UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: TAXOTERE (DOCETAXEL) EYE INJURY PRODUCTS LIABILITY LITIGATION

MDL NO. 3023

SECTION "H" (5)

THIS DOCUMENT RELATES TO:
ALL CASES

SANOFI US SERVICES INC. AND SANOFI-AVENTIS U.S. LLC'S MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS MASTER LONG FORM COMPLAINT[1]

In 2002, Sanofi unilaterally sought to update the Taxotere label to alert oncologists to an adverse event observed in post-marketing surveillance: lacrimal duct obstruction. The lacrimal duct system manages the production and drainage of tears from the eyes, and the drainage portion is comprised of the puncta, canaliculi, lacrimal sac, and the nasolacrimal duct. Sanofi submitted a proposed safety warning to FDA, and FDA later approved the following label addition: "Excessive tearing which may be attributable to lacrimal duct obstruction has been reported."

This warning remains in the label today.

Plaintiffs' Master Complaint nevertheless claims that the Taxotere label is inadequate because it allegedly does not inform oncologists that Taxotere may cause a limited sub-type of lacrimal obstruction—"stenosis" (or narrowing)—of the puncta, canaliculi, and nasolacrimal duct and does not specifically advise oncologists how to treat this outcome. Plaintiffs' claims should be dismissed for at least three reasons:

[1] Sanofi hereby incorporates by reference all arguments made by the 505(b)(2) Defendants in their motion to dismiss submitted this same day (Rec. Doc. 41).

First, because the Taxotere label has warned since 2002 of the very injury for which Plaintiffs now seek recovery, it is adequate as a matter of law. Plaintiffs attempt to circumvent this fact by arguing that the label is inadequate because it does not provide specific treatment instructions to physicians. Treatment instructions, however, are not required in a drug label. Indeed, individualized medical judgments about how to treat a patient are best left to trained physicians, not drug manufacturers.

Second, federal law preempts Plaintiffs' claims because Sanofi could not have unilaterally changed the lacrimal duct obstruction warning after 2002—nor was there reason to. Sanofi submitted a Changes Being Effected (or "CBE") label change to FDA in 2002 to specifically add a warning to the adverse events section of the label. To show that Sanofi theoretically *could* have changed the warning again without prior FDA approval, Plaintiffs must identify "newly acquired information," as narrowly defined by federal regulation. Plaintiffs cannot. The operative warning reflects the same type, frequency, and severity of the risk seen in the literature and case reports before 2002.

Third, Plaintiffs fail to meet the federal pleading requirements set forth by Federal Rules of Civil Procedure 9(b) because they do not describe with particularity their claims for negligent and fraudulent misrepresentation and concealment. Plaintiffs' claims should be dismissed.

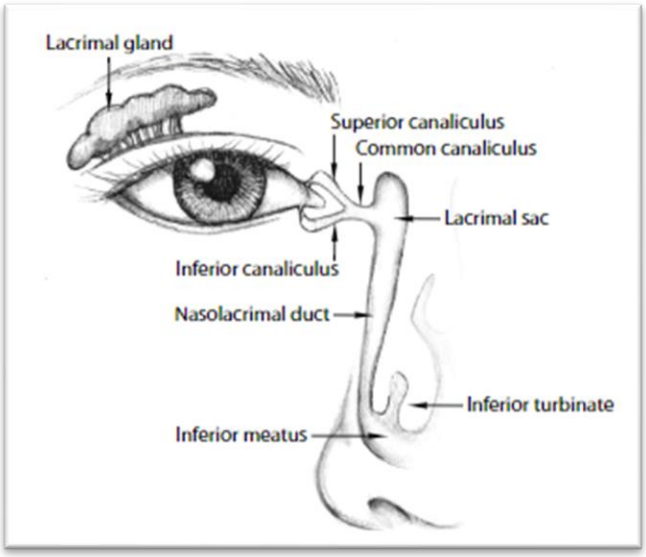
STATEMENT OF RELEVANT FACTS

Taxotere is a chemotherapy manufactured by Sanofi.[2] FDA first approved Taxotere in 1996 to treat metastatic breast cancer.[3] Plaintiffs allege they were treated with Taxotere after being

[2] Rec. Doc. 25 ¶ 4 (Master Long Form Compl. & Demand for Jury Trial as to Sanofi U.S. Servs. Inc. and sanofi-aventis U.S. LLC).

[3] Rec. Doc. 25 ¶ 17.

diagnosed with cancer.[4] Plaintiffs further claim that Taxotere caused them to sustain lacrimal injuries.[5] The lacrimal system, which includes the puncta, canaliculi, and nasolacrimal ducts, regulates the production and drainage of tears.[6]



Kintzel et al., *Docetaxel-Associated Epiphora*, PHARMACOTHERAPY 26(6):855 (2006)[7]

Plaintiffs assert that Sanofi "failed to provide a simple warning to inform the oncologists prescribing Taxotere® and the patients taking it of the importance of treatment and specialist referrals at the first sign of excessive tearing symptoms to prevent long-term and potentially irreversible lacrimal damage."[8] Plaintiffs, however, concede that Sanofi revised the Taxotere label in 2002 to warn specifically of the risk of excessive tearing that may be attributable to lacrimal

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4 Rec. Doc. 25 ¶ 8.

5 Rec. Doc. 25 ¶ 1.

6 Rec. Doc. 25 ¶ 4.

7 Rec. Doc. 25 ¶ 47 n.4 (citing Kintzel et al., *Docetaxel-Associated Epiphora*, PHARMACOTHERAPY 26(6):855 (2006)). The Court may "consider documents integral to and explicitly relied on in the complaint, that the defendant appends to his motion to dismiss, as well as the full text of documents that are partially quoted or referred to in the complaint." *Izadjoo v. Helix Energy Sols. Grp., Inc.*, 237 F. Supp. 3d 492, 506 (S.D. Tex. 2017) (quoting *In re Sec. Litig. BMC Software, Inc.*, 183 F. Supp. 2d 860, 882 (S.D. Tex. 2001)). The *Kintzel* Article is attached as **Exhibit A**.

8 Rec. Doc. 25 ¶ 1.

duct obstruction.[9]

Before 2002, the Taxotere label contained no explicit warning of lacrimal duct obstruction, *i.e.*, stenosis. In 2001, however, Dr. Bita Esmaeli—a well-known oncologist at MD Anderson Cancer Center—conducted an observational study analyzing Taxotere's potential effect on the lacrimal system.[10] This study, *Canalicular Stenosis Secondary to Docetaxel (Taxotere): A Newly Recognized Side Effect*, was accepted for publication in the journal Ophthalmology on November 28, 2000, and it is repeatedly referenced in the studies Plaintiffs cite in their Master Complaint.[11]

In her study, Dr. Esmaeli identified three case reports of metastatic breast cancer patients who developed canalicular stenosis while receiving weekly Taxotere infusions.[12] Two patients reported tearing that did not improve after they discontinued Taxotere, and both were referred to ophthalmologists.[13] One patient showed complete, or "permanent," closure of the puncta; the other patient showed moderate punctal and canalicular stenosis.[14] The publication concluded, "[e]piphora is a *newly recognized side effect* of docetaxel . . . [and] the mechanism for epiphora seems to be punctal and canalicular stenosis."[15] The publication explicitly noted, "[t]imely

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9 Rec. Doc. 25 ¶ 25.

10 Rec. Doc. 25 at ¶ 47 n.3 (citing Esmaeli et al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 CANCER, 504-07 (2003) (attached as **Exhibit B**). The 2003 Esmaeli Article in Cancer states that Dr. Esmaeli had "previously reported several patients with irreversible blockage of the lacrimal drainage apparatus as a side effect of the weekly administration of docetaxel." Ex. B at n.1 (citing Esmaeli, et al., *Canalicular Stenosis Secondary to Docetaxel (Taxotere): A Newly Recognized Side Effect*, OPHTHALMOLOGY 994 (2001) (attached as **Exhibit C**))).

11 Ex. B (*Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*) at n.1; *see also* Rec. Doc. 25 ¶ 22 n.1 (citing Esmaeli et al., *Docetaxel-Induced Histologic Changes in the Lacrimal Sac and Nasal Mucosa*, OPHTHALMIC PLASTIC AND RECONSTRUCTIVE SURGERY 4, 305–08 (2003) (attached as **Exhibit D**)). The 2003 Esmaeli Article in Ophthalmic Plastic and Reconstructive Surgery states, "We recently reported that canalicular stenosis and nasolacrimal duct blockage are the underlying mechanisms of epiphora secondary to docetaxel." Ex. D at 305 n.6 (citing Esmaeli, et al., *Canalicular Stenosis Secondary to Docetaxel (Taxotere): A Newly Recognized Side Effect*, OPHTHALMOLOGY 994 (2001)).

12 Ex. C (*Canalicular Stenosis Secondary to Docetaxel (Taxotere): A Newly Recognized Side Effect*) at 994–95.

13 *Id*.

14 *Id*.

15 *Id*. at 994 (emphasis added); *see also id.* at 995 ("Canalicular stenosis has been described in association with other

diagnosis and management of punctal and canalicular stenosis secondary to docetaxel can prevent complete closure of the canaliculi" and "recommend[ed] referral to an ophthalmologist as soon as symptoms of epiphora develop in patients receiving docetaxel."[16]

On January 9, 2002, Sanofi submitted to FDA a CBE label change to warn of this new potential side effect in the Adverse Reactions section of the Taxotere label. FDA reviewed Sanofi's safety submission to ensure the label adequately reflected the severity, duration, and frequency of this new risk.[17] On May 29, 2002, FDA's Senior Regulatory Manager of the Division of Oncology Drug Products instructed Sanofi: "With regard to your proposal for wording regarding excessive tearing, we suggest removing the reference to [redacted by FDA[18]]. We propose the following 'Excessive tearing which may be attributable to lacrimal duct obstruction has been reported.'"[19] Likewise, on July 3, 2002, FDA finalized their "Project Manager Review of the Labeling" memorandum and again instructed Sanofi as to the specific language to add to the Taxotere label.[20] FDA also concluded that "adequate information had been presented to

chemotherapeutic agents such as 5-flourouracil, but, to our knowledge, it has not been reported as a side effect of docetaxel.").

16 *Id*. at 995.

17 **Exhibit E**, July 9, 2002, FDA, CENTER FOR DRUG EVALUATION AND RESEARCH MEDICAL REVIEW (publicly available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/020449Orig1s017.pdf). On a motion to dismiss, the Court may also consider documents outside of the complaint that "the plaintiff has actual notice of . . . and relied upon in framing the complaint." *Gayle v. Pfizer Inc.*, 452 F. Supp. 3d 78, 90–91 (S.D.N.Y. 2020) (quoting *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991)), *aff'd*, 847 F. App'x 79 (2d Cir. 2021). This Court should consider the publicly available FDA documents regarding the 2002 label change because the Master Complaint acknowledges that "Sanofi updated the Post-Marketing Experiences section of the Taxotere label in 2002[.]" Rec. Doc. 25 ¶ 25. Moreover, courts routinely take judicial notice of publicly available FDA documents because their authenticity and contents are not reasonably subject to dispute. *See, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) ("[T]he district court took appropriate judicial notice of publicly-available documents and transcripts produced by the FDA, which were matters of public record directly relevant to the issue at hand.").

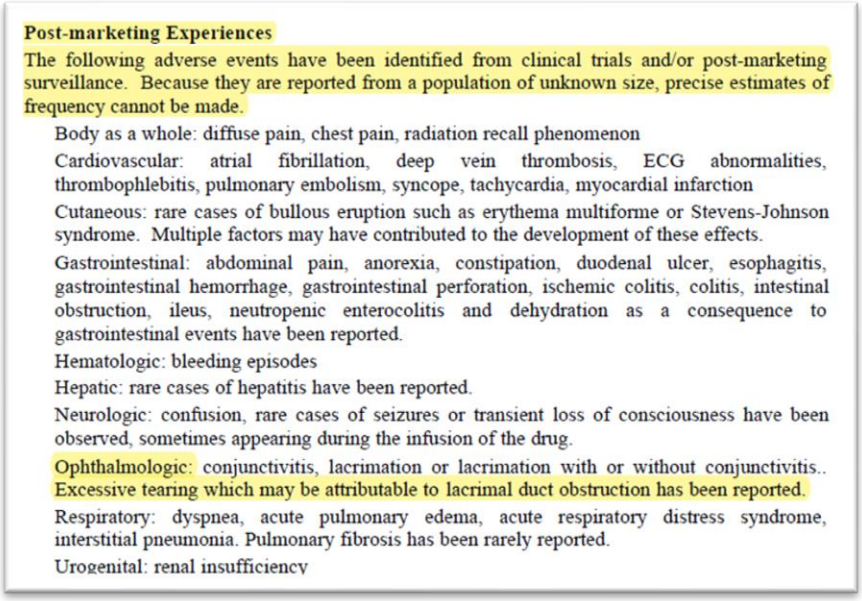
18 FDA redacted this language pursuant to 5 U.S.C. § 552, Rule (b)(4).

19 Ex. E (CENTER FOR DRUG EVALUATION AND RESEARCH MEDICAL REVIEW) at 48.

20 *Id*. at 40–43.

demonstrate that [Taxotere was] safe and effective for use as recommended in the submitted final printed labeling (package insert and patient package insert submitted January 9, 2002)."[21]

As instructed by FDA, Sanofi added this language to in the "Post-Marketing Experiences" subsection of the Adverse Reactions section[22] of the Taxotere label in September 2002:



Post-marketing Experiences

The following adverse events have been identified from clinical trials and/or post-marketing surveillance. Because they are reported from a population of unknown size, precise estimates of frequency cannot be made.

Body as a whole: diffuse pain, chest pain, radiation recall phenomenon

Cardiovascular: atrial fibrillation, deep vein thrombosis, ECG abnormalities, thrombophlebitis, pulmonary embolism, syncope, tachycardia, myocardial infarction

Cutaneous: rare cases of bullous eruption such as erythema multiforme or Stevens-Johnson syndrome. Multiple factors may have contributed to the development of these effects.

Gastrointestinal: abdominal pain, anorexia, constipation, duodenal ulcer, esophagitis, gastrointestinal hemorrhage, gastrointestinal perforation, ischemic colitis, colitis, intestinal obstruction, ileus, neutropenic enterocolitis and dehydration as a consequence to gastrointestinal events have been reported.

Hematologic: bleeding episodes

Hepatic: rare cases of hepatitis have been reported.

Neurologic: confusion, rare cases of seizures or transient loss of consciousness have been observed, sometimes appearing during the infusion of the drug.

Ophthalmologic: conjunctivitis, lacrimation or lacrimation with or without conjunctivitis.. Excessive tearing which may be attributable to lacrimal duct obstruction has been reported.

Respiratory: dyspnea, acute pulmonary edema, acute respiratory distress syndrome, interstitial pneumonia. Pulmonary fibrosis has been rarely reported.

Urogenital: renal insufficiency

Taxotere Label at 23 (Revised: Sept. 2002)

Since its inclusion, FDA has approved the Taxotere label on at least 17 separate occasions, and there has been no change to the warning on lacrimal duct obstruction.[23]

Plaintiffs' Master Complaint asserts five claims against Sanofi premised on its purported failure to instruct oncologists on how to treat patients with excessive tearing: (1) strict products liability – failure to warn; (2) negligence; (3) negligent misrepresentation; (4) fraudulent

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21 *Id.* at 9.

22 Inclusion within this section of the label is limited to those events for which there is some basis to believe there is a causal relationship between occurrence of an adverse event and the use of a drug. 21 C.F.R. § 201.57(c)(7).

23 *See* Drugs@FDA: FDA-Approved Drugs, Taxotere, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process, (search "Taxotere," then click tab for "Approval Date(s) and History, Letters, Labels, Reviews for NDA 020449"). For example, Sanofi changed its label on July 30, 2002; January 30, 2003; April 24, 2003; August 11, 2005; June 7, 2006; April 20, 2010; September 7, 2011; December 15, 2011; April 13, 2012; June 26, 2013; December 13, 2013; November 14, 2014; December 11, 2015; October 5, 2018; June 6, 2019; December 17, 2019; and May 15, 2020. *Id.*

misrepresentation; and (5) fraudulent concealment. Plaintiffs, however, have failed to state a claim for any asserted cause of action.

LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) mandates that a court dismiss a cause of action that fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). To state a claim, a pleading must set forth "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (holding plaintiffs must plead "enough facts to state a claim to relief that is plausible on its face"). The plausibility standard demands more than "a formulaic recitation of the elements of a cause of action" or "naked assertions devoid of further factual enhancement." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted).

Besides satisfying the pleading requirements enunciated in *Twombly*, *Iqbal*, and their progeny, a party asserting a fraud claim must also satisfy Federal Rule of Civil Procedure 9(b), which requires a party to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Under Rule 9(b), claims for fraud must be pleaded with particularity. Fed. R. Civ. P. 9(b). At a minimum, Rule 9(b) requires the "who, what, when, where, and how" of the alleged fraud. *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997) (citing *Williams v. WMX Tech., Inc.*, 112 F.3d 175, 179 (5th Cir. 1997)). MDL courts regularly hold plaintiffs to their Rule 9(b) pleading burden for fraud-based causes of action in "master" or "consolidated" complaints. *See, e.g., In re Ford Motor Co. Vehicle Paint Litig.*, No. MDL 1063, 1996 WL 426548 (E.D. La. July 30, 1996) (dismissing fraudulent misrepresentation claim in master complaint for failure to plead reliance).

ARGUMENT

I. THE TAXOTERE LABEL IS ADEQUATE AS A MATTER OF LAW.

Since 2002, the Taxotere label has warned of "excessive tearing which may be attributable to lacrimal duct obstruction." Like the 2015 warning for permanent alopecia in MDL 2740, Sanofi's 2002 warning of the possibility of lacrimal duct obstruction has "clearly and consistently warned of the precise injury Plaintiffs suffered." *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 462 F. Supp. 3d 650, 653 (E.D. La. 2020). Accordingly, the Taxotere label was (and remains) adequate.

"It is axiomatic that an essential element of a failure to warn claim is a defendant's failure to adequately warn about the alleged risks associated with its product." *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 462 F. Supp. 3d at 652 (quoting *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 2014 WL 2738224, at *8 (D.N.J. June 17, 2014)). Warnings are adequate if they are reasonable under the circumstances. *Ziliak v. AstraZeneca LP*, 324 F.3d 518, 521 (7th Cir. 2003). A reasonable warning is one that is "accurate, clear, consistent, and as a whole convey[ed] an unmistakable meaning as to the consequences of ingesting [the drug]." *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 462 F. Supp. 3d at 652 (alterations in original) (internal citations and quotations omitted). MDL transferee courts, including this Court, have previously issued omnibus orders finding a drug label adequate as a matter of law. *See, e.g., id.* at 653 (citing cases finding a drug label adequate as a matter of law).

Plaintiffs claim the Taxotere label is inadequate for essentially three reasons: (1) it does not warn of stenosis as a cause of excessive tearing; (2) it does not warn of the "potentially irreversible nature of the injury"; and (3) it does not warn of the need to provide treatment and refer patients to a lacrimal specialist at the first sign of excessive tearing because of its rapid

onset.[24] These arguments are without merit.

A. The Taxotere label warns of the risk of which Plaintiffs complain.

The Taxotere warning is adequate as a matter of law because warning of the possibility of lacrimal duct obstruction encompasses the possibility of stenosis. The lacrimal duct system—as Plaintiffs recognize in their Master Complaint—includes the puncta, canaliculi, and nasolacrimal ducts.[25] If the lacrimal duct system experiences "obstruction," this indicates the lacrimal ducts are "clogged or blocked."[26] "Stenosis," similarly refers to a "narrowing" of the lacrimal ducts, which results in clogged or blocked tear ducts.[27]

Physicians and scholars use the terms interchangeably to refer to a condition where patients experience excessive tearing due to a tear duct blockage. The Court need not look further than the articles cited in Plaintiffs' Master Complaint to determine that Sanofi's use of lacrimal duct obstruction was adequate to warn of Plaintiffs' alleged injuries. Indeed, these articles use lacrimal duct obstruction and canalicular stenosis to describe the same medical condition. For example, the first article quoted by Plaintiffs, *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*,[28] uses "stenosis" and "lacrimal obstruction" interchangeably:

> Despite the previous publication of several articles by our group regarding **canalicular stenosis** and **lacrimal obstruction** resulting

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[24] Rec. Doc. 25 ¶¶ 25, 60.

[25] Rec. Doc. 25 ¶ 4 (asserting that "Taxotere may cause damage to the lacrimal system, including punctal, canalicular, and/or nasolacrimal duct stenosis"); *see also Lacrimal Duct*, MERRIAM-WEBSTER, https://www.merriam-webster.com/medical/lacrimal%20duct (last visited June 28, 2022) (defining the lacrimal duct as "any of several small ducts that carry tears from the lacrimal gland to the fornix of the conjunctiva").

[26] *Obstruction*, Merriam-Webster Medical Dictionary, https://www.merriam-webster.com/dictionary/obstruction#medicalDictionary (defining obstruction as "a condition of being clogged or blocked") (last visited June 28, 2022); *see also Reid v. Time Warner Cable*, 2016 WL 743394, at *2 (E.D.N.Y. Feb. 22, 2016) (taking judicial notice of the online medical dictionary definition of "alveoloplasty").

[27] *Stenosis*, Merriam-Webster Medical Dictionary, https://www.merriam-webster.com/dictionary/stenosis#medicalDictionary (defining stenosis as "a narrowing or construction of the diameter of a bodily passage or orifice") (last visited June 28, 2022).

[28] Rec. Doc. 25 ¶ 47 (citing Ex. B (*Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*)).

> from docetaxel therapy, we still frequently encounter advanced cases of **this condition** because of delayed diagnosis.[29]

This article, which studied "canalicular and nasolacrimal duct **stenosis**" as a side effect of docetaxel[30] goes on to conclude:

> CONCLUSIONS. Canalicular and nasolacrimal **duct obstruction** is a common side effect of weekly docetaxel therapy and can occur even when this drug is used in the neoadjuvant setting.[31]

Consistent with the Taxotere label, another article cited by Plaintiffs, *Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving Adjuvant Docetaxel-Based Chemotherapy*,[32] defines the alleged injury as "lacrimal duct obstruction" or "LDO":

> **Purpose** . . . To define the incidence and impact of tearing in patients receiving adjuvant docetaxel-based chemotherapy and assess for **lacrimal duct obstruction (LDO)** as a causative factor.[33]

The article further describes "stenosis" as a form of "lacrimal obstruction."

> It has been suggested that tearing may result from canalicular and nasolacrimal duct **stenosis**, and in severe cases, permanent sclerosing canaliculitis has been a reported cause. Given that **lacrimal obstruction** has been considered the primary cause of tearing . . . .[34]

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[29] Ex. B (*Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*) at 507 (emphasis added).

[30] *Id*. at 504 ("BACKGROUND. The current study was conducted to report the severity and management of canalicular and nasolacrimal duct stenosis as a side effect of docetaxel therapy and to report the outcomes of surgical intervention for this condition.").

[31] *Id*. (emphasis added).

[32] Rec. Doc. 25 ¶ 49 (citing Arlene Chan, et al., *Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving Adjuvant Docetaxel-based Chemotherapy*, 31 JOURNAL OF CLINICAL ONCOLOGY 17 (2013) (attached as **Exhibit F**)).

[33] Ex. F (*Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving Adjuvant Docetaxel-based Chemotherapy*) at 2123.

[34] *Id*.

Likewise, in *Docetaxel-related Epiphora*, a third article cited by Plaintiffs,[35] the authors refer to the injury as "lacrimal drainage obstruction" and "canalicular obstruction."[36]

"Lacrimal duct obstruction" (the term proposed and approved by FDA) unmistakably conveys to physicians the potential consequences of ingesting Taxotere—the risk of obstruction, whether by stenosis or any other clogging or blockage, to the lacrimal ducts—in terms physicians routinely use in practice and in literature. *See Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 266 (5th Cir. 2002) (finding a drug label adequate as a matter of law where the warning "clearly and unambiguously notifies the prescribing physician of the particular adverse reaction that forms the basis of the plaintiff's complaint"). This warning is clear, and it has been consistent in the Taxotere label since 2002. Plaintiffs' assertion that "stenosis" must be present to warn prescribers of this risk is contradicted by the very literature upon which they rely.

Trivial semantic differences between Plaintiffs' proposed warning of "stenosis" and the FDA-approved warning of "obstruction" are immaterial. Owen & Davis on Prods. Liab. § 9:22 (4th ed. 2019) (warnings "need not be perfect, only 'reasonable'"); *see also Kling v. Key Pharms., Inc.*, 35 F.3d 556 (4th Cir. 1994) ("The warning . . . must be reasonable, but 'not the best possible warning.'"). Instead, courts determine if the FDA-approved label conveys the alleged risk in clear terms. *See, e.g., Salvio v. Amgen Inc.*, 2012 WL 517446, *4 (W.D. Pa. Feb. 15, 2012).

In *Salvio*, for example, the decedent contracted mucormycosis, a fungal infection, after taking Enbrel, an arthritis medication. The manufacturer moved to dismiss, asserting that Enbrel's label adequately warned of the risk of infection. *Id*. In response, the plaintiff argued that, although the package insert warned broadly of the risk of infection, it did not warn of the *specific* risk of

[35] Rec. Doc. 25 ¶ 47 (citing Ex. A (*Docetaxel-Associated Epiphora*)).

[36] Ex. A (*Docetaxel-Associated Epiphora*) at 855.

invasive fungal infections, such as mucormycosis. *Id*. at *4, 6. In granting the manufacturer's motion, the court explained that the broad language in the drug's label warning of serious infection encompassed the more specific risk of developing the type of fungal infection that allegedly led to the decedent's death. *Id*. at *6. Because the warning "advise[d] physicians of the specific risks at issue," the label was adequate as a matter of law. *Id*. at *5–6; *see also In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 2022 WL 855853, at *20 (D.N.J. Mar. 23, 2022) (finding the manufacturer's warning adequate because it encompassed the injury plaintiffs allegedly sustained despite not using plaintiffs' preferred warning language).

Like *Salvio*, where a warning of infection encompassed a specific type of infection (i.e., a fungal infection), the Taxotere warning of "lacrimal duct obstruction" encompassed a specific type of obstruction (i.e., a narrowing, or "stenosis"). Thus, the fact that the Taxotere label may lack the *exact* words Plaintiffs prefer is immaterial. Indeed, no warning would ever be adequate if all a plaintiff had to allege was that the warning should have been conveyed in different, self-selected terms. Because the warning of lacrimal duct obstruction adequately conveys the risk of stenosis to the lacrimal system, the Taxotere label is adequate as a matter of law.

B. The label adequately conveys the risk of irreversibility absent treatment.

Not only does the term "obstruction" encompass stenosis, but it also advises physicians of the risk of permanency absent intervention.[37] An obstruction, by definition, remains unless an

[37] Any suggestion that Sanofi should have included specific data demonstrating the frequency of lacrimal duct obstruction is without merit. *See* **Exhibit G**, FDA, GUIDANCE FOR INDUSTRY, ADVERSE REACTIONS SECTION OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS – CONTENT AND FORMAT 8 (2006), https://www.fda.gov/media/72139/download. As Plaintiff Jade Porter explained in briefing before her case was transferred for consolidation, "Nowhere in Plaintiff's First Amended Complaint does she allege any statistical data from these post-2002 studies should have been added to post-marketing adverse events sections, or anywhere else on the label. Rather, Plaintiff alleges this accumulating data is newly acquired information which triggered Sanofi's duty to strengthen its warning to actually inform oncologists of the potentially permanent damage to the lacrimal system and convey a sense of urgency to act immediately when a patient presents with tearing." Pl.'s Resp. in Opp. to Defs.' Mot. to Dismiss at 13–14, *Porter v. Sanofi US Services Inc.*, No. 3:21-cv-01891-EMC (N.D. Cal. Aug. 10, 2021).

intervening force removes it.[38] Taxotere's warning to oncologists of the risk of an obstruction therefore puts oncologists on notice that a blockage could remain permanent unless treated.[39] *See In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 813 (N.D. Ohio 2004) ("[P]hysicians are highly trained and able to make much better medical judgments than the consumer, [so] warnings that might not be adequate to average consumers may very well be adequate to physicians."), *aff'd sub nom., Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006).

Unlike in MDL 2740, Plaintiffs here do not allege that the Taxotere label failed to warn of a separate, permanent injury for which there is allegedly no treatment.[40] Indeed, Plaintiffs do not assert that there was a *Sedlacek*-like article that allegedly should have raised an alarm for an emerging adverse reaction. Nor do they allege that the medical literature has identified a new injury akin to those plaintiffs' "PCIA" (permanent chemotherapy induced alopecia) allegations. This is because they cannot. There is no discussion in the literature of some new or distinct condition called "PCS" (permanent canalicular stenosis).

Instead, Plaintiffs allege a single injury—stenosis, *i.e.*, lacrimal duct obstruction—that *could possibly* become irreversible *if not properly treated*.[41] In other words, and in direct contrast

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[38] *Obstruction*, Merriam-Webster Medical Dictionary, https://www.merriam-webster.com/dictionary/obstruction#medicalDictionary (defined as "a condition of being clogged or blocked") (last visited June 28, 2022)

[39] Plaintiffs claim the Taxotere label represented that lacrimal duct obstruction was "reversible upon discontinuation of treatment." Rec. Doc. 25 ¶ 25. While the label does have a sentence stating, "These were reversible upon discontinuation of the infusion," that sentence does not apply to the warning on lacrimal duct obstruction. To the contrary, that sentence was added separate and apart from the warning on lacrimal duct obstruction and applies to the sentence *preceding it*, which provides, "[r]are cases of *transient* visual disturbances (flashes, flashing lights, scotomata) typically occurring during drug infusion and in association with hypersensitivity have been reported." *Compare* **Exhibit H**, Taxotere Label at 23 (July 9, 2002); *with* **Exhibit I**, Taxotere Label at 27 (Apr. 4, 2003). By definition, "transient disturbances" are "reversible." Plaintiffs' attempt to manipulate this sentence in their favor is contrary to the plain language of the label.

[40] **Exhibit J,** *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, Rec. Doc. 4407 (2d Am. Master Compl.) ¶ 181.

[41] Rec. Doc. 25 ¶ 1 ("Sanofi failed to provide a simple warning to inform the oncologists prescribing Taxotere® and the patients taking it of the importance of appropriate treatment and specialist referrals at the first sign of excessive tearing symptoms to prevent long-term and potentially irreversible lacrimal damage."); ¶ 23 ("Without

with the allegations in MDL 2740, any "permanent" injury Plaintiffs suffered was the result of a treatment decision separate and apart from the prescription of Taxotere. But, as discussed below, manufacturers have no duty to provide treatment instructions to oncologists, who are better positioned to exercise their medical judgment to treat their patients based on a patient's individualized circumstances and medical history.

C. There is no duty to provide treatment instructions in the label.

Plaintiffs attempt to salvage their claims by alleging that Sanofi failed to provide adequate treatment instructions to physicians and patients.[42] But, "the law does not mandate that pharmaceutical manufacturers and marketers provide such specific instructions that they leave little room for doctors' reasonable medical judgment." *See In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d at 814. For good reason. "Doctors are in a unique position to determine how best to treat their patients—a much better position than that of a far-away official in a pharmaceutical company, whose job is merely to write warnings." *Id*. at 814.

In the *In re Meridia Products Liability Litigation*, for example, the MDL court rejected the plaintiffs' arguments that the drug's label did not "give enough guidance to doctors regarding at what point they should discontinue the drug or how frequently they must monitor patients' blood pressure." *Id*. at 813. The court held that such an argument "overlooks the fact that such judgments are often better left to the doctors' discretion." *Id*. Likewise, in *Bergstresser v. Bristol-Myers*

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early intervention, patients that develop irreversible stenosis will experience persistent, life-altering symptoms that can only be treated through invasive surgical intervention.").

[42] Rec. Doc. 25 ¶ 25. Indeed, because Plaintiffs allege only that they would have undergone different treatment *after* Taxotere—not that they would not have taken Taxotere—Plaintiffs cannot prove proximate causation under the learned intermediary doctrine. Rec. Doc. 25 ¶ 71 ("Plaintiffs and their physicians would have taken preventative measures during the course of chemotherapy to prevent punctal, canalicular, and/or nasolacrimal duct stenosis had Sanofi provided an adequate warning of the risk and preventability of these side effects."); *see In re Taxotere (Docetaxel) Prods. Liab. Litig. (Phillips)*, 994 F.3d 704, 708 (5th Cir. 2021) ("To prove causation in this context, a 'plaintiff must show that a proper warning would have changed the decision of the [prescribing] physician, i.e. that but for the inadequate warning, the [prescribing] physician would not have used or prescribed the product.'" (internal citations omitted)).

Squibb Company, the district court rejected the plaintiff's failure-to-warn claim asserting that the label for Abilify, an antipsychotic medication, did not provide adequate instructions to physicians regarding the symptoms of dystonia (muscle contractions leading to abnormal postures). 2013 WL 6230489, at *7 (M.D. Pa. Dec. 2, 2013). In rejecting this argument, the Court noted that "[t]he law does not require that the drug manufacturer provide such detailed information or instructions so as to remove the medical judgment of the physicians, who are in the best position to monitor and treat their patients and make medical judgments with respect to their care." *Id.*

The same reasoning applies here. Plaintiffs cannot rely on an unrecognized duty to provide treatment instructions to physicians to save their failure-to-warn claims. *See Swayze v. McNeil Labs., Inc.*, 807 F.2d 464, 472 (5th Cir. 1987) ("Drug manufacturers must adequately warn physicians of the potential side effects of their prescription drugs; thereafter, the physician, with his special knowledge of the patient's needs, assumes the burden of presiding over the patient's best interests."); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974) ("We cannot quarrel with the general proposition that . . . the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use.").

Similarly, Plaintiffs cannot base their failure-to-warn claims on their allegations that Sanofi's FDA-approved Patient Information Leaflet should have "urge[d] the patient to immediately report" excessive tearing to his or her oncologist.[43] As a legal matter, "a drug manufacturer has a duty to warn *the prescribing physician, rather than the patient*, of potential risks associated with the use of the drug." *In re Taxotere (Docetaxel) Prods. Liab. Litig. (Phillips)* at 708 (emphasis added). As a factual matter, the label has always informed patients to tell their doctors about any side effects they experience, including excessive tearing. From 2002 to 2010,

[43] Rec. Doc. 25 ¶ 27.

the label directed Plaintiffs: "If you have questions or concerns, be sure to ask your doctor or nurse."[44] Thereafter, the label alerted patients: "Tell your doctor if you have any side effect that bothers you or does not go away."[45] Plaintiffs' claims therefore fail to the extent they are premised on Sanofi's alleged failure to warn *them* about the risks associated with Taxotere.

II. PLAINTIFFS' CLAIMS ARE PREEMPTED BECAUSE THE MASTER COMPLAINT DOES NOT IDENTIFY "NEWLY ACQUIRED INFORMATION."

Under the Supremacy Clause of the United States Constitution, federal law "shall be the supreme Law of the Land[.]" *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617 (2011) (quoting U.S. Const. art. VI, cl. 2). When federal and state law conflict—such as when it is impossible for a party to comply with both federal and state laws—federal law preempts state law. *Id.*; *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019).

The federal law at issue here is the Food, Drug, and Cosmetics Act. 21 U.S.C. § 301 et seq. The Act provides for the premarket approval of new drugs by the Food and Drug Administration (FDA). *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). When FDA approves a new drug application, it also approves the exact text of the proposed label. *Id.* at 568. Once FDA approves the initial label, a manufacturer may only make a unilateral change to the label—that is, without preapproval from FDA—under the CBE regulation. *Id.* (citing 21 U.S.C. §§ 314.70(c)(6)(iii)(A), (C)). Unless the drug manufacturer could have utilized the CBE regulation to update the label, the Act preempts any state-law duty to provide a different warning.[46] *See PLIVA, Inc.*, 564 U.S. at 618–24.

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[44] *See, e.g.*, Ex. H, Taxotere Label at 1 (2002).

[45] *See, e.g.*, **Exhibit K**, Taxotere Label at 61 (2010).

[46] State-law claims that would require FDA preapproval—that is, a non-CBE label change—are preempted because it would be impossible for a drug manufacturer to comply with the alleged state-law duty to warn until after FDA made a decision on the proposed label change. *PLIVA, Inc.*, 564 U.S. at 618–24; *Gibbons*, 919 F.3d at 707–08.

A CBE change must be supported by "newly acquired information." Newly acquired information is a narrow term defined by regulation:

> [D]ata, analyses, or other information not previously submitted to [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3(b). As a result, the CBE regulation requires a showing that: (1) the manufacturer had information that it did not submit to FDA; and (2) this information revealed a risk that was different, more severe, or more frequent than previously known.

The Master Complaint selectively cites from several articles published after Sanofi revised its label in 2002. These articles, however, do not identify: (1) a different risk; (2) a more severe risk; or (3) a more frequent risk that would support a Taxotere CBE label change.

First, the articles cited in the Master Complaint identify the same risk—lacrimal duct obstruction—that the Taxotere label has warned about since 2002. Newly acquired information must identify a risk not already included in the Taxotere label because the approved label "obviously reflects what was 'previously included in submissions to FDA.'" *Roberto v. Boehringer Ingelheim Pharms., Inc.*, 2019 WL 5068452, at *14 (Conn. Super. Ct. Sept. 11, 2019); *see also Knight v. Boehringer Ingelheim Pharms., Inc.*, 984 F.3d 329, 339 (4th Cir. 2021) (research paper identifying potential risks not newly acquired information where "the physician label in place since November 2011, and even before, warned of these risks").

Although Plaintiffs concede that the Taxotere label has identified lacrimal duct obstruction as a potential cause of excessive tearing since 2002, they suggest that the label does not identify

"stenosis" as a potential cause of excessive tearing.[47] This is a distinction without a difference. As discussed, the articles cited within the Master Complaint use these terms interchangeably. This is unsurprising considering stenosis ("[A] narrowing or construction of the diameter of a bodily passage or orifice") is a type of obstruction ("[A] condition of being clogged or blocked") that can occur within the lacrimal system.[48] As such, the articles cited in the Master Complaint do not identify a different risk from the 2002 label.

Second, the Master Complaint does not identify a greater frequency of lacrimal duct obstruction. A frequency analysis requires a known user population (or denominator). *Cf. Gayle*, 452 F. Supp. 3d at 88 (citation to 6,000 unanalyzed adverse event reports in complaint was not newly acquired information), *with Risperdal & Invega Cases*, 263 Cal. Rptr. 3d 412, 417, 425–26 (Cal. Ct. App. 2020) (statistical analysis of five pediatric studies commissioned by drug manufacturer that revealed that children prescribed risperidone for eight to twelve weeks who showed elevated prolactin levels were 2.8 times more likely to have suffered prolactin-related side effects was newly acquired information). And while a study may identify a frequency based on a subset of case reports, FDA discourages inclusion of these rates in the Adverse Reactions section because of the potential for bias and inconsistent rate determinations.[49] Frequency, instead, is ordinarily derived from all reported adverse events in the database used.[50]

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47 Rec. Doc. 25 ¶ 25.

48 *Cf. Stenosis*, Merriam-Webster Medical Dictionary, https://www.merriam-webster.com/dictionary/stenosis#medicalDictionary ("[A] narrowing or construction of the diameter of a bodily passage or orifice") (last visited June 28, 2022), *with Obstruction*, Merriam-Webster Medical Dictionary, https://www.merriam-webster.com/dictionary/obstruction#medicalDictionary ("[A] condition of being clogged or blocked") (last visited June 28, 2022); *see also Reid v. Time Warner Cable*, 2016 WL 743394, at *2 (E.D.N.Y. Feb. 22, 2016) (taking judicial notice of the online medical dictionary definition of "alveoloplasty").

49 Ex. G (GUIDANCE FOR INDUSTRY, ADVERSE REACTIONS SECTION OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS – CONTENT AND FORMAT) at 8.

50 *Id*.

To this end, the FDA-approved Taxotere label explains that the adverse events identified, such as lacrimal duct obstruction, were "reported from a population of unknown size, [so] precise estimates of frequency cannot be made."[51] The Master Complaint does not identify any frequency of lacrimal duct obstruction that should be included in the Taxotere label. Plaintiffs instead rely on one article, which identifies incidence rates of epiphora in patients taking docetaxel.[52] Plaintiffs, however, allege that the Taxotere label omitted the risk of stenosis, not epiphora.[53] Even if this article identified a frequency of lacrimal duct obstruction (or "stenosis"), it would not be included in the label because it measures a subset of case reports. As a result, the articles cited do not identify "newly acquired information" showing a greater frequency of lacrimal duct obstruction.

Third, the Master Complaint fails to identify a more severe risk of lacrimal duct obstruction after 2002. Sanofi informed FDA of this exact risk when it submitted a CBE label change. *See Roberto*, 2019 WL 5068452, at *14; *Knight*, 984 F.3d at 339. Faced with this clear warning, the Master Complaint attempts to sidestep any scientific discussion of the risk before 2002 by selectively removing most references to pre-2002 articles that individual Plaintiffs previously cited in their complaints.[54] The post-2002 studies cited in the Master Complaint, however, still demonstrate that cases of patients with complete obstruction emerged well before Sanofi submitted

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51 *See* Ex. H, Taxotere Label at 23 (2002).

52 Rec. Doc. 25 ¶ 47 ("In this prospective, observational study, epiphora was seen in 64% of patients in the weekly docetaxel group and in 39% of the docetaxel every 3 weeks group.").

53 *See, e.g.*, Rec. Doc. 25 at 1. As Plaintiff Jade Porter explained in briefing before her case was transferred for consolidation, "[i]n her First Amended Complaint Plaintiff acknowledges that the 2002 label warns of excessive tearing, and both the pre- and post-2002 studies discuss the incidence of excessive tearing in patients taking Taxotere. However, the newly acquired information Mrs. Porter has pled demonstrates an increase in the frequency of **permanent stenosis**, not simply excessive tearing." Pl.'s Resp. in Opp. to Defs.' Mot. to Dismiss at 13–14, *Porter v. Sanofi US Services Inc.*, No. 3:21-cv-01891-EMC (N.D. Cal. Aug. 10, 2021).

54 *See, e.g.*, Complaint at 11 n.10, *Porter v. Sanofi US Services Inc.*, No. 3:21-cv-01891-EMC (N.D. Cal. Mar. 17, 2021) (citing Esmaeli et al., *Canalicular Stenosis Secondary to Weekly Docetaxel: A Potentially Preventable Side Effect*, 13 EUROPEAN SOC'Y FOR MED. ONCOLOGY 218 (2001)).

its 2002 CBE label change. *See In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 42–43 (1st Cir. 2015) (affirming dismissal of claims as preempted where plaintiffs challenged drug's FDA-approved labeling but did not allege that the information on which their claims relied "was unknown to the FDA prior to label approval").

The Master Complaint, for example, cites to an article published in 2003 by Dr. Bita Esmaeli, which states that she had "previously reported several patients with irreversible blockage of the lacrimal drainage apparatus as a side effect of the weekly administration of docetaxel."[55] In support, Dr. Esmaeli cited to her 2001 article, *Canalicular Stenosis Secondary to Docetaxel (Taxotere): A Newly Recognized Side Effect*, which identified three case reports of metastatic breast cancer patients who developed canalicular stenosis while receiving weekly Taxotere infusions, including one patient with complete, or "permanent," closure of the puncta.[56] The Master Complaint does not allege that FDA was unaware of these cases of lacrimal duct obstruction (identified, per the Master Complaint, in 2001) before approving Sanofi's CBE label change in 2002. Nor could it. In light of this "newly recognized side effect," Sanofi sought a label change to warn of this exact adverse event identified in Sanofi's post-marketing surveillance.

Without any newly acquired information as to the risk itself, Plaintiffs assert that Sanofi failed to instruct physicians about the proper treatment of lacrimal duct obstruction.[57] This claim is also preempted because the CBE only permits a drug manufacturer to add or strengthen a warning to address a "clinically significant hazard." 21 C.F.R. § 201.57(c)(6)(i). The addition of treatment recommendations oversteps a drug manufacturer's authority under the CBE regulation

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55 Ex. C (*Canalicular Stenosis Secondary to Docetaxel (Taxotere): A Newly Recognized Side Effect*) at 994.

56 *Id*. at 994–95.

57 That is, "Sanofi failed to provide a simple warning to inform the oncologists prescribing Taxotere® and the patients taking it of the importance of appropriate treatment and specialist referrals at the first sign of excessive tearing symptoms to prevent long-term and potentially irreversible lacrimal damage." Rec. Doc. 25 ¶ 1.

because a manufacturer may only revise its label unilaterally to include "newly acquired information," which is a new *risk* or a higher frequency or severity of a *risk*. 21 C.F.R. § 314.3(b). Treatment recommendations for a previously identified risk are not "newly acquired information" because, by definition, they do not identify a new risk or a greater frequency or severity of the risk. *Id.* As a result, federal law also preempts this claim.

III. PLAINTIFFS' FRAUD CLAIMS DO NOT SATISFY RULE 9(B).

Plaintiffs' Master Complaint includes three claims premised on alleged misrepresentations: negligent misrepresentation, fraudulent misrepresentation, and fraudulent concealment. Because these claims sound in fraud, they must satisfy Federal Rule of Civil Procedure 9(b). *See Benchmark Elec., Inc. v. J.M. Huber Corp.*, 343 F.3d 719, 723 (5th Cir. 2003), *modified on denial of reh'g*, 355 F.3d 356 (5th Cir. 2003).

Rule 9(b) is only satisfied if Plaintiffs supply "the particulars of time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what that person obtained thereby, otherwise referred to as the who, what, when, where, and how of the alleged fraud." *U.S. ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 384 (5th Cir. 2003) (internal citations and quotation marks omitted). Yet, Plaintiffs allege no factual basis for their fraud claims. Instead, Plaintiffs assert only general allegations that Sanofi made representations about docetaxel through marketing or labeling.[58]

[58] *See, e.g.*, Compl. ¶ 83 ("Sanofi negligently represented to Plaintiffs, their healthcare, providers, the healthcare community, and the public in general that Taxotere has been tested and was found to be safe and effective for indicated use."); ¶ 84 ("Sanofi concealed its knowledge of Taxotere defects from Plaintiffs, their healthcare providers, and the public in general and/or the healthcare community specifically."); ¶ 92 ("Sanofi fraudulently omitted from this vague report of 'lacrimal duct obstruction' and/or 'excessive tearing' that Taxotere could and did cause life altering damage to the lacrimal system, including punctal, canalicular, and/or nasolacrimal duct stenosis."); ¶ 99 ("Sanofi misrepresented the design characteristic and safety of Taxotere for intended use.").

These allegations are insufficient to state a claim under Rule 9(b) because Plaintiffs do not identify with particularity what, to whom, when, or how these representations were made. *Dorsey v. Portfolio Equities, Inc.*, 540 F. 3d 333, 339 (5th Cir. 2008) (plaintiff "must allege specific facts supporting an inference of fraud"). The Fifth Circuit "interprets Rule 9(b) strictly," and to avoid dismissal, a plaintiff must "specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Id.*; *see also Eckhardt*, 751 F.3d at 681 (finding plaintiff failed to allege sufficient facts for his fraud claim to survive in a pharmaceutical product liability case). Plaintiffs' vague allusions to "material and false"[59] representations do nothing of the sort. *See Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1019 (5th Cir. 1996). Plaintiffs' fraud-based claims should be dismissed.

CONCLUSION

For all of these reasons, this Court should grant Sanofi's motion to dismiss Plaintiffs' Master Complaint.

Respectfully submitted,

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[59] Rec. Doc. 25 ¶ 93.

CERTIFICATE OF SERVICE

I hereby certify that on June 28, 2022, I electronically filed the foregoing with the Clerk of the Court using the ECF system, which sent notification of such filing to all counsel of record.

/s/ *Douglas J. Moore*