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SENT VIA ECF

April 8, 2025

Honorable Kenneth D. Bell
United States District Judge
Western District of North Carolina
7200 Charles R. Jonas Federal Building
401 West Trade Street
Charlotte, NC 28202

Re: *In re Gardasil Products Liability Litigation*, Case No. 3:22-md-03036-KDB

Dear Judge Bell:

Pursuant to the Court's First Case Management Order, dated March 10, 2023 (ECF No. 77), Defendants Merck & Co., Inc. and Merck Sharp & Dohme LLC (collectively, "Merck") respectfully submit this letter setting forth Merck's position regarding how the Court's March 11, 2025 Order granting Merck's Motion for Summary Judgment (hereinafter, "MSJ Order") (ECF No. 305) applies and/or should be applied to "Plaintiffs in the MDL other than the Bellwether Plaintiffs" and proposing next steps in light of the MSJ Order.

Plaintiffs' cases currently fall into three categories: (1) bellwether POTS and POI cases adjudicated in the MSJ Order, (2) non-bellwether POTS and POI cases, and (3) non-POTS and non-POI cases ("Other Injury Cases"). The parties have met and conferred and reached agreement in principle on the first two categories of cases as set forth below. The parties, however, are at an impasse regarding next steps in the Other Injury Cases. Merck is prepared to further discuss its position regarding next steps at a status conference, if useful to the Court.

I. Bellwether POTS and POI Cases

The parties agree that final judgment should be entered in the sixteen bellwether POTS and POI cases adjudicated in the MSJ Order.[1] As a result, the parties respectfully request that the Court enter

[1] The bellwether plaintiffs and their actions' corresponding docket numbers are as follows: Mary Ellouise Bond (3:23-cv-00058); Lakia Brayboy (3:22-cv-00509); Maeson Derr (3:22-cv-00381); Logan Dunn (3:23-cv-00129); Savannah Smithson Flores (3:22-cv-00397); Kameron Hilton (5:22-cv-00030); Cooper Humphries (3:22-cv-00395); Chaunna Lane (3:23-cv-00116); Kristen Linton obo C.K. (3:23-cv-00125);

final judgment in those bellwether cases.

II. Non-Bellwether POTS and POI Cases

The parties have conferred and agree that the Court's MSJ Order applies to non-bellwether Plaintiffs alleging POTS and/or POI. Merck provided Plaintiffs with a list of cases where MDL Plaintiffs allege POTS and/or POI in their most recent complaints. By Merck's count, approximately 127 Plaintiffs allege POTS and/or POI. Plaintiffs are in the process of reviewing Merck's proposed list of impacted Plaintiffs. The parties propose that, by April 15, 2025, Plaintiffs will confirm the list of impacted non-bellwether Plaintiffs with Merck. The parties further propose that by April 22, 2025, they will file a joint stipulation identifying the non-bellwether POTS and POI Plaintiffs whose claims are impacted by the MSJ Order. Merck understands that Plaintiffs will seek to preserve their ability to appeal these cases without waiver as part of the stipulation. Final judgment should then be entered in those cases consistent with the bellwether POTS and POI cases.

III. Other Injury Cases

Plaintiffs have requested that Merck agree to a stay of all cases in the MDL pending their planned appeal of the MSJ Order. Merck objects to Plaintiffs' request for a stay for the reasons detailed below. Merck proposes instead that the Court continue to prioritize the dispositive issue of federal implied preemption and set forth a plan that allows for the efficient resolution of the Other Injury Cases.[2] As Merck stated in its position statement at the commencement of this MDL, the MSJ Order should serve as a "lodestar in resolving what few claims, if any, may remain." ECF No. 12. The MSJ Order provides a framework for the efficient and expedited resolution of Other Injury Cases that allows the parties to proceed directly to expert discovery, if any, and summary judgment briefing.

MDL courts have discretion to broadly apply individual dispositive rulings across an MDL through a variety of procedural mechanisms, including orders to show cause and *Lone Pine* orders. *See, e.g.*, *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, No. 23-1032, 2024 WL 3423709 (3d Cir. July 16, 2024) (affirming the dismissals of claims for alleged shingles-related injuries attributed to a Merck vaccine after the MDL court excluded the specific causation expert's opinions in the bellwether shingles cases and based on the non-bellwether plaintiffs' subsequent inability to produce specific causation evidence, as required by the court's *Lone Pine* order); Ex. A, *In re Rezulin Prods. Liab. Litig.*, MDL No. 1348 (S.D.N.Y.) (issuing a *Lone Pine* order requiring each plaintiff to consider whether good grounds existed to continue prosecuting his or her claim in light of the court's previous order and ordering expert reports with specified requirements); Ex. B, *In re Fosamax (Alendronate Sodium): Prods. Liab. Litig.*, MDL No. 2243 (D.N.J.) (ordering plaintiffs to show cause as to why their claims should not be dismissed on preemption grounds pursuant to the court's order granting summary judgment).

Merck proposes that, no later than May 30, 2025, Lead Plaintiffs' Counsel should be required to identify (1) which alleged injuries in the Other Injury Cases they intend to further pursue in good faith in light of the Court's MSJ Order, and (2) which MDL Plaintiffs (by name and docket number) allege those injuries. Cases brought by the remaining Plaintiffs should be dismissed with prejudice. Currently, the Other Injury Cases include a host of alleged injuries, ranging from cervical cancer to catatonic schizophrenia to alopecia. Prompt identification of alleged injuries Plaintiffs intend to continue to

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Madelyn Lipscomb (3:22-cv-00396); Madelyn Malloy (3:22-cv-00407); Corrine McElerney (3:22-cv-00382); Jaden McTighe (3:23-cv-00130); Megan Marie Roeder (3:22-cv-00431); Nalon Soileau (3:22-cv-00399); and Tanja & Scott Wagner OBO S.W. (3:22-cv-00362).

[2] While Merck requests that the Court prioritize implied preemption guided by the MSJ Order, Plaintiffs' claims also independently fail, among other reasons, for lack of causation evidence and as preempted under the National Childhood Vaccine Injury Act.

prosecute (and on which they believe they have a basis to defeat an implied preemption summary judgment motion) should streamline the adjudication procedure. *See In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, MDL No. 2804, 2023 WL 8258533, at *2 (E.D. Pa. Nov. 29, 2023) (requiring counsel to "review" cases attributing certain non-shingles injuries to a Merck vaccine; to identify cases in which counsel, "in good faith, does not believe the claims to be meritorious;" and to produce signed expert declarations concerning causation for any remaining cases, where similar cases had failed for lack of admissible expert opinions).

Under Merck's proposal, the parties would then meet and confer and, by June 13, 2025, submit a proposed case management order that sets forth expert discovery deadlines, if any, and implied preemption summary judgment briefing deadlines on the remaining Other Injury Cases. No additional fact discovery or individual plaintiff-specific case workup is warranted. Expert discovery, should Plaintiffs wish to provide expert testimony in support of their opposition to Merck's summary judgment briefing focused on implied preemption, is the appropriate next step. Plaintiffs have engaged in years of fact discovery on Merck, which was not limited in scope to the injuries of POTS and POI. Indeed, the jointly stipulated First and Second Case Management Orders provided deadlines for the close of fact discovery that expressly included "all Merck fact discovery." ECF No. 77; ECF No. 122. Many of the document productions Merck made were not limited in any way. Some examples include the Gardasil and Gardasil-9 regulatory files and Periodic Safety Update Reports. In fact, in response to Plaintiffs' demands, Merck produced 100 fields of information from its adverse experience report database "MARRS" for every Gardasil and Gardasil-9 adverse experience report regardless of what condition was reported, which totaled over 188,000 reports. In addition, Merck ran over 21,000 search term combinations—all chosen by Plaintiffs—to identify potentially relevant documents in over 85 current and former employees' custodial files. Merck has produced in this MDL over 1.6 million documents and terabytes of electronic data, from over 100 document sources. Plaintiffs also took over 20 Rule 30(b)(1) depositions and multiple Rule 30(b)(6) depositions, again covering a wide range of topics. Thus, Plaintiffs have had ample opportunity to marshal their evidence on preemption, including: (a) the date Plaintiffs allege Merck should have added their desired warning(s) to the Gardasil label; (b) the proposed contents of their desired warning(s); and (c) the "newly acquired information" that Plaintiffs claim Merck had by the date identified demonstrating "reasonable evidence of a causal association" consistent with the Court's MSJ Order.

As noted above, Merck objects to Plaintiffs' request for a stay of the MDL pending their anticipated appeal of this Court's MSJ Order to the Fourth Circuit. ***First***, Merck does not believe that Plaintiffs will prevail in their appellate challenge to the MSJ Order, and Merck is eager to vigorously and promptly defend itself against all remaining claims. Unnecessary and prolonged delays created by a stay could undermine the public's confidence in the safety and efficacy of this important cancer-preventing vaccine. Just as the MDL proceeded while Plaintiffs appealed the Court's Rule 12 Orders, work should continue during Plaintiffs' appeal of the MSJ Order.

Second, Merck would be prejudiced by a stay of the MDL, and Plaintiffs' attempted forum shopping in California (and now New Jersey) state court would be rewarded. Plaintiffs' MDL counsel, who petitioned the JPML to create this MDL in the first place, now seek to halt the MDL proceedings pending a Fourth Circuit decision on their as-yet-unfiled appeal, which will significantly delay the final resolution of these cases. Meanwhile, the same Plaintiffs' counsel have indicated their desire to proceed with jury trials in the 6 pending California state court Gardasil POTS cases. Those California plaintiffs' counsel, who again serve as lead counsel in this MDL, have declined to stay those state court cases pending the Fourth Circuit's decision. The *Jennifer Robi* trial is set to re-commence in September 2025—followed by another trial every few months thereafter through 2026.[3]

[3] The first *Robi* trial was adjourned at her counsel's request in exchange for no money from Merck weeks into plaintiff's case-in-chief.

What's more, Plaintiffs' co-lead MDL counsel (Wisner Baum) is now attempting to litigate Gardasil claims in a third forum—New Jersey state court. On March 21, 2025, just 10 days after the MSJ Order, Plaintiffs' co-lead MDL counsel filed a 7-plaintiff complaint in the Superior Court of New Jersey. Two of those plaintiffs are citizens of North Carolina; two are citizens of Illinois; one is a citizen of Minnesota; and one is a citizen of Florida. Only one is a New Jersey citizen. As with Plaintiffs in this MDL, each plaintiff in the newly filed case alleges that he or she "sustained serious autoimmune injuries as a result of" his or her Gardasil vaccinations. Ex. C, *Bednarczyk, et al. v. Merck & Co., Inc., et al.*, Case No. UNN-L-001147-25 (N.J. Super. Ct. Law Div. Mar. 21, 2025), Compl. ¶¶ 249–308 (hereinafter "*Bednarczyk*"). On March 24, Merck removed the action to the District of New Jersey and subsequently filed a notice of tag-along with the JPML. Plaintiffs' co-lead MDL counsel filed a notice opposing the JPML's Conditional Transfer Order ("CTO") on April 2. This notice marked the first time any plaintiff—including several current MDL Plaintiffs whose cases were removed from New Jersey state court—has opposed transfer to the Gardasil MDL since the 2022 formation of the MDL. In their notice, plaintiffs indicated that they "are in the process of preparing a motion to remand which they intend to timely file in the District of New Jersey" and "ask that the District of New Jersey adjudicate the forthcoming remand motion." *See* Ex. D, Notice of Opposition to CTO.

Interestingly, and perhaps recognizing that transfer is inevitable, on April 2 (the same day they opposed the CTO in the JPML), two of the *Bednarczyk* plaintiffs direct-filed nearly identical complaints in this MDL. *See McMahan v. Merck & Co., Inc., et al.*, Case No. 3:25-cv-00234 (ECF No. 1); *J.S. by and through his guardian ad litem Kenyondra Langford v. Merck & Co., Inc., et al.*, Case No. 3:25-cv-00233 (ECF No. 1). Merck has moved to stay this new case in the District of New Jersey and will oppose plaintiffs' motion to vacate.[4] Of course, an anticipated motion to remand is not a basis to sidestep transfer. *See, e.g.,* Ex. E, Transfer Order at 1–2, *In re Eliquis (Apixaban) Prods. Liab. Litig.*, MDL No. 2754 (J.P.M.L. May 30, 2017), ECF No. 170 (denying plaintiffs' motion to vacate CTO premised on pending remand motion); *In re: Gadolinium Contrast Dyes Prods. Liab. Litig.,* MDL No. 1909, 2012 WL 7807340, at *1 (J.P.M.L. Apr. 16, 2012) (denying motion to vacate CTO and holding that "[w]e have long held that jurisdictional objections are not an impediment to transfer. Plaintiff can present his motion for remand to state court to the transferee court"). Judicial economy calls for motions to remand, if any, to be heard by this MDL Court at an appropriate time.

For these reasons, Merck respectfully requests that the Court deny Plaintiffs' request for a stay, continue to prioritize preemption, and adopt Merck's proposal setting forth next steps consistent with the MSJ Order that it "shall be applied to Plaintiffs in the MDL other than the Bellwether Plaintiffs in accordance with the prior Orders of the Court . . . ." ECF No. 305 at 35.

Respectfully submitted,

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[4] Plaintiffs' motion to vacate is due on April 17. Merck's opposition will be filed by May 8, and Plaintiffs' reply is due on or before May 15.

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