs.[2] (Doc. Nos. 3524, 3525, 3585.) The parties also filed motions to exclude certain experts. (Doc. Nos. 3521, 3586, 3613.) On October 20, 2020, the Court heard oral arguments on the motions and thereafter took the matter under submission.[3]

III. LEGAL STANDARD

Federal Rule of Civil Procedure 56 governs motions for summary judgment. Summary judgment permits a court to enter judgment on factually unsupported claims, *see Celotex Corp. v. Catrett*, 477 U.S. 319, 327 (1986), and may also be used on affirmative defenses. *Dam v. Gen'l. Elec. Co.*, 265 F.2d 612, 614 (9th Cir. 1958). Granting summary judgment is proper if 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). A fact is material when, under the governing substantive law, it could affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute about a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

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[2] From their briefs, it appears that Amylin and Lilly, who are responsible for Byetta, are jointly defending themselves in the instant motions before this Court. Throughout this Order, the Court will take the parties' lead and refer primarily to Amylin for simplicity.

[3] Pursuant to the agreement of all parties and in an effort to promote the convenient and efficient resolution of nearly identical summary judgment and evidentiary motions pending in the state and federal proceedings, the Court held joint oral argument with Judge Highberger of the Los Angeles County Superior Court, who is presiding over the pancreatic cancer cases pending in state court (Case No. JCCP 4272). *See In re Phenylpropanolamine (PPA) Products Liab. Litig.*, 460 F.3d 1217, 1222 (9th Cir. 2006) (noting a court's statutory charge in a multidistrict litigation proceeding is to promote the just and efficient conduct of the actions pursuant to 28 U.S.C. § 1407). The Court also participated in a subsequent motion hearing before Judge Highberger on December 8, 2020. While these hearings were held jointly, the Court has deliberated on the case individually and without discussion of the merits with the state court judge.

The moving party has the initial burden of demonstrating that summary judgment is proper. *See Adickes v. S.H. Kress & Co.,* 398 U.S. 144, 152 (1970). The burden then shifts to the opposing party to provide admissible evidence beyond the pleadings to show that summary judgment is not appropriate. *See Celotex,* 477 U.S. at 322, 324. The court must review the record as a whole and draw all reasonable inferences in favor of the non-moving party. *Hernandez v. Spacelabs Med. Inc.,* 343 F.3d 1107, 1112 (9th Cir. 2003). However, unsupported conjecture or conclusory statements are insufficient to defeat summary judgment. *Id.; Surrell v. Cal. Water Serv. Co.,* 518 F.3d 1097, 1103 (9th Cir.2008). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient" to survive summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). A party opposing summary judgment must come forward with "significant probative evidence tending to support its claim that material, triable issues of fact remain." *Sanchez v. Vild*, 891 F.2d 240, 242 (1989).

IV. DISCUSSION

Defendants assert that they are entitled to summary judgment because it is impossible to comply with both the FDA's regulatory scheme and state law failure-to-warn requirements, and because there is no genuine dispute of material fact as to general causation. Plaintiffs maintain that Defendants have not established preemption, and that their experts have established a pathway to causation. Both Plaintiffs and Defendants move to exclude certain experts. The Court discusses these motions in turn.

A. PREEMPTION MOTION

The preemption question before the Court is whether Defendants are entitled to summary judgment based on the affirmative defense of federal preemption because it is impossible for Defendants to comply with both the FDA's regulations and the state law failure-to-warn requirements upon which Plaintiffs rest their claims.

1) Relevant Law

Under the Supremacy Clause of the United States Constitution, "Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372

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