**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF NORTH CAROLINA**
**CHARLOTTE DIVISION**
**CIVIL ACTION NO. 3:22-MD-03036-KDB**

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| **IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION** | **MDL No. 3036** |
| | **THIS DOCUMENT RELATES TO:**[1] |
| | **CASE NO. 3:22-CV-00117, *Bergin v. Merck & Co., Inc. et al.*** |
| | **AND** |
| | **CASE NO. 3:22-CV-00585, *America v. Merck & Co., Inc. et al.*** |

**ORDER ON MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS**

Since August 2022, this Court has been the forum for a multi-district litigation ("MDL") in which nearly two hundred cases[2] asserting vaccine injury claims against Defendants Merck & Co., Inc. and Merck, Sharp & Dohme LLC (together, "Merck") have been consolidated. (Doc. No. 2). Each Plaintiff alleges that he or she has suffered harm caused by vaccination with Gardasil, a Human Papillomavirus ("HPV") vaccine which seeks to prevent cervical and other cancers believed to be associated with HPV.

Prior to the creation of the MDL, several motions to dismiss pursuant to Federal Rule of Civil Procedure ("Rule") 12 were either decided or pending in cases which then became

[1] As explained further in this Order, this motion has been filed and considered by the Court as a "bellwether" motion that will be applicable to all cases (unless an exception is made for a particular case for good cause shown) to the extent that similar allegations and claims are asserted.
[2] At the most recent case management conference, Plaintiffs' counsel informed the Court that the number of consolidated cases could increase by hundreds more over time.

consolidated in the MDL. All pending motions were stayed by this Court's First Pretrial Order. However, the Court permitted Merck to file proposed "bellwether" Rule 12 motions in two cases, *Bergin v. Merck & Co., Inc. et al.*, No. 3:22-CV-00117, and *America v. Merck & Co., Inc. et al.*, No. 3:22-CV-00585. (*See* Doc. Nos. 35 at pp. 2-4; Doc. No. 58 at 7). In February 2023, Merck filed a Motion for Partial Judgment on the Pleadings in *Bergin* and *America* (Doc. No. 68) seeking dismissal of Plaintiffs' alleged "design defect" and "direct warning" claims based on the argument they are preempted by the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1, *et seq*. (the "Vaccine Act") and their "manufacturing defect" and fraud claims for allegedly inadequate pleading. The motion has been fully briefed and the Court held oral argument on the motion on March 11, 2024.

After careful review of the motion, the parties' briefs and exhibits and their oral arguments, the Court will **in part GRANT** and **in part DENY** the motion for the reasons described below.

## I. LEGAL STANDARD

Merck moves for partial judgment on the pleadings under Federal Rule of Civil Procedure 12(c). Rule 12(c) provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." *See In re Bland Companies, Inc. Fair Lab. Standards Act & Wage & Hour Litig.*, 517 F. Supp. 3d 484, 492–93 (W.D.N.C. 2021) (quoting *Burbach Broad. Co. of Del. v. Elkins Radio Corp.*, 278 F.3d 401, 405–06 (4th Cir. 2002)). A motion for judgment on the pleadings is governed by the standard applicable to a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Butler v. United States*, 702 F.3d 749, 751–52 (4th Cir. 2012); *Shipp v. Goldade*, No. 5:19-CV-00085-KDB-DCK, 2020 WL 1429248, at *1 (W.D.N.C. Mar. 19, 2020).

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for "failure to state a claim upon which relief can be granted" tests whether the complaint is legally and factually sufficient. *See* Fed. R. Civ. P. 12(b)(6); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Coleman v. Md. Court of Appeals*, 626 F.3d 187, 190 (4th Cir. 2010), *aff'd*, 566 U.S. 30 (2012). A court need not accept a complaint's "legal conclusions, elements of a cause of action, and bare assertions devoid of further factual enhancement." *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 255 (4th Cir. 2009). The court, however, accepts all well-pled facts as true and draws all reasonable inferences in Plaintiff's favor. *See Conner v. Cleveland Cty., N. Carolina*, 22 F.4th 412 (4th Cir. 2022); *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 440 (4th Cir. 2011). In so doing, the Court "must view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the nonmoving party." *Pa. Nat'l Mut. Cas. Ins. Co. v. Beach Mart, Inc.*, 932 F.3d 268, 274 (4th Cir. 2019). Construing the facts in this manner, a complaint must contain "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Pledger v. Lynch*, 5 F.4th 511, 520 (4th Cir. 2021) (quoting *Ashcroft*, 556 U.S. at 678). Thus, a motion to dismiss under Rule 12(b)(6) or Rule 12(c) determines only whether a claim is stated; "it does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Republican Party v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992).

In analyzing a Rule 12 motion, a court may consider "documents incorporated into the complaint by reference and matters of which a court may take judicial notice." *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). In particular, when considering a Rule 12(c) motion, "a court may consider official public records, documents central to plaintiff's claim,

and documents sufficiently referred to in the complaint ... so long as the authenticity of these documents is not disputed." *Chapman v. Asbury Auto. Grp., Inc.*, No. 3:13 cv 679, 2016 WL 4706931, at *1, 2016 U.S. Dist. LEXIS 121043 (E.D. Va. Sept. 7, 2016) (quoting *Witthohn v. Fed. Ins. Co.*, 164 F. App'x 395, 396-97 (4th Cir. 2006)); *see also Goines v. Valley Cmty. Servs. Bd.*, 822 F.3d 159 (4th Cir. 2016). "[I]n the event of conflict between the bare allegations of the complaint and any attached exhibit, the exhibit prevails." *Slater v. Bank of Am.*, No. 1:10-1091, 2012 WL 2997880 at *7, 2012 U.S. Dist. LEXIS 101687 (S.D. W. Va. June 26, 2012) (citing *Fayetteville Investors v. Commercial Builders, Inc.*, 936 F.2d 1462, 1465 (4th Cir. 1991)).

## II. RELEVANT FACTS AND PROCEDURAL HISTORY

HPV is a viral infection that is passed between people through skin-to-skin contact. It is the most common sexually transmitted disease. (*See* Doc. No. 76-1 (Bergin Second Amended Complaint ("Bergin SAC")) at ¶¶ 34-35)).[3] There are numerous strains of HPV, with approximately 18 to 24 strains believed to be associated with cervical and/or anal cancer. (Bergin SAC at ¶ 37). Gardasil is a vaccine manufactured and sold by Merck approved by the Food and Drug Administration ("FDA") as protection against cervical, vulvar, vaginal, and anal cancer and their associated precancerous lesions, as well as genital warts, caused by certain strains of HPV. (*See* Bergin SAC at ¶¶ 49-52; Doc. Nos. 68-2, 68-3 and 68-4 (Gardasil Prescribing

[3] The Court notes and Plaintiffs' counsel acknowledged at oral argument that the operative *Bergin* and *America* complaints are similar, if not identical, with respect to their general allegations and claims against Merck. For convenience, the Court will cite only to the *Bergin* SAC, except as necessary to reflect Ms. America's allegations related to her particular circumstances.

Information).[4] An initial formulation of Gardasil targeting four HPV strains was approved in 2006 and a second version (Gardasil 9) adding five more strains associated with cervical and anal cancer was approved in 2014. Believing it to be "safe and effective" in preventing cancer,[5] the Centers for Disease Control recommends HPV vaccination for both girls and boys through age 26 years. (Bergin SAC at ¶¶ 50, 52, Doc. Nos. 68-7, 68-10). Currently, only Gardasil 9 is sold in the United States. (*See* Bergin SAC at ¶¶ 44, 46, 51, and 53).

Plaintiff Payton Bergin alleges that in June 2013 and February 2014, when she was 13 years old, she received two injected doses of Gardasil in North Carolina. (Bergin SAC at ¶¶ 344–345, 347). The vaccination was given upon her doctor's recommendation and with her mother's consent. (*Id*.). Plaintiff alleges that her mother agreed to her receiving the Gardasil vaccine after being exposed to direct-to-consumer marketing by Merck, including Merck's "ubiquitous representations concerning the safety and efficacy of Gardasil." (*Id*. at ¶¶ 345, 349, 502-516).

[4] As noted, the Court may properly take judicial notice of and consider certain publicly available information related to Gardasil in ruling on Defendants' motion without converting it into a motion for summary judgment. *See Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 607 (4th Cir. 2015); *Stratton v. Merck & Co*., No. CV 2:21-02211-RMG, 2021 WL 5416705, at *2 (D.S.C. Nov. 17, 2021) (considering publicly available FDA statements and Gardasil label); *Proffitt v. Bristol-Myers Squibb Co.*, No. 1:17-cv-04391, 2018 WL 3318893, at *4 & n.1 (S.D.W. Va. July 5, 2018) (considering alleged defective medication's label on motion for judgment on the pleadings); *Mills v. Bristol-Myers Squibb Co.*, No. CV 11-968-PHX-FJM, 2011 WL 3566131, *3 n.2 (D. Ariz. Aug. 12, 2011) ("We may consider the Plavix label attached as an exhibit to defendants' motion to dismiss ... because it is a matter of public record.").

[5] To be clear, for purposes of this motion the Court does not rely on the FDA's statements concerning the safety and efficacy of Gardasil, which are disputed by Plaintiffs, beyond the existence of the statements and the notice thereby provided to medical providers and the public.

With respect to her injuries, Ms. Bergin alleges that prior to receiving her Gardasil injections, she had no known autoimmune diseases, and no autonomic issues. (*Id*. at ¶ 346). However, following her two Gardasil vaccinations, Ms. Bergin says that she experienced a series of physiological and neurological adverse events, including but not limited to mobility issues, short-term memory loss, chronic fatigue, severe headaches, tiredness, dizziness, fainting, hallucinations, chronic joint pain, amnesic spells, and encephalopathy. (*Id*. at ¶¶ 350-403). Thus, she alleges that Gardasil caused a wide variety of "autoimmune, autonomic, and neurological[] injuries" including "hypersomnia, orthostatic intolerance, autonomic dysfunction, and postural orthostatic tachycardia syndrome ("POTS")" (*Id.* at ¶ 405).[6]

As required by the Vaccine Act,[7] Ms. Bergin filed a petition for compensation in the United States Court of Federal Claims related to her alleged injuries, but her claim was later dismissed at her request. (*See* Bergin SAC ¶ 408; *see also Bergin v. Sec'y of Health & Hum. Servs.*, No. 17- 241V, 2020 WL 5800718, at *3 (Fed. Cl. Sp. Mstr. Sept. 1, 2020)). She filed her case against Merck in this Court on March 18, 2022.

Plaintiff Ashley America alleges that in October 2014 and April 2015, when she was 18 years old, she received two injected doses of Gardasil in New York. (Doc. No. 76-2 (America

[6] More broadly, Plaintiffs contend there is a significant body of medical literature that shows Gardasil can cause serious autoimmune and neurological injuries and adverse symptoms similar to those Bergin and America allege they have suffered, a causal link which Merck (and the FDA) deny and is currently the subject of extensive discovery among the parties. *See* Doc. Nos. 76 at fn.1., 68 at 4-5; 68-17 "FDA Information on Gardasil – Presence of DNA Fragments Expected, No Safety Risk".

[7] Pursuant to the Vaccine Act, no one may bring "a civil action for damages" against a vaccine manufacturer "for damages arising from a vaccine-related injury" unless she has first filed and exhausted a petition for compensation in the U.S. Court of Federal Claims. *See* 42 U.S.C. § 300aa-11(a)(2)(A).

Amended Complaint ("America AC") at ¶¶343-345)). She asserts that in obtaining her consent, her doctor informed her Gardasil was a safe and effective vaccine for preventing cervical cancer, which she claims mirrored statements Merck made through its physician and consumer marketing and advertising. (*Id*. ¶¶ 345 & 440-442). With respect to alleged injuries caused by her vaccination, she claims that she experienced various adverse events, including chronic syncope (fainting), chronic dizziness, headaches, and concentration issues. She attributes "various medical conditions" to Gardasil, including "symptoms of POTS," "non- epileptic seizures, related to autoimmune dysregulation, and neurocardiogenic syncope related to dysregulation of the autonomic nervous system." (*Id*. ¶¶ 345-351).

Ms. America filed a petition in the U.S. Court of Federal Claims pursuant to the Vaccine Act and, following that court's ruling, elected to pursue her claims in civil court. (*See id.* ¶ 356; *see also America v. Sec'y of Health & Hum. Servs.*, No. 17-542V, 2022 WL 278151, at *35 (Fed. Cl. Sp. Mstr. Jan. 4, 2022)). On October 10, 2022, Plaintiff filed her case against Merck in the U.S. District Court for the Northern District of New York, which was transferred to this Court on October 26, 2022.

## III. DISCUSSION

### A. The Scope of the Issues Before the Court and Relevant Authority

As discussed below, this Order resolves various issues concerning Plaintiffs' alleged claims related to "design defects" in the Gardasil vaccine, the scope of Plaintiffs' "failure to warn" claims, and the sufficiency of Plaintiffs' "manufacturing defect" and fraud claims. However, it is also important to clarify the issues that are not before the Court in this motion. All the Plaintiffs in the MDL, including Plaintiffs Bergin and America, allege that they were injured as a result of

receiving the Gardasil vaccine. The most fundamental liability merits issue raised by their claims is the medical/scientific question of whether the Plaintiffs' various alleged injuries were caused by their Gardasil injections. This causation issue is not now before the Court, and the Court expresses no view at this time as to that question.

Second, with respect to Plaintiffs' claims that Merck is liable for failure to properly warn Plaintiffs' prescribing doctors (which are being permitted to proceed), Merck contends that such claims are impliedly preempted by the FDA's approval of the vaccine's "label," which limits how Merck can warn doctors without additional FDA approval – unless Merck has "newly acquired information" as defined in the relevant regulations. *See* 21 C.F.R § 601.12(f)(2)(i). As with "causation," these issues of "implied preemption" / "newly acquired information" are hotly contested, not yet before the Court, and the Court expresses no view as to their merits by this Order. Rather, the Parties and the Court expect both causation and implied preemption issues to be addressed in summary judgment motions later this year.[8]

Also, further clarification is important with respect to how this Order will be applied to the MDL consolidated cases beyond *Bergin* and *America*. It has been the Court's belief that Merck's Rule 12 motion would, as requested by Merck (and opposed by Plaintiffs), be considered as a "bellwether" motion that would resolve the questions presented as to similar allegations and claims made throughout the consolidated cases. However, the Court has not yet been explicit about that expectation. It will do so now.

[8] There are other issues that may become relevant to later proceedings, such as the issue of Vaccine Court exhaustion mentioned above, that are not at issue in this motion.

The Court has the authority to apply the ruling here to other consolidated cases, *see* Manual of Complex Litigation § 22.632, and finds that it is both fair and efficient to do so in these circumstances. It would be wasteful and contrary to the spirit of the MDL to require Merck to move to dismiss essentially the same pleadings in every case. Plaintiffs have had the opportunity to express their view that Rule 12 motions were unnecessary and "objected" to the "characterization" of Merck's motion as a "bellwether" motion. *See* Doc. No. 40 at 3. And, since the Court's scheduling of the motion (implicitly overruling the objection), no plaintiff has disavowed Plaintiffs Bergin and America's response, which of course has been prepared by the same counsel they share with those plaintiffs. Therefore, the Court's ruling here will apply to all substantially similar allegations/claims asserted in the cases subject to the MDL.[9]

Finally, the Court notes that while it has taken an entirely fresh look at the relevant issues and considered Merck's motion *de novo*, it does not write on an blank slate. Prior to transfer, at least four federal district courts and two California trial courts issued written decisions on motions to dismiss Gardasil complaints. *See Flores v. Merck & Co.*, No. 3:21-CV-00166, 2022 WL 798374, at *3–9 (D. Nev. Mar. 16, 2022); *Herlth v. Merck & Co.*, No. 3:21- CV-438, 2022 WL 788669, at *5–10 (D. Conn. Mar. 15, 2022); *Colbath v. Merck & Co., Inc., et al.*, No. 3:21-cv-120-W, 2022 WL 935195 (S.D. Cal. Mar. 29, 2022); *Stratton v. Merck & Co., Inc., et al.*, 2021 WL 5416705

[9] Nevertheless, prior to applying the result here to all current and future MDL cases, the Court will allow any party who wants to move to avoid the application of this ruling to her or his claims to do so within 30 days of this Order (or within 30 days of joining the MDL, whichever comes later). In the absence of the granting of such a motion upon a showing of good cause (not to include simply disagreeing with the Court's ruling or a plaintiff having asserted allegations or claims that are only immaterially different), the Court's ruling here will apply to all substantially similar allegations/claims asserted in the cases subject to the MDL.

(D.S.C. Nov. 17, 2021); *Shain v. Merck*, Case No. 21STCV35340 (CA Superior Court, Los Angeles County) (August 4, 2022); *Brunker v. Merck*, Case No. 56-2022-00563045 (CA Superior Court, Ventura County) (September 26, 2022). Each of the federal cases granted Merck's motion to dismiss, at least in part, but the state courts both denied Merck's "demurrer" under California state procedure. As cited and discussed below, the Court generally finds the collective view of these federal judges from across the country to be persuasive.

However, the different standard applicable to motions to dismiss ("demurrers") under California law undermines the applicability of those decisions here. Unlike Rule 12 motions under the Federal Rules of Civil Procedure, in California "a general demurrer cannot be sustained as to a portion of a cause of action." *Brunker*, Doc. No. 76-3, at p.2 (citing *Daniels v. Select Portfolio Servicing Inc.*, 246 Cal.App.4th 1150, 1167 (2016)); *Shain*, Doc. No. 76-4 at 10 ("Ordinarily, a general demurrer does not lie as to a portion of a cause of action and if any part of a cause of action is properly pleaded, the demurrer will be overruled.").[10] Thus, for example, the California courts were required to reject Merck's arguments that a Plaintiff's negligence claim contained preempted "design defect" claims – regardless of the merits of that argument – if the cause of action also included a permissible "failure to warn" allegation. Accordingly, in light of this fundamentally different standard of review, although the state court decisions have been considered, the Court has given them substantially less weight.

[10] Moreover, the Court's opinion in *Shain* is stated only to be a "tentative ruling," and the Court could not find any indication on the docket that a "final" ruling has been entered.

B. The Vaccine Act

There is no dispute among the Parties that Gardasil is a childhood vaccine covered by the Vaccine Act. As explained by the Supreme Court in *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228–30 (2011), Congress enacted the Vaccine Act to "[t]o stabilize the vaccine market and facilitate compensation" to putative plaintiffs by establishing a no-fault compensation program "designed to work faster and with greater ease than the civil tort system." *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995). The program allows a person injured by a vaccine, or her legal guardian, to file a petition for compensation against the Secretary of Health and Human Services in the United States Court of Federal Claims, where a special master makes an informal adjudication of the petition, subject to objections reviewed by that court. *See* 42 U.S.C. § 300aa–11, 12.

More specifically, claimants who show that an injury listed in a "Vaccine Injury Table" (which lists compensable adverse side effects of approved vaccines) are prima facie entitled to compensation without any showing of causation. A claimant may also recover for unlisted side effects, and for listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation. Unlike in tort suits, claimants under the Act are not required to show that the administered vaccine was defectively manufactured, labeled, or designed. Successful claimants receive compensation for medical, rehabilitation, counseling, special education, and vocational training expenses; diminished earning capacity; pain and suffering; and $250,000 for vaccine-related deaths. Attorney's fees are provided, not only for successful cases, but even for unsuccessful claims that are not frivolous. If the claimant is satisfied with the court's judgment she can accept it; if not, she can file a tort action against the vaccine manufacturer.

Payments to successful claimants are made from a fund created by an excise tax on each vaccine dose. *See generally, Bruesewitz*, 562 U.S. at 228-229.

Most significant to the pending motion, the "*quid pro quo*" for this no-fault compensation system funded by vaccine manufacturers, is "the provision of significant tort-liability protections for vaccine manufacturers," which was "designed to stabilize the vaccine market."[11] *Bruesewitz*, 562 U.S. at 229. Several provisions of the Act are relevant here:

> **(b) Unavoidable adverse side effects; warnings**
>
> **(1)** No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.
>
> **(2)** For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—
>
> **(A)** that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or
>
> **(B)** by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).
>
> **(c) Direct warnings**

[11] Congress' concerns about the stability of the vaccine market centered around vaccines against diphtheria, tetanus, and pertussis ("DTP"), which were blamed for children's disabilities and developmental delays. This led to a massive increase in vaccine-related tort litigation, which destabilized the DTP vaccine market, causing two of the three domestic manufacturers to withdraw and left the remaining manufacturer with potential tort liability that exceeded its annual sales by a factor of 200. *See Bruesewitz*, 562 U.S. at 227.

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

42 U.S.C. § 300aa–22.

Therefore, pursuant to the Act, 1) all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects are preempted, *Bruesewitz*, 562 U.S. at 243, and 2) claims alleging liability for failure to properly warn injured plaintiffs or their parents are expressly barred. *See Stratton*, 2021 WL 5416705, at *5; *Flores*, 2022 WL 798374 at *4; *Colbath*, 2022 WL 935195 at *3; *G.M. v. Sanofi Pasteur Inc.*, No. CV 14-9549 FMO (ASX), 2016 WL 7638186, at *4 (C.D. Cal. Mar. 22, 2016) ("To the extent plaintiff alleges that defendant failed to warn her or the public of the risks that the Fluzone vaccine could cause transverse myelitis, such claims are expressly preempted by the Vaccine Act.").

The Court will discuss how the Vaccine Act (and relevant state law) relates to Plaintiffs' claims below.

C. The *Bergin* and *America* Complaints

Spanning more than 120 pages and nearly 550 paragraphs, many with multiple subparagraphs, the Bergin SAC asserts claims under North Carolina law for negligence, gross negligence, failure to warn, manufacturing defect, breach of warranty, common law fraud and unfair trade practices. The America AC is nearly as long with 97 pages and seeks to recover for negligence, strict liability for failure to warn and manufacturing defects, breach of warranty and

common law fraud under New York law. Despite this length and breadth,[12] it is challenging for the Court to discern the precise nature of Plaintiff's claims, which in many instances rely on sprawling and conclusory allegations and lump numerous theories of liability together.

For example, in their negligence claims, both Ms. Bergin and Ms. America allege that Merck breached its duties of care in the "research, development, manufacturing, testing, marketing, supply, promotion, advertisement, packaging, labeling, sale, and distribution of Gardasil." Bergin SAC at ¶ 419; America AC at ¶ 368. Indeed, Plaintiffs could just as well have said, "in every manner possible." Accordingly, the Court has attempted to summarize and categorize Plaintiff's more specific allegations with respect to the various issues raised by this motion both to decide the merits of the motion and to give the Parties guidance moving forward as to the scope of the claims that the Court finds may continue.

D. "Design Defect" Claims

Merck's first attack on Plaintiffs' claims is that they reflect, in part, "design defect" claims preempted by the Vaccine Act. *See Bruesewitz*, 562 U.S. at 243. In response, Plaintiffs do not dispute that "design defect" claims are preempted, but rather deny that the complaints make any such claims. While Plaintiffs are correct that the *Bergin* and *America* complaints do not explicitly refer to, and in fact affirmatively disclaim, any "design defect" claims (and told the Court at oral argument that they carefully scrubbed the word "design" from the complaints in response to Merck's earlier successful motions to dismiss), the Court must look at the true nature of the

[12] Other courts have criticized similar Gardasil complaints as "lengthy, difficult to follow, and replete with run-on sentences," while making claims "in blunderbuss fashion." *See Flores*, 2022 WL 798374 at *4; *Herlth*, 2022 WL 788669 at *6.

allegations, not just how Plaintiffs have self-described their claims. *See* Bergin SAC at ¶ 467 ("This is not a design defect claim."). Viewing the complaints through that substantive lens, it is clear that Plaintiff have asserted a number of preempted "design defect" claims within their "negligence" and "manufacturing defect" causes of action.

1. Gardasil's Ingredients

Plaintiffs allege that Merck includes numerous "dangerous" ingredients in Gardasil, including HPV LI-DNA fragments, sodium borate (borax), polysorbate 80 and yeast. *See, e.g.*, Bergin SAC at ¶¶ 136-162, 422(u); 469-470 (Gardasil vaccine is "defective and unreasonably dangerous" because it contains "dangerous and undisclosed" "ingredients and toxins"). The FDA is aware of all these components in Gardasil;[13] therefore, an attack on the ingredients of Gardasil is an attack on the design of Gardasil itself. *See Stratton*, 2021 WL 5416705, at *2. In other words, in challenging what is included in Gardasil – the Gardasil "recipe" – Plaintiffs are simply complaining about how Gardasil is designed. Therefore, such claims are preempted by the Vaccine Act.

2. Gardasil's Development (Including Clinical Trials)

A second set of "design defect" allegations included in Plaintiffs' negligence claims is that Merck failed to properly "develop" the Gardasil vaccine, including inadequate or negligently designed clinical trials. *See, e.g.*, Bergin SAC at ¶¶ 422 (a), (c), (d), (e), (f), (g), (h), (i), and (j). As with their challenge to Gardasil's ingredients, Plaintiffs' allegations that Gardasil – as a complete

[13] Plaintiffs' allegations that these ingredients were not disclosed is contradicted by publicly available documents that show the FDA is aware of the presence of such substances. Doc. Nos. 68-17 ("FDA Information on Gardasil – Presence of DNA Fragments Expected, No Safety Risk"); 68-4 (Gardasil Prescribing Information) (listing other ingredients).

product – was improperly developed is in substance a claim that the vaccine is defectively designed.

This "design defect" claim includes Plaintiffs' attacks on Merck's clinical trials. An allegation of "inadequate testing" is not an independent wrong; that is, it is not harmful in and of itself, but rather it allegedly leads to a failure to include the best/safest ingredients in the vaccine.[14] As such, it relates to the design of the vaccine. Plaintiffs suggest that "inadequate" testing is part of its "failure to warn" claim. To be sure, a failure to warn doctors about risks discovered in clinical trials (like risks discovered post approval) could be the subject of a negligence claim not prohibited by the Vaccine Act. *See* § 300aa-22(b)(2)(B).[15] However, claims that Merck simply did not do "enough testing" or did the "wrong kind of testing" yet a vaccine was still approved is an attack on the design of the approved vaccine, not a failure to warn claim.

In sum, Plaintiffs' claims that Merck was negligent in its "development" of the vaccine, including claims related to clinical trials, are design defect claims barred by the Vaccine Act.

3. Gardasil's Overall Safety and Efficacy

Finally, Plaintiffs include several allegations in their negligence claims to the effect that Merck is liable for failing to adequately disclose the "lack of efficacy and risk of serious harm" and failure to use care in the "research, manufacturing, labeling, development, etc." of Gardasil "so as to avoid the risk of serious harm." *See, e.g.*, Bergin SAC at ¶¶ 414, 422 (b) and (k). As with

[14] To the extent Plaintiffs are claiming that Merck committed a fraud on the FDA, such state law claims are preempted. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that plaintiffs' state-law fraud-on-the-FDA claims conflicted with, and are therefore impliedly pre-empted by, federal law).

[15] Again, any duty to warn medical providers may be limited by the "implied preemption" defense discussed earlier and not at issue in this motion.

their allegations related to ingredients and development, Plaintiffs' broad claims that Gardasil is not "safe and effective" is effectively an allegation that the entire design of the vaccine is defective. Therefore, such claims are prohibited by the Vaccine Act, and Merck is entitled to have them dismissed.

E. "Failure to Warn" Claims

Plaintiffs include in their negligence claims numerous allegations that Merck failed to disclose certain important information or warn "Plaintiff, Plaintiff's parent(s), Plaintiff's medical providers and the general public" about Gardasil's risks, etc. *See, e.g.*, Bergin SAC at ¶¶ 421, 422 (l)-(t), (v)-(w), 429. Under the Vaccine Act, whether or not these claims state a valid cause of action turns on the identity of the person whom Plaintiffs contend that Merck failed to properly warn. In short, Plaintiffs may purse claims against Merck for failure to warn Plaintiffs' medical providers, but may not assert similar claims related to the failure to warn Plaintiffs, their parents or the general public.[16]

As discussed above, the Vaccine Act bars liability claims against vaccine manufacturers for failing to provide "direct warnings" to Plaintiffs and their legal representatives (including their parents). The Act provides that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury . . . solely due to the manufacturer's *failure to provide direct warnings to the injured party (or the injured party's legal representative)*." 42 U.S.C. § 300aa- 22(c) (emphasis added). The Vaccine Act "eliminat[es] liability for not providing

[16] At oral argument, when asked to explain under what authority Plaintiffs had standing to assert claims on behalf of the "general public," Plaintiffs acknowledged that those allegations are not intended to assert a separate claim, but rather are intended only to provide support for their claim for punitive damages related to their own claims.

direct warnings to a claimant." *Holmes v. Merck & Co., Inc.*, 697 F.3d 1080, 1083 (9th Cir. 2012); *see also, e.g., Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 666 (S.D. Tex. 2004) ("the Vaccine Act clearly bars claims based on a manufacturer's failure to provide warnings to the public or to consumers"). Accordingly, the courts in the earlier Gardasil motions dismissed similar claims based on the alleged failure to warn the Plaintiffs or their parents. *See, e.g., Flores*, 2022 WL 798374, at *4 (dismissing "the part[s] of [plaintiff's] claim[s] that [were] premised on Merck's failure to warn Flores and her mother" directly); *Stratton*, 2021 WL 5416705, at *5 ("The Court finds that, as to Defendants['] alleged failure to warn Plaintiff directly, the Vaccine Act bars Plaintiff's claim.").[17]

Plaintiffs urge the Court to read the Vaccine Act's prohibition on "direct warning" claims narrowly, arguing that the statute's use of the word "solely" in Section 22(c) should be interpreted as allowing Plaintiffs' "direct warning" claims to proceed because they also alleged Merck failed to give sufficient warnings to Plaintiffs' medical providers. The Court declines the invitation to reach such an absurd result, which Plaintiffs conceded at the hearing no court considering the Vaccine Act has ever adopted. Permitting a claim for failing to warn plaintiffs or their parents that is expressly barred by the statute simply because they have similarly alleged that the vaccine manufacturer failed to adequately warn someone else – a critical exception found nowhere in the

[17] Those courts also found plaintiffs' direct warning claims barred by the learned intermediary doctrines under Nevada and South Carolina law. *Flores*, 2022 WL 798374, at *5; *Stratton*, 2021 WL 5416705, at *4. New York and North Carolina both recognize the learned intermediary doctrine—which holds that a drug manufacturer's duty to warn is fulfilled by warning the prescribing physician, not the patient directly—and similarly bar Plaintiffs' direct warning claims here. *See, e.g., Martin v. Hacker*, 83 N.Y.2d 1, 9, 628 N.E.2d 1308 (1993); N.C. Gen. Stat. § 99B-5(c).

statute – would as a practical matter nullify the prohibition. A better reading, consistent with the clear intent of the Act, is that the word "solely" was included just to emphasize that despite the prohibition on "direct warning" claims, a Plaintiff would still be able to assert a claim for failure to warn the medical providers to whom warnings must be given under the "learned intermediary" doctrine. Simply put, the statute "solely" (i.e. "only") bars direct warning claims while claims for failing to provide warnings to others are permitted. Holding that the statutory prohibition on direct warning claims is nullified by a claim against medical providers, which the statute intends to allow, would thus turn the use of "solely" in the statute on its head.[18]

Therefore, the Court will enforce the Vaccine Act's bar of "direct warning" claims as written and grant Merck's motion to dismiss Plaintiffs' claims that Merck failed to properly warn Plaintiffs and their parent(s).

F. "Manufacturing Defect" Claims

Plaintiffs assert a separate claim for "manufacturing defect" in both *Bergin* and *America*. *See* Bergin SAC at ¶¶ 466-479, America AC at ¶¶ 402-415. They allege generally and only "upon information and belief" that the Gardasil vaccine was "defective and unreasonably dangerous because [Merck] failed to comply with manufacturing specifications required by the governing manufacturing protocols and also required by the regulatory agencies," claiming that

[18] Plaintiffs' additional argument that a vaccine manufacturer should not be permitted to mislead consumers, including Plaintiffs, if it chooses to advertise also must be rejected. First, Plaintiffs have cited to nothing in the Vaccine Act or relevant authority that suggests that Congress intended to eliminate the Act's protections for vaccine manufacturers as soon as they advertise an approved childhood vaccine (which are vaccinations that public policy would presumably want to encourage through advertising). Further, other federal regulations prevent vaccine manufacturers from dishonest advertising. *See* 21 C.F.R. § 202.1 *et seq*.

the vaccines contained "ingredients and toxins that were not disclosed in the FDA-approved specifications and/or otherwise not disclosed in the package insert." Bergin SAC at ¶ 469; America AC at ¶ 405.

"In manufacturing defect cases, the plaintiff proves that the product is defective by … showing that it does not conform to the manufacturer's specifications" for products of that type. *Singleton v. Int'l Harvester Co.*, 685 F.2d 112, 115 (4th Cir. 1981). The gravamen of the tort is not defective design but defective execution of the design. *Wankier v. Crown Equip. Corp*., 353 F.3d 862, 867 (10th Cir. 2003); *see Stratton*, 2021 WL 5416705 at *3. Both North Carolina and New York law describe the claim similarly. *See, e.g., Boudreau v. Baughman*, 368 S.E.2d 849, 860 (N.C. 1988) ("A design defect is an injury-producing hazard accompanying normal use of a product that was intentionally manufactured according to design. A manufacturing defect, on the other hand, is caused by a miscarriage in the manufacturing process that produces an unintended result." (citations omitted)); *Dunham v. Covidien, LP*, 498 F. Supp. 3d 549, 556 (S.D.N.Y. 2020) ("To state a claim for strict products liability under a manufacturing defect theory, a plaintiff must plead that a specific product unit was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction, and that the defect was the cause of plaintiff's injury." (quotation marks omitted)).

Specifically, "the claim of selection of improper materials is a design defect claim, not a manufacturing defect claim." *Edwards v. ATRO SpA*, 891 F. Supp. 1074, 1078 (E.D.N.C. 1995), *supplemented*, 891 F. Supp. 1085 (E.D.N.C. 1995). Thus, in the vaccine context, a

manufacturing defect claim alleges that the manufacturer did not follow the vaccine formula or recipe, with the result being a harmful and *different* version of the vaccine. Here, Plaintiffs allege that the vaccine recipe itself, not any specific instances of improper manufacturing, is the problem. *See* America AC at ¶¶ 389, 408; Bergin SAC at ¶¶ 453, 472 (Gardasil reached Plaintiffs "in its intended or reasonably foreseeable manner."). That is, the alleged failings in the ingredients used in the manufacturing process are, according to Plaintiffs, always dangerous. Indeed, at oral argument, Plaintiff argued that "everybody" who received the Gardasil vaccine is the victim of a manufacturing defect. *See* Bergin SAC at ¶ 142 (noting the presence of challenged ingredient in "every Gardasil vial tested from all over the world."). A claim that *all* the doses of a vaccine are inherently and unreasonably dangerous when manufactured as intended is not a "manufacturing defect" claim. Rather, it is an allegation of a "design defect," which is barred by the Vaccine Act as discussed above.

To the extent that Plaintiffs claim that their complaints allege a departure from manufacturing specifications or the inclusion of "unintended" ingredients, those "upon information and belief" allegations are contradicted both by their pleadings, which repeatedly describe the allegedly dangerous "HPV L1-DNA fragments" as "ingredients" in Gardasil, *see* Bergin SAC at ¶¶ 137, 422(u), 471, 517(e), and by publicly available documents that show the ingredients are intended and expected. Doc. No. 68-17 ("FDA Information on Gardasil – Presence

of DNA Fragments Expected, No Safety Risk");[19] 68-4 (Gardasil Prescribing Information) (listing other ingredients).

Therefore, the Court will grant Merck's motion to dismiss Plaintiffs manufacturing defect claims.[20] *See City of High Point, N. Carolina v. Suez Treatment Sols. Inc.*, 485 F. Supp. 3d 608, 631 (M.D.N.C. 2020) (dismissing claim where plaintiff offered "no allegations that the [product] contained a defect from manufacturing and no allegations concerning the manufacturing process"); *see also Stratton*, 2021 WL 5416705, at *3–4 (dismissing manufacturing defect claim); *Colbath*, 2022 WL 935195, at *5 (same); *Flores*, 2022 WL 798374, at *7 (same); *Herlth*, 2022 WL 788669, at *5–6 (same).

G. Fraud Claims

Mirroring their claims of negligence and failure to warn, Plaintiffs also assert claims against Merck for common law fraud under North Carolina and New York law. Plaintiffs allege that Merck made numerous fraudulent statements and omissions in its "ubiquitous" advertising to the public and marketing to the medical community. *See, e.g.* Bergin SAC at ¶¶ 501-502, 510. However, beyond an allegation that Ms. Bergin's mother was "exposed to" Merck's "One Less"

[19] This publicly available FDA statement regarding the "DNA Fragments" challenged by Plaintiffs was issued in October 2011, long before Plaintiffs received their Gardasil vaccine in 2013 and 2014. Therefore, Plaintiffs cannot plausibly contend that the presence of this "ingredient" was undisclosed at the time of their vaccination.

[20] Plaintiffs suggest that this Court's decision in *Lynch v. Nucor Corp.*, No. 323CV00029KDBDCK, 2023 WL 3874034, at *3–4 (W.D.N.C. June 7, 2023) supports their arguments. Not so. In *Lynch*, applying Arizona law, the Court found that Plaintiff's allegation that the same steel sourced from the defendant performed differently in the front and the back of a "bullet proof" vest that failed, resulting in plaintiff's death. This permitted a plausible inference that some, but not all, of the steel had been manufactured defectively. Here, Plaintiffs allege that all doses of the vaccine contained the same allegedly dangerous ingredients, manufactured in the same way.

advertising campaign, Plaintiffs do not make any specific allegations as to the who, what, when, where, and how the alleged fraud occurred.

Merck seeks to dismiss Plaintiff's fraud claims on several grounds. First, it argues that to the extent the claims allege a fraudulent failure to adequately warn Plaintiffs, their parents and the public those claims are barred by the Vaccine Act's prohibition on "direct warning" claims. The Court agrees. As discussed above, Section 22(c) of the Act broadly provides that "no manufacturer shall be liable in a civil action for damages…" for failure to warn an injured party or their legal representative. Unlike in Section 22(b)(2)(A), there is no exception for claims of "fraud" or other intentional wrongful conduct. Instead, the statute – again as part of the *quid pro quo* to stabilize the vaccine markets – provides a safe haven for manufacturers in all "civil actions" for any "direct warning" claims. Accepting Plaintiffs' arguments that intentional tort claims, which of course include the possibility of punitive damages, are not included in the statutory prohibition would significantly undermine, if not fully eliminate, the protection intended by the statute. Therefore, Plaintiffs' fraud claims will be dismissed to the extent they assert claims based on any fraud against Plaintiffs, their parents or the public.

With respect to Plaintiffs claims of fraud on medical providers, Merck argues that those claims should be dismissed because they fail to satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b) that the circumstances of fraud must be plead with particularity. "The Rule 9(b) standard requires a party to, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby. These facts are often referred to as the who, what, when, where, and how of the alleged fraud." *Bakery & Confectionary Union & Indus. Int'l Pension Fund v. Just Born II, Inc.*,

888 F.3d 696, 705 (4th Cir. 2018); *see Corder v. Antero Res. Corp.*, 57 F.4th 384, 401 (4th Cir. 2023). If the required specific allegations of fraud are not pled then the claim must be dismissed. *See Stratton*, 2021 WL 5416705, at *6 (dismissing Gardasil fraud claim); *see also Flores*, 2022 WL 798374, at *7 (dismissing identical fraud claim); *Herlth*, 2022 WL 788669, at *10 (same).

Plaintiffs have admittedly failed to plead the specific time, place and contents of any of Merck's allegedly fraudulent statements, especially as to medical providers. At oral argument, Plaintiffs acknowledged the absence of allegations of the circumstances of fraud in the complaints, saying that they had not spoken to Plaintiffs' doctors (who they said "didn't like to talk to Plaintiffs' lawyers"). Regardless of the reasons that Plaintiffs have failed to plead their alleged claims of fraudulent misrepresentation with particularity, their clear failure to do so dooms their claims. Accordingly, the Court will dismiss Plaintiffs' fraud claims based on fraudulent misrepresentations to "medical providers" as well as "plaintiffs, parents and the general public" for whom Plaintiffs have also not plead their fraud claims with particularity.

The remaining fraud claims asserted by Plaintiffs allege "fraudulent concealment," that is, the concealment by omission of material facts that were reasonably calculated and intended to deceive and did in fact deceive a person, resulting in damages to the injured party. *See Forbis v. Neal*, 361 N.C. 519, 527 (2007); *Azure Dolphin v. Barton*, 821 S.E.2d 711, 726-28 (N.C. 2018); *Bermuda Container Line Ltd. v. Int'l Longshoremen's Ass'n, AFL-CIO*, 192 F.3d 250, 258 (2d Cir. 1999) (discussing New York law). While the absence of *any* particularized allegations regarding Merck's alleged fraudulent concealment with respect to medical providers makes this a close decision, the Court will allow Plaintiffs' fraudulent concealment claims – which are held to a more lenient standard with respect to the pleading of particularized circumstances – to proceed at this

stage. *See Colbath*, 2022 WL 935195, at *7 ("Because this allegation concerns fraudulent concealment, Plaintiff's failure to specify the time and place of the omissions will not bar his claim."); *Corder*, 57 F.4th at 401 (endorsing "relaxed" Rule 9(b) standard for allegations of fraud by omission or concealment, but not eliminating the particularity requirement). Also, in practical effect, discovery on this claim will overlap with Plaintiffs' already permitted claims that Merck failed to properly warn medical providers and the impact of the differences in proof of this claim of intentional conduct and potential damages will not arise until after Merck has an opportunity to renew its challenge at summary judgment. Accordingly, the Court will deny Merck's motion to dismiss Plaintiffs' claims of fraudulent concealment with respect to medical providers without prejudice.

H. Alleged "Shotgun" Claims

Merck asks the Court to dismiss all of Plaintiff's claims as improper "shotgun" pleadings. A "shotgun pleading" is one that "fails to articulate claims with sufficient clarity to allow the defendant to frame a responsive pleading" or one in which "it is virtually impossible to know which allegations of fact are intended to support which claims for relief." *Wilkinson v. Wells Fargo Bank, N.A.*, No. 3:19-CV-00580, 2020 WL 2542867, at *3 (W.D.N.C. May 19, 2020). As noted above, the Court questions whether the Complaint is unnecessarily long, repetitive and, in parts, vague, overly general and conclusory in its allegations and claims. Plaintiffs' counsel candidly acknowledged his regret at the length of the Complaints, but claimed it reflected Plaintiffs' effort to avoid an argument that their claims had not been sufficiently plead. In any event, notwithstanding the flaws in the Complaint, the Court finds that even to the extent Plaintiffs are on a fishing expedition, Merck is plainly aware of where Plaintiffs' boat is headed and what they

are trying to catch (as evidenced by the course and detail of the MDL proceedings to date). So, the Court declines to dismiss any portion of Plaintiffs' complaints as a "shotgun pleading."

I. Leave to Amend the Plaintiffs' Complaints

To varying degrees, the earlier courts that ruled on motions to dismiss Gardasil complaints allowed Plaintiffs an opportunity to amend their complaints to replead their claims. Two years later, this MDL litigation stands in a different posture. At oral argument, Plaintiffs recognized that at this late stage of discovery it would be inefficient and likely unproductive to request additional amended pleadings and they declined to do so. The Court agrees that further amended pleading would not be constructive. Therefore, Plaintiffs are not permitted to amend their complaints in response to this Order, other than with Merck's written consent or leave of Court granted for good cause following a separate motion under Fed. R. Civ. P. 15.[21]

## IV. ORDER

**NOW THEREFORE IT IS ORDERED THAT:**

1. Defendants' Motion for Partial Judgment on the Pleadings (Doc. No. 68) is **GRANTED in part** and **DENIED in part;**
2. The Court's ruling shall apply to all substantially similar allegations/claims asserted in the cases subject to the MDL; however, Parties who believe they have good cause (as discussed in the Order) to avoid the application of this ruling to her or his claims

[21] This ruling with respect to amended pleading is unrelated to the opportunity discussed above for MDL Plaintiffs other than Ms. Bergin and Ms. America to move that this ruling should not be applied to their complaints.

may, within 30 days of this Order (or within 30 days of joining the MDL, whichever comes later), file a motion seeking relief from this Order; and

3. Except as ordered here, this case shall move forward to further proceedings in accordance with the Court's current case management orders and the Parties' agreements.

**SO ORDERED ADJUDGED AND DECREED**.

Signed: March 20, 2024

Kenneth D. Bell
United States District Judge