UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: ZOFRAN (ONDANSETRON) PRODUCTS LIABILITY LITIGATION,	)	**MDL No. 1:15-md-2657-FDS**
This Document Relates To:	)	
All Actions	)	

MEMORANDUM AND ORDER ON
DEFENDANT'S MOTION TO DISMISS FRAUD-BASED CLAIMS

SAYLOR, J.

This is a multi-district litigation (MDL) proceeding arising out of product-liability claims that the use of the drug Zofran by pregnant women caused birth defects. Plaintiffs allege, among other things, that defendants made false and misleading statements and omissions about the use of Zofran during pregnancy in their marketing, advertising, and product labeling, and in other oral and written communications.

Defendant GlaxoSmithKline LLC has moved to dismiss plaintiffs' fraud-based claims for failure to plead with particularity as required by Fed. R. Civ. P. 9(b). For the reasons stated below, the motion will be denied. The allegations of the complaint are inadequate to state a claim for fraud based on GSK's alleged marketing and advertising campaign, and there are no allegations at all that any specific GSK representative made a false statement to a prescribing physician. Nonetheless, the allegations of fraud as to the product labeling of Zofran are sufficiently particular to satisfy the requirements of Rule 9(b).

I. Background

A. Facts Common to All Cases

Unless otherwise noted, all facts are stated as set forth in the master complaints.[1]

1. The Parties and Zofran

GlaxoSmithKline LLC ("GSK") is a pharmaceutical company based in Wilmington, Delaware. (Master Long Form Complaint-Brand Zofran Use ("Compl.") ¶¶ 2-3). It is a subsidiary of GlaxoSmithKline PLC. (*Id.* ¶ 4). Until March 23, 2015, GSK was the sponsor of the new drug applications ("NDAs") for the pharmaceutical Zofran, or ondansetron. (*Id.* ¶ 6).

Zofran is an anti-emetic—that is, a drug that prevents or treats nausea or vomiting. (*Id.* ¶ 17). In 1991, Zofran was approved for marketing in the United States. (*Id.* ¶ 23). It was approved for the prevention of nausea and vomiting induced by chemotherapy or radiation therapy and post-operative nausea and vomiting. (*Id.* ¶ 16). Generic ondansetron became available in the United States in 2007. (Master Long Form Complaint-Generic Use ("Generic Compl.") ¶ 27).

Effective March 23, 2015, Novartis AG, a pharmaceutical company based in Switzerland, purchased the right to sell Zofran products in the United States. (Compl. ¶ 7). At that time, Novartis Pharmaceuticals Corporation, an American-based subsidiary of Novartis AG, become the NDA holder for Zofran. (*Id.*).

The plaintiffs in this MDL proceeding are parents and guardians of children who allege that they were born with birth defects caused by prenatal exposure to Zofran and/or generic

[1] In this proceeding, there are two master complaints—one on behalf of all plaintiffs alleging that they ingested brand-name Zofran and another on behalf of all plaintiffs alleging that they ingested generic ondansetron—as well as individual short-form complaints for each plaintiff. The master complaints set forth the factual allegations common to all plaintiffs. For the sake of convenience, the Court will cite to the Zofran master complaint (as "the complaint") unless otherwise indicated.

ondansetron. (Compl. ¶ 1).

2. Alleged Effects of Zofran/Ondansetron on Embryonic Development

Zofran is part of a class of anti-emetics referred to as selective serotonin 5-HT3 receptor antagonists. (*Id.*). Serotonin signaling in the body triggers nausea and vomiting. (*Id.* ¶ 19). The active ingredient in Zofran, ondansetron, is believed to alleviate symptoms of nausea and vomiting by inhibiting the body's serotonin signaling. (*Id.*).

Serotonin signaling regulates developmental processes that are critical to normal embryonic development. (*Id.* ¶ 20). Inhibiting serotonin signaling during embryonic development can therefore increase the risk of birth defects. (*Id.*). According to the complaint, pre-clinical studies conducted by or on behalf of GSK in the 1980s revealed that Zofran ingested by mammals—in particular, rats and rabbits—during pregnancy crosses the placental barrier, exposing the fetus to the drug. (*Id.* ¶ 43). The complaint alleges that subsequent scientific research has confirmed that Zofran also crosses the placental barrier during human pregnancies. (*Id.* ¶ 44).

According to the complaint, animal studies conducted by or on behalf of GSK in the 1980s in Japan revealed clinical signs of toxicity, intrauterine fetal deaths, stillbirths, congenital heart defects, craniofacial defects, impairment of ossification (incomplete bone growth), and other malformations in fetuses exposed to Zofran during gestation. (*Id.* ¶ 45). The complaint also alleges that from 1992 to the present, GSK has received reports—either directly or through studies published in medical literature—of birth defects in children exposed to Zofran or ondansetron during pregnancy. (*Id.* ¶ 46).

3. Alleged Off-Label Marketing of Zofran for Pregnancy-Related Nausea and Vomiting

According to the complaint, beginning around 1997, GSK "launched a marketing scheme

to promote Zofran to obstetrics and gynecology healthcare practitioners and consumers as a safe and effective treatment for pregnancy-related nausea and vomiting." (*Id.* ¶ 29). Among other things, GSK's Oncology Division directly created new relationships with obstetricians and gynecologists, and also partnered with GSK's Consumer Health Care Division, which already had established relationships with obstetricians and gynecologists. (*Id.* ¶ 32). The two divisions allegedly entered a "co-marketing agreement" in 2001 to market Zofran to obstetricians and gynecologists for use in treating pregnancy-related nausea and vomiting. (*Id.* ¶¶ 33-34). According to the complaint, "[a]s a result of GSK's fraudulent marketing campaign," by 2002 Zofran had become the most frequently prescribed drug for treating pregnancy-related nausea and vomiting in the United States. (*Id.* ¶ 36).

Since 1993, the prescribing information for Zofran has included the following statement concerning its use during pregnancy:

> Pregnancy: Teratogenic Effects: Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at I.V. doses of up to 4 mg/kg per day and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

(*Id.* ¶ 50). The complaint alleges that "[t]his statement is false and misleading because animal studies conducted by or on behalf of GSK outside of the United States have in fact revealed evidence of teratogenic effects due to ondansetron." (*Id.* ¶ 51).[2] It further alleges that the statement is false and misleading "because [d]efendants failed to conduct post-market studies that were properly designed to identify Zofran's true teratogenic

[2] The complaint specifically alleges that a study conducted in Japan in the 1980s "revealed clinical signs of toxicity, intrauterine fetal deaths, stillbirths, congenital heart defects, craniofacial defects, impairment of ossification (incomplete bone growth), and other malformations" due to ingestion of ondansetron during pregnancy. (*Id.* ¶ 45).

risk," and misleading "because it states that Zofran should be used during pregnancy if it is clearly needed, without limiting that representation to situations where it is clearly needed for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting, or post-operative nausea and/or vomiting." (*Id.*).

Count Two alleges a claim for negligent misrepresentation. It alleges generally that defendants "falsely and negligently misrepresented material facts on which plaintiffs and their healthcare providers acted," and that defendants "also failed to disclose material facts regarding the safety and efficacy of Zofran to treat morning sickness." (*Id.* ¶¶ 72, 73). It further alleges that defendants "made misrepresentations through their advertisements, labeling, marketing, marketing persons, notices, product information, and written and oral information provided to patients and medical providers" about the safety of ingesting Zofran during pregnancy. (*Id.* ¶ 76). It then alleges:

> 77. Defendants negligently represented to the expectant mothers and the medical and healthcare community, including Plaintiffs and their healthcare providers, that:
>
> (a) Animal studies of ondansetron showed no harm to fetuses;
>
> (b) Zofran should be used during pregnancy if it is clearly needed, without limiting that representation to situations where it is clearly needed for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting, or post-operative nausea and/or vomiting;
>
> (c) As to GSK, Zofran was safe and effective for treating pregnancy-related nausea and vomiting;
>
> (d) As to GSK, Zofran was a safe and effective prophylactic treatment for preventing pregnancy-related nausea and vomiting;
>
> (e) As to GSK, Zofran had been adequately tested and studied in pregnant women;
>
> (f) As to GSK, Zofran use during pregnancy did not increase the risk of

birth defects.

(*Id.* ¶ 77). It goes on to allege in general terms that defendants had actual or constructive knowledge of the falsity of the statements. (*Id.* ¶ 78). It then alleges:

> 80. In reasonable reliance upon said representations, Plaintiffs' prescribers were induced to prescribe Zofran and recommend the drug as safe for treating pregnancy-related nausea, and Plaintiffs were induced to and did use Zofran to treat pregnancy-related nausea. . . .
>
> 81. Defendants' labeling of Zofran was also rendered misleading by the omission of the material risk information listed in the preceding count.
>
> 82. Plaintiffs and their healthcare providers justifiably relied on Defendants' representations and non-disclosures when ingesting Zofran.

(*Id.* ¶¶ 80-82).

Count Two further alleges that plaintiffs and their healthcare providers justifiably relied on defendants' misrepresentations and non-disclosures when prescribing and ingesting Zofran, and that plaintiffs' prescribing doctors would not have prescribed Zofran had they known of the risks. (*Id.* ¶ 82).

Count Eight alleges fraudulent misrepresentation, "in the broadest sense, pursuant to all applicable [state] laws." (*Id.* ¶ 127). The complaint repeats the allegations of ¶ 77, quoted above, and alleges knowledge, intent, and reasonable reliance by prescribing physicians, all in general terms. (*Id.* ¶¶ 130-33). Count Nine alleges violation of various state consumer protection laws, again in general terms.[3]

The parties agree that there are no additional case-specific allegations of misrepresentations in any of the individual short-form complaints.

[3] The generic master complaint includes the same three counts, but the fraudulent misrepresentation count is Count Five and the count alleging violations of state consumer protection laws is Count Six.

B. Procedural Background

On October 13, 2015, the Judicial Panel on Multidistrict Litigation transferred individual cases alleging birth defects due to ingestion of Zofran or ondansetron filed across the country to this court for consolidated pretrial proceedings. In response to this Court's order dated May 18, 2016, plaintiffs filed a brand-name master complaint and generic master complaint on May 31, 2016. Individual plaintiffs then subsequently filed short-form complaints adopting a master complaint with more detailed individual information concerning their claims.

The brand-name master complaint asserts 13 causes of action against defendants GSK and Novartis: negligence (Count 1); negligent misrepresentation (Count 2); negligent undertaking (Count 3); negligence *per se* (Count 4); failure to warn (Count 5); breach of express warranty (Count 6); breach of implied warranties (Count 7); fraudulent misrepresentation and concealment (Count 8); violation of state consumer protection laws (Count 9); wrongful death (Count 10); survival (Count 11); loss of consortium (Count 12); and punitive damages (Count 13). The generic master complaint is virtually identical, but does not include causes of action for failure to warn, breach of express warranty, or breach of implied warranties.

On October 13, 2016, defendant GSK filed a consolidated partial motion to dismiss all fraud-based claims against it in both the brand-name master complaint and generic master complaint.[4] For the reasons stated below, the motion to dismiss will be denied.

II. Legal Standard

On a motion to dismiss, the Court "must assume the truth of all well-plead[ed] facts and give . . . plaintiff the benefit of all reasonable inferences therefrom." *Ruiz v. Bally Total Fitness*

[4] On October 26, 2016, plaintiffs filed a motion to strike that motion. The motion to strike was denied at the November 10, 2016 status conference. On January 3, 2017, plaintiffs filed their opposition to GSK's motion to dismiss.

Holding Corp., 496 F.3d 1, 5 (1st Cir. 2007) (citing *Rogan v. Menino*, 175 F.3d 75, 77 (1st Cir. 1999)). To survive a motion to dismiss, the complaint must state a claim that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). That is, "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556). Dismissal is appropriate if the complaint fails to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) (quoting *Centro Medico del Turabo, Inc. v. Feliciano de Melecio*, 406 F.3d 1, 6 (1st Cir. 2005)).

Under Fed. R. Civ. P. 9(b), the standard for allegations of fraud is higher than the normal pleading standard. To survive a motion to dismiss, a complaint alleging fraud must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

III. Analysis

The master complaint alleges three fraud-based claims: negligent misrepresentation, fraudulent misrepresentation and concealment, and violation of state consumer protection laws. All three claims are subject to the heightened pleading requirements of Rule 9(b). *See Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985) (noting that Rule 9(b) applies to all cases in "in which fraud lies at the core of the action").

In the First Circuit, to satisfy the requirements of Rule 9(b), plaintiffs must specifically plead "the time, place and content of an alleged false representation." *Id.* at 444; *accord Rodi v.*

Southern N.E. Sch. Of Law, 389 F.3d 5, 15 (1st Cir. 2004) (stating that Rule 9(b) is satisfied by averment of "the who, what, where, and when of the allegedly false or fraudulent representation"). However, "the specificity requirement extends only to the particulars of the allegedly misleading statement itself. . . . The other elements of fraud, such as intent and knowledge, may be averred in general terms." *Rodi*, 389 F.3d at 15 (internal citation omitted).

A. Applicability of Rule 9(b)

Before reaching the adequacy of plaintiffs' fraud-based claims, the Court will first address the applicability of Rule 9(b) in the context of an MDL proceeding.

In both their motion to strike and their opposition to GSK's motion to dismiss, plaintiffs contend that the heightened pleading requirements of Rule 9(b) should not apply to an MDL proceeding in the same manner as those requirements would be applied in an individual lawsuit. (Pl. Mot. to Strike at 8; Pl. Opp. at 7). In particular, they contend that the purpose of a master complaint—which is to promote judicial efficiency and economy by having uniform pleadings—would be vitiated if a master complaint were required to include plaintiff-specific factual allegations of fraud.

The creation of an MDL proceeding does not suspend the requirements of the Federal Rules of Civil Procedure, nor does it change or lower the requirements of those rules. Rule 9(b) applies to MDL proceedings no less than any other civil proceeding in which fraud is alleged. *See, e.g., In re General Motors Corp. Anti-Lock Brake Prods. Liab. Litig.*, 966 F. Supp. 1525, 1534-35 (E.D. Mo. 1997) (holding that allegations of fraudulent advertisements, sales brochures, and owner's manuals in master complaint were insufficient under Rule 9(b)); *In re Ford Motor Co. Speed Control Deactivation Switch Prods. Liab. Litig.*, 2007 WL 2421480, at *9 (E.D. Mich. Aug. 24, 2007) (holding that allegations of fraudulent advertising in master complaint were

insufficient under Rule 9(b)). *Cf. In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 2012 WL 3582708, at *4 (N.D. Ill. Aug. 16, 2012) (deciding motion to dismiss master complaint to the extent that motion challenges the sufficiency of the factual allegations common to all plaintiffs).

To the extent plaintiffs suggest that Rule 9(b) should not be enforced by the transferee court, as it may require individualized determinations as to the adequacy of individual complaints, that assertion is likewise incorrect.[5] Rule 9(b) is a pleading requirement; if it is to have any meaning at all, it must be applied and enforced at the relative outset of a proceeding, not after months or years of discovery and motion practice. *See In re Trasylol Prods. Liab. Litig.*, 2009 WL 577726, at *9 (S.D. Fla. March 5, 2009) ("[A]ny allegation of fraud based on [statements made by drug representatives to plaintiffs' physicians] must be [pleaded] with particularity in the individual Plaintiff's complaint, and be subject to discovery during the case-specific discovery stage *if, and only if, properly alleged*.") (emphasis added).

Furthermore, it is not appropriate to plead fraud claims in general terms, in the hope that discovery will reveal greater particularity as to the actual misrepresentation. *See United Air Lines v. Gregory*, 716 F. Supp. 2d 79, 85 (D. Mass. 2010) (noting that purpose of Rule 9(b) is, among other things, to discourage fishing expeditions and strike suits). Rule 9(b) would cease to have any meaning at all if such an approach were adopted.

That leaves the question as to how allegations of fraud should be pleaded in a proceeding such as this. It is true that this case, like most MDL proceedings, employs the device of a master complaint, supplemented by individual short-form complaints that adopt the master complaint in

[5] *See In re Zimmer Nexgen*, 2012 WL 3582708, at 3-4 (discussing whether motion to dismiss requiring case-specific rulings to determine sufficiency of individual plaintiff's factual allegations should be considered by transferee court or transferor court).

whole or in part. It is also true that a master complaint could not possibly be expected to include every case-specific detail, such as a particular misleading statement made by a particular sales representative to the physician of an individual plaintiff. *See In re Trasylol*, 2009 WL 577726, at *8. But the "complaint" in this proceeding is not a single document. The master complaint has no legal effect, standing alone; it has an effect only when it is adopted by a plaintiff through the filing of an individual complaint. In other words, the complaint in each action in this proceeding consists of the master complaint *and* the individual short-form complaint, taken together. *See* MDL Order No. 14 (Docket No. 243) (ordering that short-form complaints together with the applicable master complaint are "legally operative and binding as to that plaintiff"). Accordingly, any particularized allegation of fraud applicable only as to an individual—for example, a claim that a specific sales representative made a misrepresentation to a specific physician, who then prescribed the product to the plaintiff mother—should normally be set forth in the individual short-form complaint.

With that framework in mind, the Court will address the allegations of fraud in this proceeding.

B. Alleged Misrepresentations

Broadly speaking, there are three categories of alleged misrepresentations in this case. The first category consists of statements allegedly made by GSK in its advertising, marketing, and promotional materials—in other words, statements made generally to the marketplace. The second category consists of specific statements made by GSK representatives to prescribing physicians, including statements made by sales representatives to physicians, or specific written materials provided to individual physicians. The third category consists of statements made in Zofran's product labeling. Again, as to each, the complaint must allege "the time, place and

content of [the] alleged false representation." *Hayduk*, 775 F.2d at 444. The Court will address each in turn.

1. Allegations of Misrepresentations to the Marketplace

Plaintiffs first contend that GSK knowingly misrepresented the safety of ingesting Zofran during pregnancy through its advertising and marketing efforts. However, the master complaints do not identify the time, place, or content of any actual statements made by defendants in the course of such an advertising or marketing efforts. Instead, the complaints merely allege in general terms that defendants made misrepresentations through their "fraudulent marketing campaign," including advertisements and marketing materials. (Compl. ¶¶ 36, 76).

As a general rule, broad allegations of statements made in a nationwide marketing campaign are insufficient to pass muster under Rule 9(b). *See Hayduk*, 775 F.2d at 444 ("[R]eferrals to plans and schemes are too conclusional [sic] to satisfy the particularity requirement."); *iKoch v. I-Flow Corp.*, 715 F. Supp. 2d 297, 303-04 (D.R.I. 2010) (holding that allegations of false statements made in press releases, advertising campaigns, and commercial media, without more, are insufficient under Rule 9(b)).

Here, the allegations as to a marketing campaign or a promotional scheme are couched in the broadest possible terms. There is not a single specific allegation—either in the master complaints or the individual short-form complaints—as to any advertisement, brochure, handout, slide, or other written statement, nor as to any presentation, speech, or other oral statement. Accordingly, to the extent the fraud-based claims are premised on an advertising or marketing campaign, the complaints fail to satisfy the particularity requirement of Rule 9(b).

2. Allegations of Specific Misrepresentations to Physicians

Next, plaintiffs contend that sales and other representatives of GSK provided "written

and oral information" to "patients and medical providers." (Compl. ¶¶ 36, 76). Although it is not entirely clear, it appears that plaintiffs allege that individual GSK sales representatives, in the course of meetings with individual physicians, made misrepresentations as to the safety of Zofran for use with pregnant women.

Again, the allegations are couched in very broad terms; there is not a single allegation in the master complaint or any individual complaint as to any actual statement or representation made by any sales representative to any physician. *See In re Trasylol*, 2009 WL 577726, at *9 ("[A] broad claim that a Plaintiff or a [physician] relied on fraudulent or misleading statements made directly to them, absent some recitation of what oral or written statement a particular drug representative made to a specific physician at what particular point in time, is an insufficient basis for allowing Plaintiffs to proceed with a claim for fraud premised on any such alleged statements."). Again, therefore, to the extent the fraud-based claims are premised on such individualized representations to physicians, the complaints fail to satisfy the particularity requirement of Rule 9(b).

3. Allegations Based on Misrepresentations in Labeling

Finally, plaintiffs contend that GSK misrepresented the safety of ingesting Zofran during pregnancy on its labeling. In particular, they allege that the statement concerning teratogenic effects included in Zofran's prescribing information since 1993 is misleading. (*See* Compl. ¶ 50).

The labeling-based claims satisfy the requirements of Rule 9(b), because they are sufficiently specific as to the "time, place and content of [the] alleged false representation." *Hayduk*, 775 F.2d at 444. The content of the statement is specifically quoted in paragraph 50. The time of the statement is alleged to have been a continuous period beginning in 1993. And

while the "place" of the statement could no doubt be alleged with more particularity, it is a fair inference that the labeling statement was readily available to all physicians from a variety of sources.

Accordingly, because plaintiffs adequately pleaded the content, time, and place of the allegedly false representations made in Zofran's product labeling, the fraud-based claims premised on that misrepresentation satisfy the requirements of Rule 9(b). *See Whitaker v. Herr Foods, Inc.*, 198 F. Supp. 3d. 476, 485 (E.D. Pa. 2016) (holding that plaintiff adequately pleaded fraud by identifying alleged misrepresentations made on labels of certain food products between certain dates). Whether those representations were actually false is, of course, a question for another day.

C. Alleged Reliance on Misrepresentations

Defendants contend that plaintiffs' label-based claims should fail because they have not alleged which of their physicians, if any, read that labeling and how they relied on its language to the detriment of any particular plaintiff. However, Rule 9(b)'s specificity requirement extends only to the "particulars of the allegedly misleading statement itself," but not to "[t]he other elements of fraud." *Rodi*, 389 F.3d at 15. Therefore, reliance, while an element of plaintiffs' fraud-based claims, need only be pleaded in general terms. *See AcBel Polytech, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 2014 WL 4656608, at *9 (D. Mass. Sept. 12, 2014) ("Rule 9(b)'s heightened pleading requirements do not apply to AcBel's claims of reliance.").

Here, the master complaints allege generally that plaintiffs and their physicians relied on the misrepresentation in the label in prescribing and ingesting Zofran and/or ondansetron. (*See* Compl. ¶¶ 80, 82, 133, 137). In this context, at least, that is sufficient. Pharmaceutical product labeling is highly regulated, and its very purpose is to advise prescribing physicians, who may

reasonably rely on the representations in such labeling. Whether a particular physician did, in fact, rely on the representations in the labeling is of course a question of fact that cannot be resolved on the pleadings.

IV. Conclusion

For the foregoing reasons, defendant's motion to dismiss the fraud-based claims for failure to comply with Fed. R. Civ. P. 9(b) is DENIED. To the extent that Counts Two, Eight and Nine of the brand-name master complaint and Counts Two, Five, and Six of the generic master complaint, together with the individual short-form complaints adopting those counts, are based on alleged misrepresentations in the product labeling for Zofran, the allegations in the complaints are sufficiently particularized to satisfy the requirements of Fed. R. Civ. P. 9(b).

So Ordered.

/s/ F. Dennis Saylor
F. Dennis Saylor IV
United States District Judge

Dated: April 24, 2017