April 8, 2025

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

RE: In Re: Gardasil Products Liability Litigation, 3:22-md-03036-KDB

Dear Judge Bell:

On March 11, 2025, this Court granted Merck's summary judgment motion based upon implied preemption as to the Bellwether Plaintiffs. The Bellwether Plaintiffs alleged that Gardasil caused their Postural Orthostatic Tachycardia Syndrome ("POTS") or Primary Ovarian Insufficiency ("POI"). This Court has not yet entered final judgment against the Bellwether Plaintiffs. Due to the appeal that will ensue following judgment entry, the parties are in negotiations regarding a stipulation addressing this Court's decision to apply this preemption Order to the additional Plaintiffs who also allege POTS and POI injuries. The parties are working on a stipulation that fully protects these non-bellwether POTS and POI Plaintiffs' appellate rights and prevents any waiver of their appellate rights. In this way, all cases that are directly implicated by the Court's order will be appellants for one appeal at this time, rather than a procedure that might result in many appeals that are necessary at a later time. We expect to finalize that stipulation for presentation to the Court for its consideration by April 22, 2025.

In addition to the POTS/POI cases that were the ordered subjects of the Court's preemption ruling, there are nearly a hundred plaintiffs who allege different injuries than POTS/POI. Pursuant to the parties' agreement and the Court's prior case management orders), no expert discovery has occurred as to these other injuries. The parties have not reached agreement on how these cases should be handled going forward. Plaintiffs believe that these cases should be stayed due to the inevitable guidance that the Fourth Circuit's decision will provide regarding their claims vis-a-via preemption and the massive volume of work that the parties and the Court will need to dedicate to these other cases during the pendency of an appeal that will, one way or the other, establish the legal landscape for these cases. Specifically, this MDL includes the following 98 cases involving many different injuries: alopecia/ hair loss (3 cases), aplastic anemia (1), autoimmune disease (5), Bell's Palsy (1), cervical cancer (3), chronic pain and/or fatigue (16), Crohn's/Ulcerative Colitis (1), death (4), dysautonomia/autonomic dysfunction (5), encephalitis (2), fibromyalgia (10), functional neurologic disorder (1), gastroparesis (2), Guillain-Barre syndrome (1), irritable bowel syndrome (2), immune thrombocytopenic purpura (2), lupus (5), migraines (1), multiple sclerosis (5), narcolepsy (2), neuropathy (7), orthostatic intolerance (2), reproductive conditions (PCOS, endometriosis, etc.) (5), rheumatoid arthritis/other forms of arthritis (4), seizures/epilepsy (13), and small fiber neuropathy (1). This letter will address the parties' competing proposals as to these cases.

This Court should stay the non-POTS and non-POI cases during the appeal:

For the non-POTS and non-POI cases, a stay is warranted during the POTS and POI appeal. Notably, "Courts regularly stay cases where an appeal in a *related case* will resolve (or at least greatly simplify) the issues in the stayed case." *In re Zimmer M/L Taper Hip Prosthesis*, MDL 2859, 2021 WL 5963392, at *4 (S.D.N.Y. Dec. 16, 2021) (emphasis added).[1] Here, the POTS and POI appeal will be highly informative for the Court and the parties. The Court and the parties will benefit from the Fourth Circuit's preemption analysis as to autoimmune injuries generally and the specific injuries of POTS and POI. The Court and parties will further benefit from Plaintiffs' appeal as to the limitations placed on Dr. Amato's regulatory opinions. If Plaintiffs prevail on appeal in whole or in part as to the preemption decision and the limitations on Dr. Amato's opinion, then the Court would have to apply a different standard on remand. On the other hand, if Defendants prevail on appeal, then each non-POTS and non-POI Plaintiff would have more information to determine whether—based upon the Fourth Circuit's analysis—additional expert expenses and motion practice would likely be fruitful.

Without a stay, the parties will expend significant resources. Under the prior case management orders, Plaintiffs were not obligated to adduce expert opinions for when the available evidence would support warnings for alopecia/ hair loss, aplastic anemia, Bell's Palsy, cervical cancer, chronic pain, Crohn's/Ulcerative Colitis, death, dysautonomia/autonomic dysfunction, encephalitis, fibromyalgia, functional neurologic disorder, gastroparesis, Guillain-Barre syndrome, irritable bowel syndrome, immune thrombocytopenic purpura, lupus, migraines, multiple sclerosis, narcolepsy, neuropathy, orthostatic intolerance, reproductive conditions (PCOS, endometriosis, etc.), rheumatoid arthritis/other forms of arthritis, seizures/epilepsy, or small fiber neuropathy. Nor has there been a case management order governing the process for these Plaintiffs to offer general causation experts for these injuries. It is thus no surprise that, in its decision on POTS and POI, the Court did not decide whether the available evidence supported a warning for these conditions.

If this Court does not stay the non-POTS and non-POI cases, these Plaintiffs will need an opportunity to prepare expert reports as to each type of injury. Further, that process would necessarily include time for defense expert reports and depositions of the parties' experts on each type of injury. This would be a colossal expenditure for all parties.[2] In addition, the parties would

[1] *See also Wing Shing Prods. v. Simatelex Manufactory*, 2005 WL 912184, at *l-*3 (S.D.N.Y. Apr. 19, 2005) (granting stay pending resolution of appeal of *same court's* decision in *related case*); *Greco v. NFL*, 116 F. Supp. 3d 744, 761 (N.D. Tex. 2015) ("The final outcome of [appeal in a *related case*] will likely streamline issues for dispositive motions and bellwether trials in this case. The risk of duplicative litigation is too great for this Court to ignore.") (citations omitted); *Fried v. Lehman Bros.*, 2012 WL 252139 at *5 (S.D.N.Y. Jan. 25, 2012) ("There is significant overlap between this lawsuit and the lawsuit on appeal, both legally and factually, which is a solid ground upon which to issue a stay.").

[2] A summary judgment decision that impacts a large portion of cases in an MDL is always an inflection point for potential resolution, whether summary judgment is granted or denied. In this

then need time to file opposing *Daubert* motions to each expert, with opposition briefs and replies. The evidentiary record would be extensive, as experts would need to review all available evidence to potentially support or refute a particular warning. For example, Dr. Amato submitted a 147-page report as to POTS and POI, Merck submitted 23 exhibits in its motion to exclude Dr. Amato, and Plaintiffs submitted 22 exhibits in opposition. This highlights the heavy lift for experts in this case who must review an evidentiary record that extends from the early 2000s to present day on a vaccine that has been administered around the world. Lastly, Merck would need to file a preemption motion, and Plaintiffs would need an opportunity to respond. This is no small task. For example, as to POTS and POI, the parties—like their experts—and the Court had to sift through a voluminous record. Indeed, Merck attached 80 exhibits to its preemption motion, and the Bellwether Plaintiffs attached more than 200 exhibits to their opposition.

Given the voluminous record that experts would have to review as to numerous additional injuries, Plaintiffs would need until at least the end of September 2025 to produce expert reports on these topics.[3] After production of Plaintiffs' expert reports, there would need to be at least one month for defense to serve any reports, at least two to three months for expert depositions, and at least three months for motion practice. Given the variety of the injuries claimed, this time-line would be extremely ambitious for all concerned and it does not consider potential delays due to discovery issues that the Court would have to hear and rule upon. Ultimately, we would be unlikely to reach hearings on dispositive issues until March or April of 2026. By that time, the Fourth Circuit would likely have already heard argument on the POTS and POI appeal and may have already ruled on the appeal. By way of example, the notices of appeal regarding this Court's prior dismissal Order were filed August 28-29, 2024, and the Fourth Circuit will hold oral argument on May 15, 2025. *See Needham v. Merck*, No. 24-1828 (4th Cir.). Given the likely timeline in reaching the merits of the non-POTS and non-POI cases as well as the likely timeline for the POI and POTS appeal, it best serves judicial economy and the parties' resources to await the Fourth Circuit's decision.[4] Frankly, we are a little surprised that Merck does not agree with a stay under these circumstances because it is an eminently reasonable path at this time.

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case, any potential for resolution is not served by additional significant transaction costs while an impactful appeal is pending.

[3] Plaintiffs have not yet obtained expert reports on the non-POTS and non-POI injuries because Plaintiffs' counsel fully expected that summary judgment would be denied as to the Bellwether Plaintiffs, and Plaintiffs' counsel believed that they would be currently preparing the Bellwether Plaintiffs' cases for trial.

[4] Merck would like the California state court cases to be subject to any stay pending the resolution of the Fourth Circuit appeal. However, Plaintiffs' counsel cannot stay the California state court cases due to ethical obligations to their clients to move these cases forward as efficiently as possible in order to obtain a potential resolution of the clients' cases. In addition, the Fourth Circuit's decision will not be binding on the California state court cases, so it does not make sense to stay the California cases pending the Fourth Circuit appeal.

This Court should not issue orders to show cause:

Plaintiffs also emphasize that, in the absence of a stay, an order to show cause process for the non-POTS and non-POI cases would violate these Plaintiffs' due process rights. Like the POTS and POI Plaintiffs, the other Plaintiffs are entitled to a fair and reasonable process to prepare and submit experts, engage in expert discovery, and submit evidence in opposition to summary judgment motions. The Case Management Orders in this MDL have never included a timeline for 1) submission of expert reports for non-POTS and non-POI injuries, 2) expert discovery for these cases, or 3) summary judgment or *Daubert* motion practice for these cases.[5]

Under these circumstances, an order to show cause process would violate the Plaintiffs' due process rights. The Supreme Court has long recognized that "[a] fundamental requirement of due process is the opportunity to be heard." *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965). Further, this opportunity "must be granted at a meaningful time and in a meaningful manner." *Id.* An abbreviated or expedited path to summary judgment provides neither a meaningful time, nor a meaningful manner, for Plaintiffs to present expert evidence in support of their claims.

Such a procedure would also violate the Plaintiffs' procedural rights. An order to show cause would essentially grant relief under FRCP 56(f), which allows a Court to grant summary judgment where warranted "[a]fter giving notice and a reasonable time to respond…" However, the Fourth Circuit has cautioned against swift use of Rule 56(f):

> [The Court] must, in view of the procedural, legal, and factual complexities of the case, allow the party a reasonable opportunity to present all material pertinent to the claims under consideration. These requirements ensure a litigant has a full and fair opportunity to present its case. And a district court may not short-circuit the notice and hearing process on the basis that the claim at issue lacks merit.

Moore v. Equitrans, 27 F.4th 211, 224 (4th Cir. 2022) (citation omitted). Here, Rule 56(f) is not warranted because this Court has not provided a timeline for the non-POTS and non-POI Plaintiffs to prepare expert reports and engage in expert discovery.

In addition, if this Court follows the Rule 56(f) procedure, summary judgment would be inappropriate and premature under Rule 56(d). Under that rule, the Court should "defer consider[ation]" and "allow time to obtain affidavits or declaration or to take discovery… ." Notably, "[r]elief under Rule 56(d) is broadly favored in this Circuit and should be liberally granted." *Farabee v. Gardella*, 131 F.4th 185, 193 (4th Cir. 2025) (citation omitted); *see also Greater Baltimore Ctr. for Pregnancy Concerns v. Mayor & City Council of Baltimore*, 721 F.3d 264, 281 (4th Cir. 2013) (en banc) ("Such a request is broadly favored and should be liberally granted because the rule is designed to safeguard non-moving parties from summary judgment motions that they cannot adequately oppose.") (citation omitted); *id.* at 275-76 (finding summary judgment premature, in part, because the City did not have adequate time to submit expert reports). The protections for a non-moving party are "bedrock procedural rules" and "designed to

[5] Unless otherwise ordered by Court, the deadline for an expert report is 90 days before trial under FRCP 26(a)(2)(D).

further the due process of law that the Constitution guarantees." *Id.* at 290 (quoting *Nelson v. Adams USA*, 529 U.S. 460, 465 (2000)). Here, an order to show cause would violate the rights of the non-POTS and non-POI Plaintiffs and deny these Plaintiffs an adequate opportunity to prepare expert reports, engage in expert discovery, and prepare a summary judgment opposition that considers the voluminous record in this case.

Conclusion:

For these reasons, Plaintiffs respectfully request that this Court permit the parties fourteen days to reach a stipulation for the Court's review and approval regarding the other POTS and POI cases that allows them to fully appeal with the Bellwether cases, enter judgment on all of the POTS and POI cases and stay the non-POTS and non-POI cases pending resolution of the POTS/POI Plaintiffs' appeal.

Thank you for consideration regarding this matter.

Dated: April 8, 2025

Respectfully submitted,

/s/ Paul J. Pennock

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CERTIFICATION REGARDING USE OF ARTIFICIAL INTELLIGENCE

Pursuant to the Court's June 18, 2024 Standing Order, the undersigned hereby certifies that no artificial intelligence was employed in doing the research for the preparation of this document, with the exception of such artificial intelligence embedded in the standard on-line legal research sources Westlaw, Lexis, FastCase, and Bloomberg and that every statement and every citation to an authority contained in this document has been checked by an attorney in this case and/or paralegal working at his/her discretion as to the accuracy of the proposition for which it is offered and the citation to authority provided.

/s/ Josh Autry

CERTIFICATE OF SERVICE

A copy of this filing was served on all counsel of record through this Court's electronic filing system.

/s/ Josh Autry