UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
3:22-md-03036-RJC

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION	**MDL NO. 3036** **DEFENDANTS MERCK & CO., INC. AND MERCK SHARP & DOHME LLC'S GENERAL DENIAL, LIMITED SET OF ADMISSIONS, AND PRELIMINARY LIST OF AFFIRMATIVE DEFENSES** **THIS FILING RELATES TO ALL CASES**

Pursuant to this Court's Third Pretrial Order ("PTO 3") (ECF 58), Defendants Merck & Co., Inc. and Merck Sharp & Dohme LLC (collectively, "Merck"), through undersigned counsel, hereby file their General Denial, Limited Set of Admissions, and Preliminary List of Affirmative Defenses. In accordance with the parties' agreement as memorialized in PTO 3, this filing is made in the interest of efficiency and in lieu of filing individual Answers in all cases at this time; does not waive any state-specific or case-specific defenses in any current or future case coordinated as part of *In re: Gardasil Products Liability Litigation*, MDL No. 3036 ("*In re Gardasil*"); and does not waive any of Merck's Federal Rule of Civil Procedure 12(b) defenses in any case.

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3) and PTO 3, Merck denies each and every allegation set forth in the latest pleading in any current or future case coordinated as part of *In re Gardasil*, the whole thereof, and each and every cause of action therein, except to the limited extent that the allegations of Plaintiffs in any current or future case coordinated as part of *In re Gardasil* ("Plaintiffs") match the admissions specifically set forth below. Merck also

denies that Plaintiffs have sustained or are entitled to recover damages in any sum alleged, or in any sum whatsoever. Merck additionally denies that Plaintiffs have sustained any injury, damage, or loss by reason of any act or omission on the part of Merck, or any agents, servants, or employees of Merck.

LIMITED SET OF ADMISSIONS

Pursuant to Section 4 of PTO 3, Merck hereby admits:

1. Merck & Co., Inc. is a corporation organized under the laws of the state of New Jersey with its principal place of business currently located at 2000 Galloping Hill Road, Kenilworth, New Jersey.

2. Merck Sharp & Dohme Corp. merged with Merck Sharp & Dohme LLC on May 1, 2022, with Merck Sharp & Dohme LLC as the surviving entity.

3. Merck Sharp & Dohme LLC is a limited liability company organized under the laws of the state of New Jersey with its principal place of business currently located at 2000 Galloping Hill Road, Kenilworth, New Jersey.

4. Merck & Co., Inc. is the sole member of Merck Sharp & Dohme LLC.

5. Merck Sharp & Dohme LLC will participate in *In Re Gardasil*, as if it were the prior entity, "Merck Sharp & Dohme Corp."

6. Merck Sharp & Dohme LLC will not object on the basis of being a third party to any case coordinated as part of *In Re Gardasil*.

7. Merck Sharp & Dohme LLC will not object on the basis that Merck Sharp & Dohme Corp. was the proper party to *In Re Gardasil*.

8. Merck designed and developed GARDASIL®.

9. Each 0.5 mL dose of GARDASIL® contains approximately 20 mcg of HPV 6 L1 protein, 40 mcg of HPV 11 L1 protein, 40 mcg of HPV 16 L1 protein, and 20 mcg of HPV 18 L1 protein. Each 0.5 mL dose of GARDASIL® also contains approximately 225 mcg of aluminum (as Amorphous Aluminum Hydroxyphosphate Sulfate adjuvant ("AAHS")), 9.56 mg of sodium chloride, 0.78 mg of L-histidine, 50 mcg of polysorbate 80, 35 mcg of sodium borate, <7 mcg yeast protein, and water for injection.

10. Merck manufactured, labeled, and marketed GARDASIL® in accordance with the Prescribing Information that the Food and Drug Administration ("FDA") approved for that vaccine.

11. Merck designed and developed GARDASIL®9.

12. Each 0.5 mL dose of GARDASIL®9 contains approximately 30 mcg of HPV Type 6 L1 protein, 40 mcg of HPV Type 11 L1 protein, 60 mcg of HPV Type 16 L1 protein, 40 mcg of HPV Type 18 L1 protein, 20 mcg of HPV Type 31 L1 protein, 20 mcg of HPV Type 33 L1 protein, 20 mcg of HPV Type 45 L1 protein, 20 mcg of HPV Type 52 L1 protein, and 20 mcg of HPV Type 58 L1 protein. Each 0.5 mL dose of GARDASIL®9 also contains approximately 500 mcg of aluminum (provided as AAHS), 9.56 mg of sodium chloride, 0.78 mg of L-histidine, 50 mcg of polysorbate 80, 35 mcg of sodium borate, <7 mcg yeast protein, and water for injection.

13. Merck manufactured, labeled, and marketed GARDASIL®9 in accordance with its FDA-approved Prescribing Information.

14. GARDASIL® and GARDASIL®9 are FDA-approved vaccines that, when administered in accordance with their Prescribing Information, help protect against cervical, vulvar, vaginal, and anal cancers and their associated precancerous lesions, as well as genital

warts, caused by certain types of human papillomavirus ("HPV"). GARDASIL®9 also helps protect against penile, oropharyngeal, and other head and neck cancers caused by certain types of HPV.

15. On June 8, 2006, the FDA approved GARDASIL® for vaccination in females 9 to 26 years of age for prevention of the following diseases caused by HPV Types 6, 11, 16, and 18: cervical cancer, genital warts (condyloma acuminata), and the following precancerous or dysplastic lesions: cervical adenocarcinoma in situ (AIS), cervical intraepithelial neoplasia (CIN) grade 2 and grade 3, vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3, vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3, cervical intraepithelial neoplasia (CIN) grade 1.

16. The FDA approved Merck's Biologics License Application Supplement for GARDASIL® (STN# 125126/419) on September 12, 2008, to include an indication for prevention of vulvar and vaginal cancer caused by HPV Types 16 and 18.

17. The FDA approved Merck's Biologics License Application Supplement for GARDASIL® (STN# 125126/1297.0) on October 16, 2009, to include an indication for vaccination in boys and men 9 through 26 years of age for the prevention of genital warts caused by HPV Types 6 and 11.

18. The FDA approved Merck's Biologics License Application Supplement for GARDASIL® (STN# 125126/1895) on December 22, 2010, to include an indication for vaccination in males and females 9 through 26 years of age for the prevention of, among other conditions, anal cancer caused by HPV Types 16 and 18.

19. Merck submitted the Biologics License Application for GARDASIL®9 on December 10, 2013.

20. The FDA approved Merck's Biologics License Application for GARDASIL®9 on December 10, 2014, as indicated for girls and women 9 through 26 years of age for prevention of the following diseases: cervical, vulvar, vaginal, and anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58; genital warts (condyloma acuminata) caused by HPV types 6 and 11; and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58: cervical intraepithelial neoplasia (CIN) grades 2/3 and cervical adenocarcinoma in situ (AIS), cervical intraepithelial neoplasia (CIN) grade 1, vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3, vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3, anal intraepithelial neoplasia (AIN) grades 1, 2, and 3, and indicated for boys 9 through 15 years of age for the prevention of the following diseases: anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58; genital warts (condyloma acuminata) caused by HPV types 6 and 11; and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58; anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.

21. On December 14, 2015, the FDA extended the approved indications for GARDASIL®9 to include boys and men 16 through 26 years of age.

22. On October 5, 2018, the FDA extended the approved indications for GARDASIL®9 to include women and men from 27 to 45 years of age.

23. On June 12, 2020, the FDA approved the addition of prevention of oropharyngeal and other head and neck cancers caused by HPV types targeted by the vaccine to the GARDASIL®9 indication.

PRELIMINARY LIST OF AFFIRMATIVE DEFENSES

Pursuant to Section 4 of PTO 3, Merck preliminarily lists the following affirmative defenses, (a) without waiving any state-specific or case-specific defenses in any current or future

case coordinated as part of *In re Gardasil* (which may be pleaded in a full Answer at the appropriate time, as set forth in Section 4 of PTO 3); (b) without waiving any of its Federal Rule of Civil Procedure 12(b) defenses in any current or future case coordinated as part of *In re Gardasil* (which Merck may assert by motion at a later date or on remand); (c) without waiving any defense previously raised in any case coordinated as part of *In re Gardasil*; (d) without waiving Plaintiffs' burdens of proof; (e) without admitting that Merck has any burden of proof; (f) without admitting that Plaintiffs have been or will be injured or damaged in any way; and (g) without admitting that Plaintiffs are entitled to any relief whatsoever:

1. Each and every purported cause of action fails to allege facts sufficient to constitute a cause of action against Merck.

2. To the extent there were any risks associated with any vaccine to which Plaintiffs attribute any damages (individually and collectively described below as "Gardasil"), which Merck allegedly knew or allegedly should have known and which allegedly gave rise to any duty to warn, Merck at all times discharged such duty through appropriate and adequate directions and warnings in accordance with governing law. As the directions and warnings given in connection with Gardasil complied with the Food, Drug, and Cosmetic Act ("FDCA") and the applicable requirements of 42 U.S.C. § 262, Merck invokes the presumption set forth in 42 U.S.C. § 300aa-22(b)(2) of the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act").

3. Plaintiffs' claims are barred, in whole or in part, because, under 42 U.S.C. § 300aa-22(c), Merck is not liable for any damages arising from an allegedly vaccine-related injury associated with the administration of Gardasil solely due to Merck's alleged failure to provide

direct warnings to Plaintiffs or Plaintiffs' legal representatives of any purported dangers resulting from any administration of Gardasil.

4. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred because Gardasil was not defective, was not unreasonably dangerous, was reasonably fit, was suitable, and was safe for its intended purpose.

5. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred because Merck provided legally adequate directions or warnings as to the use of Gardasil within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

6. Merck violated no duty or obligation, if any, owed to Plaintiffs' prescribing physicians or any other person to whom it arguably owed any duty or obligation (individually and collectively, "prescribing physicians").

7. The law requires that all such directions, warnings, and appropriate information be given to prescribing physicians, who act as "learned intermediaries" or "informed intermediaries" in determining the use of Gardasil. To the extent that Plaintiffs assert that Merck failed to provide adequate warnings regarding the use of Gardasil, any obligation to warn was discharged by Merck's providing adequate warnings to Plaintiffs' prescribing physicians.

8. To the extent Plaintiffs allege design defect claims against Merck, those claims are preempted and barred for the reasons set forth in *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011).

9. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred because there is no practical or technically feasible alternative design that would have prevented or reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Gardasil.

10. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred because Gardasil conformed to the applicable state of the art, it was reasonably safe, and its benefits exceeded any associated risks.

11. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred because the acts of Merck at all times (a) conformed to all governing statutes, regulations, and industry standards, and (b) were proper based upon the state of knowledge existing at the relevant times alleged.

12. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred because the public interest in the benefit and availability of Gardasil precludes liability for the risks, if any, resulting from any activities undertaken by Merck, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in Gardasil, then such risk, if any, is outweighed by the benefit of the vaccine.

13. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred based on comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

14. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred under comment k to Section 402A of the Restatement (Second) of Torts because, if Gardasil was unsafe, which Merck denies, Plaintiffs' injuries resulted from side effects that were unavoidable even though Gardasil was properly prepared and was accompanied by proper directions and warnings.

15. To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution, Article IV, clause 2.

16. The conduct of Merck has complied with, and Gardasil has been formulated, designed, tested, manufactured, processed, distributed, and labeled in accordance with, the provisions of the FDCA, 21 U.S.C. §§ 301, *et seq.*, regulations promulgated thereunder, other pertinent federal statutes and regulations, and relevant actions of federal agencies. Therefore, Plaintiffs' claims are barred by the doctrine of federal preemption, the Supremacy Clause of the United States Constitution, Article IV, clause 2, and applicable federal law. Merck could not have added the warnings that Plaintiffs advocate to the FDA-approved Prescribing Information using the applicable Changes Being Effected regulation at any relevant time because Merck did not have the newly acquired information (i.e., data demonstrating a causal association between Gardasil and any clinically significant injury that Plaintiff attributes to Gardasil and revealing risks of a different type or greater severity than those previously included in FDA submissions) needed to add any such warnings at any relevant time and/or because "clear evidence" demonstrates "that the FDA would not have approved [Plaintiffs' desired] change to [Gardasil's] label." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019).

17. Plaintiffs' claims are barred, in whole or in part, by the deference that the common law gives to discretionary action by the FDA under the FDCA, and Merck further alleges that there is no private right of action for Plaintiffs' claims under the FDCA.

18. Plaintiffs' claims are barred, in whole or in part, because under the FDCA, and specifically 21 U.S.C. § 355(o)(4)(A), the FDA has a duty to promptly notify the "responsible person" if FDA becomes aware of "new information, including any new safety information or information related to reduced effectiveness" that the FDA "determines should be included" in the label. No such change has been made to the Gardasil label with respect to Plaintiffs' alleged injuries.

19. Merck's vaccines and/or actions were not the cause in fact, not the proximate cause, not the substantial contributing cause, not a substantial contributing factor, and/or not the producing cause of Plaintiffs' injuries, if any.

20. Plaintiffs' alleged injuries, losses, and damages, if any, were not caused by any product manufactured, distributed, or sold by Merck, but rather by some other product, process, occurrence, event, or service over which Merck exercised no control or right of control.

21. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred because Plaintiffs have failed to plead certain claims with the required particularity. Specifically, Plaintiffs' claims based on any alleged fraud, deceit, or misrepresentation are not pleaded with the requisite particularity.

22. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred because Plaintiffs may not recover for any claim based on any alleged fraud, deceit, or misrepresentation because Merck has made no misrepresentations of material fact.

23. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred because Merck's advertisements and labeling with respect to Gardasil were not false or misleading and, therefore, constitute constitutionally protected commercial speech.

24. Even if not barred by the Vaccine Act, Plaintiffs' claims are additionally barred because Plaintiffs' prescribing physicians did not rely on any alleged misrepresentations.

25. Plaintiffs received all or substantially all of the benefit from Gardasil that Plaintiffs hoped and intended to receive, and, to that extent, any recovery by Plaintiffs must be correspondingly reduced.

26. Plaintiffs' damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by Plaintiffs as a result of any insurance or other health benefits plan, or any amounts paid for by insurance, other health benefits plan, or other collateral sources.

27. In the event of a finding of liability in favor of Plaintiffs, a settlement, or a judgment against Merck, Merck requests an apportionment of fault among all parties and third persons as permitted by applicable state law. Merck also requests a judgment and declaration of partial indemnification and contribution against all other parties or third persons in accordance with the apportionment of fault.

28. Merck denies any liability on its part, but if Merck is ultimately found liable to Plaintiffs, then it shall only be liable for its equitable share of any recovery by Plaintiffs, since any liability which would be found against it will be insufficient to impose joint liability.

29. Merck is entitled to an offset of any prejudgment monies received by Plaintiffs from any settling defendant pursuant to any applicable statutes.

30. To the extent, if any, that Plaintiffs attempt to seek equitable relief, Plaintiffs are not entitled to such relief because Plaintiffs have an adequate remedy at law.

31. Even if not barred by the Vaccine Act, Plaintiffs' claims for punitive or exemplary damages (collectively, "exemplary damages") are additionally barred because Plaintiffs have failed to set forth any claim for which Plaintiffs must recover before being permitted to proceed with any claim for exemplary damages.

32. Plaintiffs' claims for exemplary damages are barred pursuant to 42 U.S.C. § 300aa-23(d)(2).

33. Even if not barred by the Vaccine Act, Plaintiffs' claims, including those for exemplary damages, are barred, in whole or in part, by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

34. Even if not barred by the Vaccine Act, Plaintiffs' claims for exemplary damages are additionally barred because no act or omission by Merck was undertaken with the intent that applicable law requires Plaintiffs to prove before exemplary damages can be recovered.

35. Plaintiffs' claims for exemplary damages are barred because any such award would, if granted, violate Merck's constitutional rights.

36. Plaintiffs are not entitled to recover exemplary damages because Plaintiffs' claims for exemplary damages are in violation of the First Amendment to the United States Constitution and comparable provisions of applicable state constitutions.

37. Plaintiffs are not entitled to recover exemplary damages because the imposition of exemplary damages, based upon evidence of Merck's financial status, would violate, among other protections, Merck's rights under the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and comparable provisions of applicable state constitutions (collectively, "due process rights").

38. Plaintiffs are not entitled to recover exemplary damages because exemplary damages would result in an unconstitutionally excessive fine in violation of, among other protections, Merck's due process rights.

39. Plaintiffs are not entitled to recover exemplary damages because the standards and instructions regarding exemplary damages are inadequate, vague, and ambiguous, which can, among other things, result in extremely disparate results among similar defendants accused of similar conduct, in violation of, among other protections, Merck's due process rights.

40. Plaintiffs are not entitled to recover exemplary damages as a matter of law because, under the facts and circumstances of the case, no reasonable juror could find that Merck's actions warranted exemplary damages under any state's law.

41. If not limited by a cap on exemplary damages, Plaintiffs' claims for exemplary damages cannot be sustained because an award of exemplary damages subject to no pre-determined limit, either a maximum multiple of compensatory damages or a maximum amount, on the amount of exemplary damages that a jury may impose would violate, among other protections, Merck's due process rights.

42. The correct standard for submitting the burden of proof for exemplary damages is "clear and convincing" evidence. Any lesser standard is a violation of, among other protections, Merck's due process rights.

43. Plaintiffs' claims for exemplary damages are barred because Plaintiffs cannot establish Merck's liability, if any, for exemplary damages and the appropriate amount of exemplary damages, if any, by clear and convincing evidence. Accordingly, any award of exemplary damages would violate, among other protections, Merck's due process rights.

44. Plaintiffs' claims for exemplary damages are barred because an award of exemplary damages for the purpose of compensating Plaintiffs for elements of damages not otherwise recognized by applicable law would violate, among other protections, Merck's due process rights.

45. Plaintiffs' claims, including Plaintiffs' claims for exemplary damages, are barred because Gardasil and its labeling were subject to and received pre-market approval by the FDA.

46. Plaintiffs' claims for exemplary damages cannot be sustained under any and all standards and limitations regarding the determination and/or enforceability of exemplary damage

awards that arose in the decisions of *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), *Cooper Indus., Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and *Exxon Shipping Co. v. Baker*, 554 U.S. 471 (2008).

47. Any award of exemplary damages on Plaintiffs' claims would violate the constitutional prohibition on ex post facto laws.

48. Plaintiffs' claims are barred by the applicable statutes of limitation, are barred by the applicable statutes of repose, are barred by the doctrine of prescription, and/or are otherwise untimely pursuant to, among other provisions, 42 U.S.C. §§ 300aa-16(a)(2), 300aa-16(c), and/or 300aa-21(c).

49. Plaintiffs cannot recover for the claims asserted because Plaintiffs have failed to comply with the conditions precedent necessary to bring Plaintiffs' actions and/or each particular cause of action asserted by Plaintiffs, including, but not limited to, those set forth in 42 U.S.C. §§ 300aa-11, 300aa-16, and 300aa-21.

50. Plaintiffs failed to seek relief for the injuries alleged in their civil actions in the Court of Federal Claims before filing their civil actions as is required by the Vaccine Act.

51. Plaintiffs' claims may be barred, in whole or in part, by the doctrine of informed consent.

52. To the extent that Plaintiffs rely upon any theory of breach of warranty, any such claims are barred for lack of timely notice; for lack of privity; because of a lack of an express warranty; because of a lack of detrimental reliance; and/or because any alleged warranties were disclaimed.

53. Plaintiffs' claims may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of Merck and all its activities with respect to Gardasil have been and are conducted under the supervision of the FDA.

54. Merck invokes its right to a trifurcated trial under 42 U.S.C. § 300aa-23 and comparable provisions under applicable state law. Accordingly, Plaintiffs' civil actions shall be tried in three stages, with any determination of any amount of exemplary damages being separated from the issues of liability and general damages.

DATED: January 27, 2023

Respectfully submitted,

/s/ Dino S. Sangiamo

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of January, 2023, I electronically transmitted the attached document to all counsel of record using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Dino S. Sangiamo
Dino S. Sangiamo