UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

KORRINE HERLTH, *Plaintiff*, v. MERCK & CO., INC. *et al.*, *Defendants*.	No. 3:21-cv-438 (JAM)

ORDER GRANTING MOTION TO DISMISS

Plaintiff Korrine Herlth alleges that she was injured after receiving two doses of the Gardasil vaccine. Herlth now brings a variety of product liability claims against the vaccine's manufacturers, Merck & Co., Inc., and Merck Sharp & Dohme Corp. (collectively, "Merck"). Merck has moved to dismiss her amended complaint. For the reasons set forth below, I will grant the motion to dismiss without prejudice.

BACKGROUND

I accept the following facts as true for purposes of considering Merck's motion to dismiss. After first receiving approval by the Food and Drug Administration ("FDA") in 2006, Merck has marketed versions of its Gardasil vaccine as a safe and effective means of preventing infection by the Human Papillomavirus ("HPV").[1] HPV is a viral infection and sexually transmitted disease that is believed to be associated with cervical and other cancers.[2] Since around that same time, the Centers for Disease Control and Prevention ("CDC") has recommended that nearly all children and young adults receive the Gardasil vaccine.[3] Gardasil is

[1] Doc. #18 at 12–13 (¶¶ 46–47, 49).
[2] *Id.* at 10 (¶¶ 31–32, 34).
[3] *Id.* at 12 (¶ 46).

currently approved for men and women between the ages of 9 and 45 years old, although Merck markets the vaccine primarily to pre-teen children and their parents.[4]

Herlth was 15 years old when her pediatrician, Dr. Allison Whitaker, recommended that she receive the Gardasil vaccine.[5] With the consent of Herlth's mother, Dr. Whitaker administered Herlth's first dose of Gardasil on October 2, 2013, during a routine visit to the pediatrician's office.[6]

Before the doctor's visit, Herlth's mother had seen television ads and other marketing regarding the safety and efficacy of the Gardasil vaccine.[7] Herlth alleges that her mother relied upon those marketing materials in choosing to have her vaccinated with Gardasil.[8]

Before receiving the vaccine, Herlth was in overall good health.[9] She was a vocational agriculture student and excelled in her studies.[10] She traveled with the school choir for performances, and she enjoyed being outdoors and taking care of farm animals.[11]

But after receiving her second dose of Gardasil in December 2013, Herlth began experiencing dizziness, shakiness, headaches, and nausea. She also experienced faintness, an elevated heartrate, and unsteadiness upon standing.[12] Based on her daughter's developing symptoms, Herlth's mother withdrew her consent, and Herlth did not receive her third dose of Gardasil.[13]

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[4] *Id.* at 13 (¶ 49).
[5] *Id.* at 51 (¶¶ 348, 350).
[6] *Id.* at 51–52 (¶ 350).
[7] *Id.* at 51–52, 71–72, 74–75 (¶¶ 349–50, 429, 442, 446, 449).
[8] *Id.* at 17, 51, 76, 78 (¶¶ 83, 349, 453–54, 457).
[9] *Id.* at 52 (¶ 351).
[10] *Ibid.*
[11] *Ibid.*
[12] *Ibid.* (¶ 352).
[13] *Ibid.* (¶ 353).

Over the following months, Herlth's health worsened. She was seen by multiple physicians for a variety of severe symptoms, including: daily seizures; vision, hearing, and balance problems; fatigue; anxiety and panic attacks; convulsions; sleep problems; depression; cognitive difficulties; numbness and tingling in her lower extremities; involuntary movements and tics; weakened connective tissue and chronic joint pain; and vaginismus and endometriosis.[14] Due to her health, Herlth opted out of normal teenage activities. She pulled back from participation in school and choir, and eventually, she was forced to finish high school from home and put off attending college altogether.[15]

Based upon her post-Gardasil symptoms and the results of several tests, Herlth has been diagnosed with a variety of severe medical conditions, including Postural Orthostatic Tachycardia Syndrome ("POTS") and chronic fatigue syndrome ("CFS").[16] POTS is a condition that affects the autonomic nervous system, which is responsible for automatically regulating vital bodily functions. POTS affects the body's ability to adjust the heartrate and compensate for blood flow, especially when the individual moves from a lying to standing position.[17] Individuals with POTS frequently experience dizziness, lightheadedness, vertigo, chronic headaches, vision issues due to the loss of blood flow to the brain, light and sound sensitivity, loss of consciousness, shortness of breath, chest pain, gastrointestinal issues, body pains, insomnia, and confusion and/or difficulty sleeping.[18] Researchers have allegedly linked POTS, CFS, and a variety of other autoimmune diseases to the Gardasil vaccine.[19]

[14] *Ibid.* (¶ 354).
[15] *Ibid.* (¶ 355).
[16] *Id.* at 53 (¶ 357).
[17] *Id.* at 40 (¶ 274).
[18] *Ibid*.
[19] *Id.* at 38, 40, 53 (¶¶ 262–64, 276, 357).

On January 13, 2016, Herlth filed a petition for compensation in the Office of the Special Masters of the U.S. Court of Federal Claims (sometimes called "Vaccine Court").[20] Under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. § 300aa-10 *et seq.*, an individual seeking compensation for an alleged vaccine-related injury must begin by filing a petition in Vaccine Court. *Id.* at § 300aa-11. If the injured party receives an unfavorable outcome, only then may she file a civil action against the vaccine manufacturer. *Id.* at § 300aa-21. On July 2, 2020, the Vaccine Court dismissed Herlth's claim for "insufficient proof." *Herlth v. Sec'y of Health & Hum. Servs.*, 2020 WL 4280698, at *2 (Fed. Cl. 2020).

On March 30, 2021, Herlth filed this federal lawsuit. Count One of her amended complaint alleges violations of the Connecticut Product Liability Act ("CPLA"), Conn. Gen. Stat. § 52-572m *et seq*. Gathered under her CPLA claim are a variety subclaims, including for failure to warn, manufacturing defect, and negligence.[21] Count Two is a claim for common law fraud. Merck now moves to dismiss the amended complaint for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure.[22]

DISCUSSION

The standard that governs a motion to dismiss under Rule 12(b)(6) is well established. A complaint may not survive unless it alleges facts that, taken as true, give rise to plausible grounds to sustain a plaintiff's claims for relief. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Kim v. Kimm*, 884 F.3d 98, 103 (2d Cir. 2018). As the Supreme Court has explained, this "plausibility" requirement is "not akin to a probability requirement," but it "asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. In other words, a valid

[20] *Id.* at 55 (¶ 361); *see also Herlth v. Sec'y of Health & Hum. Servs.*, 2020 WL 4280698 (Fed Cl. 2020).
[21] In her opposition to Merck's motion to dismiss, Herlth agreed to dismiss her CPLA subclaim for breach of express warranty. *See* Doc. #24 at 24 n.5.
[22] Doc. #20.

claim for relief must cross "the line between possibility and plausibility." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007). A court must "accept as true all factual allegations and draw from them all reasonable inferences; but [it is] not required to credit conclusory allegations or legal conclusions couched as factual allegations." *Hernandez v. United States*, 939 F.3d 191, 198 (2d Cir. 2019).[23]

Count One – Connecticut Product Liability Act (CPLA)

Count One of the amended complaint alleges three subclaims for liability under the CPLA: (1) failure to warn, (2) manufacturing defect, and (3) negligence. I will address each subclaim in turn.

Failure to warn

Merck argues that Herlth's failure-to-warn claim as presently pleaded in the amended complaint is preempted by the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq*. I agree.

Under Connecticut law, manufacturers of products have a duty to ensure that their products are accompanied by adequate warnings or instructions. *See* Conn. Gen. Stat. § 52-572q(a); *LaMontagne v. E.I. DuPont De Nemours & Co., Inc.*, 41 F.3d 846, 859 (2d Cir. 1994). At the same time, the FDCA strictly regulates the labeling of all pharmaceuticals. *See* 21 U.S.C. § 301 *et seq.*; *Wyeth v. Levine*, 555 U.S. 555, 566–68 (2009). Before the FDA will approve the marketing of a new vaccine or other drug, the manufacturer must submit and the FDA must approve the exact text of the proposed label. *See* 21 U.S.C. § 355(b)(1)(A)(vi); *Wyeth*, 555 U.S. at 568; *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 707 (2d Cir. 2019).

[23] Unless otherwise indicated, this opinion omits internal quotation marks, alterations, citations, and footnotes in text quoted from court decisions.

Generally speaking, a manufacturer may only change a vaccine label after the FDA approves a supplemental application. *See* 21 C.F.R. § 601.12(f)(1); *Wyeth*, 555 U.S. at 568. The exception to this rule is when a manufacturer may unilaterally modify its label through compliance with the "changes being effected" ("CBE") regulation. *See Gibbons*, 919 F.3d at 707. The CBE regulation allows a manufacturer to change its label without the FDA's preapproval if the changes "reflect newly acquired information" concerning contraindications, warnings, precautions, possible adverse reactions, or proper dosage and administration. *See* 21 C.F.R. § 601.12(f)(2)(i).[24]

A state law failure-to-warn claim against a drug manufacturer is preempted unless the drug manufacturer can simultaneously comply with its state law duty to warn *and* with federal labeling requirements under the FDCA. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618–19 (2011). Because Merck secured FDA approval of its label in the first instance, Herlth's failure-to-warn claim is therefore preempted by federal law unless she has pleaded a labeling deficiency that Merck could have unilaterally corrected in accordance with the requirements of the CBE regulation. *See Gibbons*, 919 F.3d at 708; *Ignacuinos v. Boehringer Ingelheim Pharms. Inc.*, 490 F. Supp. 3d 533, 541 (D. Conn. 2020), *aff'd*, 8 F.4th 98 (2d Cir. 2021).

Under the terms of the CBE regulation, a manufacturer may unilaterally change its label only if it has "newly acquired information." 21 C.F.R. § 601.12(f)(2)(i). Any "information will be considered newly acquired if it consists of data, analyses, or other information not previously submitted to the agency." *Id.* at § 601.12(f)(6). Such information "may include (but [is] not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of

[24] A similar CBE regulation applies for non-vaccine drugs. *See Gibbons*, 919 F.3d at 707 (citing C.F.R. §§ 314.70(c)(6)(iii) & 314.3(b)). Because Herlth does not identify any material difference between the CBE regulation governing vaccines and the CBE regulation governing other drugs, this ruling relies in part on precedent like *Gibbons* that applies the CBE regulation governing non-vaccine drugs.

previously submitted data . . . if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." *Ibid.*

Moreover, the regulations include a causation requirement between the newly acquired information and an adverse reaction to the drug: "newly acquired information 'must provide reasonable evidence of a causal association of a clinically significant adverse reaction linked to a drug.'" *McGrath v. Bayer HealthCare Pharms. Inc.*, 393 F. Supp. 3d 161, 167 (E.D.N.Y. 2019) (quoting 21 C.F.R. § 201.57(c)(6)(i)); *Gayle v. Pfizer Inc.*, 452 F. Supp. 3d 78, 85 (S.D.N.Y. 2020) (same), *aff'd*, 847 F. App'x 79 (2d Cir. 2021).

How does all this apply here? Because of the requirement that the information be "newly acquired," Herlth must allege that there was significant adverse risk information revealed to Merck at some point *after* the FDA's approval of Gardasil in June 2006. And because of the requirement under state law that a failure to warn have caused a plaintiff's injury, *see Sharp v. Wyatt, Inc.*, 31 Conn. App. 824, 835 (1993) *aff'd*, 230 Conn. 12 (1994), Herlth must plead facts to plausibly show that the newly acquired information was available to Merck *before* Herlth's second dose of Gardasil in December 2013 and that the information related to the same category of injuries alleged by Herlth.

Herlth has not plausibly pleaded these necessary facts. To be sure, her amended and lengthy complaint is replete with allegations about the potential risks of Gardasil, but most of those risks bear no relation to Herlth's alleged injuries. For example, Herlth cites studies purportedly showing that Gardasil increases the risks of fertility problems and perhaps even cancer itself.[25] But fertility problems and cancer are not among her alleged injuries.

[25] Doc. #18 at 43–44, 36 (¶¶ 285–86, 243–44).

More relevant to Herlth's own injuries is an allegation that "Gardasil has been linked to a myriad of autoimmune disorders, including . . . POTS."[26] But apart from that conclusory allegation, she does not allege newly acquired information containing "reasonable evidence" as required under 21 C.F.R. § 201.57(c)(6)(i) of a causal association between Gardasil and POTS. Herlth's allegations linking Gardasil to POTS primarily consist of citations to scientific journal and news articles. In addition to several articles published in the late 2010s—that is, well after Merck could have acted upon them to prevent Herlth's alleged injuries—she cites nine articles that were published between 2006 and 2013.[27] Aside from listing them, Herlth does not explain how these sources support her allegations. Upon review, some describe no more than a theoretical relationship between Gardasil and POTS, while others consist of case reports from individual patients. Several do not specifically relate to POTS or her other injuries, and others do not appear to specifically relate to the Gardasil vaccine.

To the extent that the Second Circuit's decision in *Gibbons* requires a plaintiff to allege newly acquired information at the pleading stage, Herlth argues that this requirement is no longer good law in light of the Supreme Court's later decision in *Merck Sharp & Dohme Corp. v.*

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[26] *Id.* at 38 (¶ 263).

[27] *Id.* at 41, 53–54 (¶¶ 276, 357) (citing Darja Kanduc, *Peptide Cross-reactivity: The Original Sin of Vaccines*, 4 FRONTIERS IN BIOSCIENCE 1393 (June 2012); Nancy B. Miller, *Clinical Review of Biologics License Application for Human Papillomavirus 6, 11, 16, 18 L1 Virus Like Particle Vaccine* (S. cerevisiae) (STN 125126 GARDASIL), manufactured by Merck, Inc. at 393-394 (Table 302) (June 8, 2006); Svetlana, Blitshetyn, *Postural Tachycardia Syndrome After Vaccination with Gardasil*, 17 EUROPEAN J. OF NEUROLOGY e52 (2010); D.T. Little and H.R. Ward, *Premature ovarian failure 3 years after menarche in a 16-year-old-girl following human papillomavirus vaccination*, BMJ CASE REPORTS (Sept. 30, 2012); 72nd Report on the Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by Programme for Appropriate Technology in Health (PATH) in India (August 2013); E. Israeli et al., *Adjuvants and Autoimmunity*, 18 LUPUS 1217 (2009); Darja Kanduc, *Quantifying the Possible Cross-Reactivity Risk of an HPV16 Vaccine*, 8 JOURNAL OF EXPERIMENTAL THERAPEUTICS AND ONCOLOGY 65 (2009); Darja Kanduc, *Potential Cross-Reactivity Between HPV16L1 Protein and Sudden Death Associated Antigens*, 9 JOURNAL OF EXPERIMENTAL THERAPEUTICS AND ONCOLOGY 159 (2011); Serena Colafrancesco et al., *Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune Inflammatory Syndrome Induced by Adjuvants*, 70 AM. J. REPRODUCTIVE IMMUNOLOGY 209 (2013); Murizo Rinaldi et al., *Anti-Saccharomyces Cerevisiae Autoantibodies in Autoimmune Diseases: From Bread Baking to Autoimmunity*, 45 CLINICAL REVIEWS IN ALLERGY AND IMMUNOLOGY 152 (October 2013)).

Albrecht, 139 S. Ct. 1668, 1684 (2019). According to Herlth, *Albrecht* clarified that preemption is an affirmative defense and that the burden falls on the defendant to show the *non*-existence of newly acquired information. I do not agree.

In *Albrecht*, the defendant drug manufacturer had conceded that it could have amended its label pursuant to the CBE regulation, 139 S. Ct. at 1675, and the Supreme Court considered only whether the claims were nonetheless preempted due to a showing by the defendant of "clear evidence that the FDA would not have approved a change to the . . . label," *id.* at 1672. Thus, *Albrecht* clarified the standard for a showing of "clear evidence." *See id.* at 1678 (holding that clear evidence is evidence that the manufacturer fully informed the FDA of justifications for a new warning and that the FDA, in turn, declined to approve the new warning). But *Albrecht* said nothing of a plaintiff's pleading requirements in cases where the defendant has *not* conceded the existence of newly acquired information. *See also Gibbons*, 919 F.3d at 708 (clarifying a two-step analysis wherein a plaintiff must plead newly acquired information, and only then does the burden shift to the defendant to show "clear evidence" that FDA would reject proposed label change); *see McGrath*, 393 F. Supp. 3d at 170–71 (distinguishing *Albrecht* on similar grounds).

Herlth further argues that the drug labeling preemption principles applied by the Second Circuit in *Gibbons* do not apply to vaccines like Gardasil. According to Herlth, because the Vaccine Act expressly preempts state law design-defect claims against vaccine manufacturers, *see Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 231–32 (2011), it follows that Congress impliedly decided against preemption of failure-to-warn claims for vaccines. But it makes no sense to infer from the fact that Congress decided to make it harder to sue a vaccine maker for a design defect that it must have intended to open the floodgates to suing vaccine makers for a failure to warn. In general, "neither an express pre-emption provision nor a saving clause bars the ordinary working

of conflict pre-emption principles." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (conflict preemption defense still available under FDCA despite express preemption provision in Medical Device Amendments).

In sum, because the amended complaint does not plead facts to plausibly establish that there was newly acquired information about the risks of Gardasil that caused Herlth's injuries, it does not allege facts sufficient to avoid preemption. Accordingly, I will dismiss the amended complaint's CPLA claim to the extent that it relies on a failure-to-warn theory of liability.

Manufacturing defect

Merck next argues that Herlth has failed to allege a plausible *manufacturing*-defect claim, as distinct from a *design*-defect claim that—as noted above—is expressly preempted by the Vaccine Act. I agree.

"Generally speaking, a manufacturing defect is a mistake in the assembly process, which results in a product that differs from the manufacturer's intended result." *Moss v. Wyeth Inc.*, 872 F. Supp. 2d 162, 166 (D. Conn. 2012) (citing *Miller v. United Techs. Corp.*, 233 Conn. 732, 779 (1995)). By contrast, "[a] design defect . . . exists when the product is otherwise properly manufactured, but is nonetheless unreasonably dangerous because its attributes can cause unexpected injury." *Ibid.* For complex products like vaccines, the product is defectively designed if "the risk of danger inherent in the design of the product outweighs its utility." *Ibid.*

Here, the amended complaint alleges various ways in which Gardasil is unreasonably dangerous, but it does not allege that the Gardasil doses that Herlth received deviated either from their manufacturer's intended result or from run-of-the-mill dosages of Gardasil vaccine. Aside from a conclusory allegation that the Gardasil manufacturing process "failed to comply with manufacturing specifications required by the governing manufacturing protocols and . . .

regulatory agencies," the crux of Herlth's claim is that Gardasil generally "contain[s] ingredients and toxins that were not disclosed in the FDA-approved specifications and/or otherwise not disclosed in the package insert."[28]

The amended complaint goes on to allege that Gardasil contains "dangerous and undisclosed HPV L1-DNA fragments" and the "toxic nerve agent" phenylmethylsulfonyl fluoride ("PMSF").[29] But it is not alleged that either ingredient was present in Gardasil due to a mistake or flaw in the manufacturing process.

In short, the complaint alleges a design-defect claim dressed up as a manufacturing-defect claim; it does not allege a plausible manufacturing-defect claim. *See Stratton v. Merck & Co., Inc.*, 2021 WL 5416705, at *3 (D.S.C. 2021) (dismissing similar manufacturing defect claim as to Gardasil). Accordingly, I will dismiss the amended complaint's CPLA claim to the extent that it relies on a manufacturing-defect theory of liability.

Negligence

In blunderbuss fashion, the amended complaint lumps a number of disparate theories of product liability under the general header of "negligence." According to Herlth, Merck breached its duty of reasonable care in "design, research, manufacture, advertisement, supply, promotion, packaging, sale, and distribution of Gardasil."[30] I have difficulty discerning from Herlth's sprawling and conclusory allegations and subsequent briefing the precise nature of her negligence claim. However, to the extent that she alleges negligent design, negligent manufacture, or negligent failure to warn, her claims fail for all of the reasons discussed above.

[28] Doc. #18 at 68 (¶ 411).
[29] *Ibid.* (¶¶ 412–13).
[30] Doc. #18 at 56–57 (¶ 368); *see also* Doc. #24 at 31–32.

Many of the allegations that Herlth tosses in under the general heading of "Negligence" discordantly allege fraud and intentional misrepresentation.[31] As an initial matter, the CPLA defines a "product liability claim" to "include[] all claims or actions brought for personal injury, death or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product," and it states that such claims "shall include, *but [are] not limited to*, all actions based on the following theories: Strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; *misrepresentation or nondisclosure, whether negligent or innocent*." Conn. Gen. Stat. § 52-572m (emphasis added). In view that the CPLA does not exclude product-related fraud or *intentional* misrepresentation claims, I will assume for present purposes that the CPLA allows for claims of fraud or intentional misrepresentation. *See Hunte v. Abbott Lab'ys, Inc.*, 2021 WL 3679303, at *14 (D. Conn. 2021) (assuming without deciding issue).

For claims allowed under the CPLA that have a common law equivalent, a plaintiff must allege the facts necessary to allow for recovery under the common law. *See Ferry v. Mead Johnson & Co., LLC*, 514 F. Supp. 3d 418, 431 (D. Conn. 2021). To state a claim for intentional misrepresentation, a plaintiff must establish "(1) that a false representation was made as a statement of fact; (2) that it was untrue and known to be untrue by the party making it; (3) that it was made to induce the other party to act on it; and (4) that the latter did so act on it to his injury." *Id.* at 446 (quoting *Updike, Kelly, & Spellacy, P.C. v. Beckett*, 269 Conn. 613, 643 (2004)).

[31] The "Negligence" allegations of the amended complaint run for seven pages of the amended complaint. Doc. #18 at 56-63 (¶¶ 367-386). Several of the paragraphs expressly allege fraud or misrepresentation. *Id.* at 60-63 (¶¶ 377(q)-(u), 382, 385). The CPLA count of the complaint otherwise incorporates many of the other allegations elsewhere in the complaint that allege fraud. Doc. #18 at 56 (¶ 364).

Because intentional misrepresentation claims sound in fraud, a heightened pleading standard applies. *Ibid*. Specifically, Rule 9(b) of the Federal Rules of Civil Procedure provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Thus, to survive a motion to dismiss under Rule 9(b), the complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Ferry*, 514 F. Supp. 3d at 446 (quoting *U.S. ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017)). In other words, Rule 9(b) requires that the plaintiff identify "the who, what, when, where, and how" for each act of purported fraud. *Walters v. Performant Recovery, Inc.*, 124 F. Supp. 3d 75, 79 (D. Conn. 2015).

Relative to other elements of a claim sounding in fraud, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Nonetheless, the Second Circuit has made clear that plaintiffs in fraud cases must still "allege facts that give rise to a strong inference of fraudulent intent." *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006). This strong inference can be shown "(a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Id.* at 290–91. When pleading that a defendant had a motive and opportunity to commit fraud, a plaintiff cannot rely on "a general profit motive common to all corporations." *Landesbank Baden-Wurttemberg v. Goldman, Sachs & Co.*, 478 F. App'x. 679, 681 (2d Cir. 2012).

Herlth alleges that Merck intentionally misrepresented its Gardasil vaccine to both consumers—including Herlth and her mother—and also to medical providers. Beginning with

the alleged misrepresentations aimed at consumers, Herlth fails to allege any fraudulent statement with the particularity required by Rule 9(b). She alleges that Merck misrepresented the safety and efficacy of Gardasil through "incomplete warnings and instructions" and "statements it made in its publications, ubiquitous television advertisements, billboards, print advertisements, online advertisements and website, and other written materials intended for consumers, patients, parents of minor-aged patients, medical providers, and the general public, that Gardasil was safe and effective at preventing cancer."[32] To the extent that she claims to have been deceived by "incomplete warnings and instructions," Herlth's intentional misrepresentation subclaim is duplicative of her preempted failure to warn claim.

With respect to Merck's "ubiquitous" marketing and advertising materials, Herlth points to just two statements with any degree of particularity. The first is the "Mom, Dad, did you know?" ad campaign, which allegedly "said nothing about potential side effects."[33] But Herlth alleges that the ad aired in 2016—three years *after* she received the Gardasil vaccine. Thus, even if the ad contained known untruths intended to induce reliance, Herlth and her mother could not have plausibly "act[ed] on it to [their] injury." *See Updike, Kelly & Spellacy, P.C.*, 269 Conn. at 643.

The second set of statements—those conveyed by the "One Less" ad campaign—are also insufficient. According to the amended complaint, the ads "proclaimed that Gardasil was a 'cervical cancer vaccine' and that any young girl vaccinated with Gardasil would become 'one less' woman with cervical cancer."[34] Herlth also alleges that the ads "portrayed Gardasil as if there were no question as to the vaccine's efficacy in preventing cervical cancer, and [they]

[32] *Id.* at 73–4 (¶¶ 441–42).
[33] *Id.* at 17 (¶ 81).
[34] *Id.* at 17–18 (¶ 83).

disclosed none of Gardasil's side effects."[35] Herlth alleges that her mother was "exposed to" the ads,[36] and while it is not altogether clear that she is referring to the same "One Less" ads, she elsewhere alleges that her mother "saw and relied upon" certain Gardasil ads in advance of consenting to Herlth's vaccination.[37]

But setting aside the accuracy of her portrayal of the ads—elsewhere in the complaint Herlth alleges that the "One Less" ads *did* list side effects, including "pain, swelling or redness at injection site, fever, and/or nausea"[38]—Herlth does not "demonstrate with specificity why and how each statement [was] false or misleading." *Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32, 38 (2d Cir. 2012). Indeed, aside from the ad's purportedly "false[] procla[mation] that Gardasil was a 'cervical cancer vaccine'"[39]—which Herlth contradicts elsewhere by admitting that cervical cancer was among the vaccine's approved indications[40]—she does not allege any *specific* statements in the ad that were made with knowing falsity. Instead, what she describes is a perfectly ordinary advertisement, highlighting a product's strengths while deemphasizing its weaknesses. Without more specificity, the complaint does not demonstrate with particularity or plausibility that the ad was either false or misleading.[41]

Nor does the complaint allege a strong inference of fraudulent intent, either "(a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b)

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[35] *Ibid*.
[36] *Id.* at 74 (¶ 442).
[37] *Id.* at 17 (¶ 83).
[38] *Id.* at 74 (¶ 442).
[39] *Id.* at 17 (¶ 83).
[40] *Id.* at 12 (¶ 46).
[41] While acknowledging the distinct elements of a claim for intentional misrepresentation, it is telling that breach of warranty claims in Connecticut require something more than a drugmaker's affirmance that its products are "safe and effective." *See, e.g.*, *Fraser v. Wyeth*, 857 F. Supp. 2d 244, 257–58 (D. Conn. 2012) ("a drug manufacturer's representation in advertising or a warning label that a product is safe or effective, or an advertisement or warning label that does not adequately highlight a particular known or knowable risk does not create an express warranty in the absence of a guarantee that the particular product is free from all harmful side effects"). Similarly here, it is not obviously false or misleading for a vaccine maker to represent a vaccine as effective or list its potential side effects in a non-exhaustive manner.

by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Lerner*, 459 F.3d at 290–91. Aside from conclusory allegations of Merck's potential profit motive, the complaint does not suggest any motive or strong circumstantial evidence of recklessness. *See Chill v. Gen. Elec. Co.*, 101 F.3d 263, 268 (2d Cir. 1996) (motives that "could be imputed to any . . . for-profit endeavor[are] not sufficiently concrete for purposes of inferring scienter").

Herlth's claim of fraud against medical providers is alleged with even less particularity. In addition to the advertising campaigns discussed above, the complaint alleges that Gardasil was promoted to doctors through "door-to-door marketing" and in-person presentations.[42] But it does not specifically allege how any of these marketing efforts reached Herlth's pediatrician. As a result, the complaint does not plausibly allege that Herlth's pediatrician or anyone else acted upon Merck's alleged misrepresentations in a manner that resulted in Herlth's injuries. *See Ferry*, 514 F. Supp. 3d at 450–51 (dismissing fraud claim where complaint does not allege that plaintiffs or their doctor ever looked at purported fraudulent website).

In addition to her fraud-on-consumers and fraud-on-medical providers arguments, Herlth also makes a number of vague allegations pertaining to intentional misrepresentations aimed at the FDA. Among other "fraudulent activities that led regulators . . . to be duped into believing that Gardasil is safe and effective,"[43] the complaint alleges that Merck: evaluated Gardasil against an improper placebo in clinical trials, underrepresented pre-teen girls and boys among its trial participants, manipulated dosages in clinical trials, used overly exclusionary criteria in selecting the clinical study patient population, and failed to disclose to the FDA certain Gardasil ingredients.

[42] *See id.* at 14, 21 (¶¶ 63, 116).
[43] *Id.* at 76–77 (¶ 455).

But Herlth's fraud-on-the-FDA claims fail for two reasons. First, she fails to satisfy the heightened pleading standard under Rule 9(b), both because her allegations of "fraudulent activity" lack particularity—including where, when, and how the alleged misrepresentations were communicated to the FDA—and because her conclusory allegations do not permit a strong inference of fraudulent intent. She alleges no facts constituting strong circumstantial evidence of conscious misbehavior or recklessness, nor does she plausibly allege that Merck had any genuine opportunity to commit fraud—especially given the strictly regulated nature of pre-market drug approval.

Second, the Supreme Court has explicitly held that state law claims alleging "fraud on the FDA" are preempted under the FDCA. *See Buckman*, 531 U.S. at 348. In *Buckman*, the Supreme Court considered a state law fraud claim premised on the defendant's fraudulent misrepresentations to the FDA. *Id.* at 344. The plaintiffs, who were injured by a medical device, argued that the defendant's fraud was a "but for" cause of their injuries. *Ibid*. But the Supreme Court rejected their claims, holding that state law actions for fraud on the FDA "inevitably conflict with the FDA's responsibility to police fraud." *Id*. at 350.

Since *Buckman*, the Second Circuit has further clarified that state tort claims are preempted only when the cause of action assigns liability "*solely* on the basis" of fraud against the FDA. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 98 (2d Cir. 2006) (emphasis in original).[44] Here, to the extent that she alleges "fraudulent activities" undertaken to deceive the FDA, Herlth seeks to assign liability solely on the basis of purported fraud against the FDA.

[44] That is not to say that allegations of fraud against the FDA can have no place in state product liability law. An allegation of fraud on the FDA may be used to overcome a vaccine manufacturer's presumption of immunity in failure-to-warn cases, for example. *See* 42 U.S.C. §§ 300aa-22(b)(2), 300aa-23(d)(2); *Bruesewitz*, 562 U.S. at 239 n.25; *see also Desiano*, 467 F.3d at 98 (allowing state law action requiring plaintiff to plead fraud-on-the-FDA merely as a means of overcoming drug manufacturer's presumption of immunity).

Thus, even if Herlth could satisfy Rule 9(b)'s heightened pleading standard, her intentional misrepresentation claim would nonetheless be preempted to the extent that it alleges fraud on the FDA.

That leaves a possible claim for negligent misrepresentation. To state a claim for negligent misrepresentation, a plaintiff must establish (1) that the defendant made a misrepresentation of fact (2) that the defendant knew or should have known was false, (3) that the plaintiff reasonably relied on the misrepresentation and thus (4) suffered pecuniary harm. *See Ferry*, 514 F. Supp. 3d at 446 (citing *Nazami v. Patrons Mut. Ins. Co.*, 280 Conn. 619, 626 (2006)). Courts disagree about whether the heightened pleading standard of Rule 9(b) applies to negligent misrepresentation claims. *See ARMOUR Capital Mgmt. LP v. SS&C Techs., Inc.*, 2018 WL 1368908, at *6 (D. Conn. 2018) (describing the disagreement). Nonetheless, courts agree that Rule 9(b) applies to negligent misrepresentation claims whenever they are "couched in fraud-like terms of known falsity." *See Ferry*, 514 F. Supp. 3d at 446; *ARMOUR Capital Mgmt. LP v. SS&C Techs., Inc.*, 2020 WL 64297, at *2 (D. Conn. 2020).

In my view, Herlth's negligent misrepresentation claims are indeed couched in fraud-like terms such that a heightened pleading standard applies. Her negligent misrepresentation claims are nearly indistinguishable from her claims of fraud, and indeed, the two claims are premised on many of the same alleged bad acts. Moreover, the negligence claim itself appears to assert that all of the same acts were both "negligent *and fraudulent*."[45] Thus, after evaluating her claims under the heightened pleading standard of Rule 9(b), I conclude that Herlth fails to state a claim for negligent misrepresentation for the same reasons as I have explained for her claims of fraud and intentional misrepresentation.

[45] Doc. #18 at 62 (¶ 382) (emphasis added).

Count Two – common law fraud

Count Two of the amended complaint alleges a claim for common law fraud. But it is well-established that the CPLA is the "exclusive remedy for—and the only cause of action available to—plaintiffs in Connecticut for product liability claims." *Ferry*, 514 F. Supp. 3d at 431. "The statute does not abolish common law claims in product liability actions, but instead incorporates them into a single count to simplify pleadings." *Collazo v. Nutribullet*, 473 F. Supp. 3d 49, 51 (D. Conn. 2020).

If a plaintiff wants to allege a claim for fraud arising from a product-related injury, she must do so under the umbrella of the CPLA rather than as a standalone common law claim. *See Fraser v. Wyeth, Inc.*, 857 F. Supp. 2d 244, 252 (D. Conn. 2012); *see also Doe v. Bausch & Lomb, Inc.*, 443 F. Supp. 3d 259, 270 (D. Conn. 2020) (dismissing standalone common law fraud and fraudulent omissions claims seeking recovery for product-caused injury). In addition, for the reasons that I have already explained above with respect to the allegations of fraud that Herlth has alleged under the rubric of her "Negligence" subclaim under the CPLA, Herlth has failed to adequately plead a claim for fraud. Accordingly, I will dismiss Count Two without prejudice to the extent that a claim for fraud may be properly re-alleged as a sub-claim under the CPLA.

CONCLUSION

For the reasons set forth above, the Court GRANTS the defendants' motion to dismiss the amended complaint (Doc. #18). This dismissal is without prejudice to the filing of a motion to re-open and an amended complaint within 30 days if the plaintiff has grounds to allege facts that would overcome the concerns stated in this ruling. The Clerk of the Court is directed to close the case without prejudice to re-opening in the event of the filing of a motion to re-open and an amended complaint.

It is so ordered.

Dated at New Haven this 15th day of March 2022.

/s/ ***Jeffrey Alker Meyer***
Jeffrey Alker Meyer
United States District Judge