

**UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF NORTH CAROLINA**

**IN RE: GARDASIL PRODUCTS
LIABILITY LITIGATION**

MDL No. 3036

**THIS DOCUMENT RELATES TO ALL
CASES**

Civil Action No. 3:22-md-03036-KDB

JOINT STATUS REPORT FOR APRIL 25, 2024 PRETRIAL CONFERENCE

The parties jointly submit the following status report ahead of the Pretrial Conference scheduled on April 25, 2024, at 10:00 a.m.:

I. PLEADINGS

A. Merck's Federal Rule of Civil Procedure Rule 12 Motions

On March 20, 2024, the Court entered its Order on Merck's Federal Rule of Civil Procedure 12(c) motion in the Bergin (W.D.N.C.) and America (N.D.N.Y.) cases. (D.E. 132.) Pursuant to the Court's Order, Plaintiffs intend to file a motion by April 19, 2024 related to the application of this ruling on other plaintiffs in the MDL.

Merck anticipates filing a Federal Rule of Civil Procedure 12(b)(1) motion to dismiss for lack of subject matter jurisdiction in the Tessa Needham (Case No. 3:24-cv-00291) and Shanie Roman (Case No. 3:24-cv-00278) MDL matters. The parties are conferring on a briefing schedule and will be prepared to discuss at the April MDL conference.

Merck also intends to file a motion under Federal Rule of Civil Procedure 12(b)(1) and 12(c) in the Junious Nielsen (Case No. 3:23-cv-00729) matter. Based on Merck's investigation, this pro se plaintiff does not appear to have ever submitted a claim in VICP for

alleged Gardasil-related injuries before filing a complaint in this MDL. Accordingly, Merck submits that this complaint should also be dismissed under the Vaccine Act for lack of subject matter jurisdiction. In addition, this plaintiff fails to state a claim because Merck cannot discern the nature of his alleged injuries or legal claims.

II. DISCOVERY

A. Merck Depositions and Discovery

Following the October 2023 MDL Conference, the parties jointly proposed an order with respect to discovery limits on Rule 30(b)(1) and Rule 30(b)(6) depositions of Merck witnesses, additional search terms run on Merck documents, and 42 additional Merck document sources, bringing the total number of document sources from which Merck produced or is producing documents to approximately 110. The Court entered the parties' jointly proposed order as the Second Case Management Order (D.E. 122).

To date, seven Rule 30(b)(6) depositions related to Merck's pharmacovigilance processes and Gardasil clinical trials have occurred. A Rule 30(b)(6) deposition related to Merck's sales and marketing of Gardasil is currently set to occur on April 24, 2024.

To date, six Rule 30(b)(1) depositions of current and former Merck employees have occurred. Five additional depositions of former Merck employees are scheduled to occur in April and May. The parties are meeting and conferring about the scheduling of three additional requested Rule 30(b)(1) depositions of current and former Merck employees subject to the Second Case Management Order (D.E. 122). Merck witness depositions have been and will continue to be crossed-noticed in the individual California state court matters.

To date, Plaintiffs have requested at least 37 of the 42 additional Merck document sources allotted pursuant to the parties' agreement in the Second Case Management Order (D.E. 122).

Merck continues to object to two of those requested document sources, and the parties are in the process of meeting and conferring about those disputed sources. Merck is continuing to produce documents from the various agreed document sources on a rolling basis pursuant to the parties' agreement in the Second Case Management Order (D.E. 122).

The written discovery deadline was February 15, 2024.¹ The MDL Plaintiffs served written discovery in the form of five sets of Requests for Productions, four sets of Interrogatories, and two sets of Requests for Admissions. Merck has responded to the requests for production and will respond to the remaining requests by April 19. The parties are meeting and conferring about certain of Merck's responses to various discovery requests.

The current fact discovery deadline in the MDL is June 13, 2024. Despite the parties' best efforts, the parties have determined that a 60-day extension on the fact discovery deadline is required to complete the necessary fact discovery. The parties recognize and agree that depositions of certain bellwether plaintiffs' healthcare providers may need to be completed after this deadline based on those providers' schedules. The parties are diligently working to finalize a proposed Order to this effect in advance of the April MDL conference. The parties will submit either a jointly proposed scheduling order or competing proposed scheduling orders by Tuesday, April 23. The parties will be prepared to discuss at the April MDL Conference.

Merck's Additional Statement: Based on the Court's guidance at the March conference and to further facilitate coordination with the California state court matters, Merck proposes that, after the requested 60-day extension, Merck's implied preemption motion for summary judgment be expedited with briefing completed by November 2024 with general causation Rule 702 and

¹ The parties have agreed that Merck's case-specific discovery requests to the bellwether plaintiffs can be deferred to Phase III of the litigation (if applicable) and as described in the First Case Management Order (D.E. 77).

summary judgment briefing to be completed in early 2025. The parties are conferring regarding these proposed amendments to the scheduling order for the Court's consideration.

B. California Coordination

There are currently seven Gardasil cases pending in California state court. Bijan Esfandiari (Plaintiffs' co-lead counsel in this MDL) is counsel of record in those state court matters. In the Second Pretrial Order, the Court stated that it "expects the parties to coordinate on discovery and other appropriate pretrial proceedings with any related state court litigation to avoid unnecessary duplication and inconsistency to the extent possible." (D.E. 27.) Consistent with the Court's instruction, the parties have, to date, coordinated those individual state court matters with this MDL in various ways, including by cross-noticing Merck witness depositions in the California state court matters and addressing generic discovery disputes in the MDL.

As agreed and reported in the October 2023 Joint Status Report (D.E. 113) and the Second Case Management Order (D.E. 122), Merck and Plaintiffs' counsel for the cases pending in California agreed in principle to submit an agreed stipulation in each of the California Gardasil cases requesting an approximately 120-day continuance on the trial dates and respective pretrial deadlines in those matters. To date, the trial dates and respective pretrial deadlines in four California Gardasil cases have been continued to 2025. The parties' previously-agreed stipulations of approximately regarding 120-day continuances of the remaining three California trials will be submitted to the respective California state courts. The first California Gardasil trial, Jennifer Robi, is currently scheduled to begin on October 7, 2024.

Plaintiffs' Statement: *Robi* was filed July 27, 2016, and is approaching its eighth year of civil litigation. On January 16, 2024, the *Robi* court agreed to continue the trial date to October 7, 2024. The case has been pending so long that the attorney who initially filed the case on behalf of

Ms. Robi has since passed away. Merck provides no justification as to why a case which it has been litigating since 2016, needs to be further extended. Nor has Merck demonstrated why discovery in both *Robi* and in the MDL could not continue to be coordinated even if the Court grants Merck's requested two-month extension of fact discovery in the MDL. Indeed, even with the discovery extension that Merck is proposing for the MDL (i.e., extending fact discovery deadline until August 12, 2024), it would still allow discovery in this case to coordinate with *Robi*, given that the current fact discovery deadline in *Robi* is September 7, 2024. The Fourth Circuit has observed, "it is a time-honored statement that 'justice delayed is justice denied'" *In re PSLJ, Inc.*, 904 F.2d 701 (4th Cir. 1990), and to give teeth to that statement, California has legislation which require each civil case be tried within five-years of inception otherwise it is automatically dismissed. While the *Robi* trial court has on multiple occasions agreed to extend that five-year rule, given the age of the case and the significant life-altering disabling injuries Ms. Robi has endured (and continues to endure) as a result of her Gardasil injection, any further extension of her trial date would be highly prejudicial and unnecessary. For those reasons, Robi and her counsel have not agreed to stipulate to a further continuance of the *Robi* trial date. With regards to the other six California cases, as with Robi, the discovery cut-offs in the state court cases are currently set for dates that are *after* the August 12th discovery cut-off that the parties are requesting for the MDL, it is unclear why the state court cases need to be further continued when they can continue to be coordinated with the MDL even if the discovery deadline were to be extend in the MDL.

Merck's Statement: Merck intends to file a motion for a continuance in the *Robi* California state court matter to allow for coordination with the MDL consistent with the Court's expectation that the parties will "coordinate on discovery and other appropriate pretrial proceedings with any related state court litigation to avoid unnecessary duplication and

inconsistency to the extent possible” (D.E. 27.) and in light of the parties’ planned request for an extension on the schedule in the MDL and Merck’s proposed briefing schedule. Ms. Robi’s counsel and MDL Plaintiffs’ counsel Bijan Esfandiari have agreed to extensions—both before the MDL was formed and since—to allow for coordination. The parties even agreed in a stipulated Order, entered by the *Robi* Court on January 16, 2024, to continue the trial date “with the possibility of a further continuance if needed due to the MDL proceedings, and with all related deadlines to be reset accordingly.” *See Robi v. Merck & Co., Inc., et al.*, Case No. BC628589 (Cal. Sup. Ct., Los Angeles Cty.), 1/16/2024 Order Continuing Trial Date to Coordinate with Multidistrict Litigation (“MDL”) Proceedings. In that same stipulated January 2024 Order, Ms. Robi and her counsel also agreed to extend the state statutory mandatory time for bringing the *Robi* action to trial up to and including December 31, 2025 (14 months after her current trial date). *Id.* And notably, the Order reflects that “The Parties wish to follow the MDL Court’s instruction to coordinate discovery and other appropriate pretrial proceedings to avoid unnecessary duplication and inconsistency.” *Id.* To date, no healthcare providers have been deposed in that case, and Merck’s initial summary judgment briefing, which will be at least in part duplicative of the anticipated briefing in the MDL, is due in June 2024.

Plaintiffs’ counsel also have not agreed, at this time, to further continuances in the six other California Gardasil cases. After *Robi*, the next California state court trial is scheduled to begin in the Kayla Carrillo matter in January of 2025. The parties will be prepared to discuss California coordination at the April MDL conference.

C. Plaintiffs’ Third-Party Subpoenas

Plaintiffs’ counsel have served subpoenas on multiple third parties. Plaintiffs have served or informed Merck they intend to serve subpoenas *duces tecum* on five individuals who serve as

experts on behalf of the government in the VICP. The parties met and conferred regarding Merck's objection to these subpoenas, and Plaintiffs are in the process of modifying their requests. Any deadline to respond or file a motion has been tolled until the parties confer further. Plaintiffs have also served subpoenas *duces tecum* and for depositions on four authors of the Chao (2011) study, which is a publication of data from Merck's postmarketing commitment study related to the FDA's approval of Gardasil. Two authors were subpoenaed in the MDL, and two different authors were subpoenaed in the *Robi* California state court matter. The parties will be prepared to discuss at the April MDL conference.

D. Bellwether Case Updates

Almost all depositions of bellwether Plaintiffs and, if applicable, their parents have occurred, and the parties are scheduling the depositions of the bellwether Plaintiffs' health care providers consistent with the Stipulation and Order Regarding Deposition Scheduling of and Contact with Plaintiffs' Treating Healthcare Providers in the Initial Bellwether Pool (D.E. 114).

On February 15, 2024, Merck served on the bellwether plaintiffs one set of Requests for Productions, Interrogatories, and Requests for Admissions. As noted above, the parties agreed that Merck's additional case-specific discovery requests to the bellwether plaintiffs can be deferred to Phase III of the litigation (if applicable).

Merck has issued subpoenas *duces tecum* to multiple bellwether plaintiffs' parents. Certain bellwether plaintiffs' parents have produced documents in response to the subpoenas; others are preparing documents in response to Merck's subpoena. The parties are meeting and conferring about the scope of Merck's third-party subpoenas.

E. Privilege Log

Over several months, the parties met and conferred about Merck's privilege log. Plaintiffs

have identified documents they assert have been improperly withheld or redacted. In response, Merck has re-reviewed many of those documents and has re-produced some of those documents in part or in full and confirmed its original privilege designations over other documents. While the parties have not completed the process of conferring about all of the documents Plaintiffs have or expect to challenge, the parties currently disagree how about to resolve their remaining disputes about certain documents for which Merck maintained its privilege designation in whole or in part following challenge. The parties will be prepared to discuss these disputes at the April Conference and seek guidance from the Court as necessary.

F. Plaintiffs' Fact Sheet Productions

Plaintiffs have produced Plaintiff Fact Sheets Part I, II, III, and IV, additional authorizations, and responsive documents in several cases. The parties will continue to meet and confer about ESI production of materials Plaintiffs produced as part of PFS productions. Merck is reviewing the received PFSs and productions for deficiencies and will be meeting and conferring with Plaintiffs regarding Merck's observed deficiencies, if any. Plaintiffs continue to supplement and produce PFSs and documents on an ongoing basis as complaints are filed.

G. Defendant Fact Sheets

Merck has served several DFSs pursuant to the DFS Order and is continuing to serve and supplement DFSs. Plaintiffs are reviewing the received DFSs for deficiencies and are meeting and conferring with Merck regarding Plaintiffs' observed deficiencies.

Date: April 18, 2024

/s/ K. Rachel Lanier
K. Rachel Lanier
Co-Lead Counsel for Plaintiffs
THE LANIER LAW FIRM

Respectfully submitted,

/s/ David C. Wright III
Allyson M. Julien
Co-Lead Counsel for Merck
GOLDMAN ISMAIL TOMASELLI

2829 Townsgate Road, Suite 100,
Westlake Village, CA 91361
rachel.lanier@lanierlawfirm.com

Bijan Esfandiari
Co-Lead Counsel for Plaintiffs
WISNER BAUM
11111 Santa Monica Blvd., Suite 1750
Los Angeles, CA 90025
Telephone: (310) 207-3233
Facsimile: (310) 820-7444
besfandiari@wisnerbaum.com

Paul J. Pennock
Co-Lead Counsel for Plaintiffs
MORGAN & MORGAN
350 Fifth Avenue, Suite 6705
New York, NY 10118
Telephone: (212) 738-6839
ppennock@forthepeople.com

Allison Mullins
Liaison Counsel for Plaintiffs
MULLINS DUNCAN HARRELL &
RUSSELL PLLC
300 N. Greene Street, Suite 2000
Greensboro, NC 27401
Telephone: (336) 645-3321
amullins@turningpointlit.com

BRENNAN & BAUM LLP
200 South Wacker Drive
22nd Floor
Chicago, IL 60606
Telephone: (312) 881-5968
Facsimile: (312) 881-5191
ajulien@goldmanismail.com

David E. Dukes
Co-Lead Counsel for Merck
NELSON MULLINS RILEY &
SCARBOROUGH LLP
1320 Main Street, 17th Floor
Columbia, SC 29201
Telephone: (803) 255-9451
Facsimile: (803) 256-7500
david.dukes@nelsonmullins.com

David C. Wright III
Liaison Counsel for Merck
ROBINSON, BRADSHAW & HINSON P.A.
101 N. Tryon Street, Suite 1900
Charlotte, NC 28246
Telephone: (704) 377-8322
Facsimile: (704) 373-3922
dwright@robinsonbradshaw.com