UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NORTH CAROLINA

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO ALL CASES**	**MDL No. 3036** **Civil Action No. 3:22-md-03036-KDB**

JOINT STATUS REPORT FOR JULY 18, 2024 PRETRIAL CONFERENCE

The parties jointly submit the following status report ahead of the Pretrial Conference scheduled on July 18, 2024, at 1:30 p.m.:

I. PLEADINGS

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

Merck filed 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), Shanie Roman (Case No. 3:24-cv-00278), and Angela Walker (Case No. 3:24-CV-00433) MDL matters (D.E. 144). Plaintiffs' response to Merck's motion was filed on June 17, 2024 (D.E. 153), and Merck's reply was filed on July 2, 2024 (D.E. 157).

Merck also filed 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 (D.E. 141). Pro se Plaintiff Nielsen's response to Merck's motion was due by June 17, 2024. Merck mailed copies of its motion to Plaintiff Nielsen's original mailing address and to the new address that was subsequently identified. To date, no response has been filed or otherwise served on Merck. On July 9, the Court entered an Order directing Plaintiff Nielson to respond on or by July 26.

II. DISCOVERY

A. Merck Depositions and Discovery

1. Overall schedule

On May 13, 2024, the Court entered an Order granting the Parties' joint request to extend the fact discovery deadlines and subsequent expert discovery and briefing deadlines in the Second Case Management Order (D.E. 140). Phase I fact discovery as set forth in the Order is set to close on August 5, 2024, with the exception that case-specific depositions can continue to occur after the deadline.

The Parties agree that none of the issues below warrant any change to the discovery limits as set forth in the Second Case Management Order or to the case deadlines as set forth in the recently stipulated and entered Order granting the parties' Joint Motion to Modify Case Management Order (D.E. 122, 138, 140). In view of the August 5 fact discovery deadline and with leave of the Court, the parties are prepared to each submit supplemental six-page, double-spaced statements regarding any remaining disputes by Tuesday, July 16 at 5 p.m. ET. The parties propose these supplemental statements to aid the Court in resolving any remaining issues.

2. Rule 30(b)(6) depositions

To date, eight Rule 30(b)(6) depositions related to Merck's pharmacovigilance processes, Gardasil clinical trials, and Merck's sales and marketing of Gardasil have occurred.

3. Merck witness depositions

a. General status

To date, fourteen Rule 30(b)(1) depositions of current and former Merck employees have occurred subject to the Second Case Management Order (D.E. 122). Three additional depositions of current or former Merck employees are scheduled to occur. The parties are meeting and

conferring about the scheduling of two additional requested Rule 30(b)(1) depositions of current and former Merck employees. Due to one witness's unavailability due to working internationally, the parties agreed that one of those depositions can occur after the close of fact discovery, and no subsequent deadlines will be affected. On July 9, Plaintiffs requested five additional depositions of current and former Merck employees. Merck is assessing these recently received deposition requests to determine if it has any objections. The parties will be prepared to discuss this matter at the July MDL Conference. Merck witness depositions have been and will continue to be crossed-noticed in the individual California state court matters.

b. Additional time with certain witnesses

At the time of this filing, Plaintiffs and Merck are meeting and conferring concerning Plaintiffs' request for three additional hours of deposition testimony beyond the 7 hours allotted under the Rules and Deposition Protocol with three Merck witness depositions (current Merck employee Dr. Bernhard Heiles (deposed on April 24, 2024), former Merck employee Dr. Veronica Urdaneta (deposed on May 8, 2024), and former Merck employee Dr. Fabio Lievano (deposed on May 16, 2024)). The parties disagree regarding Plaintiffs' request for three additional hours of deposition with each of these witnesses. The parties will be prepared to discuss at the July MDL Conference.

c. Requested deposition of Julie Gerberding

Plaintiffs requested the deposition of former Merck employee Dr. Gerberding, who served as the Director of the CDC and then became President of Merck Vaccines. Merck has objected to Plaintiffs' request for Dr. Gerberding's deposition on multiple grounds. First, Merck's understanding is that if Plaintiffs seek deposition testimony regarding Dr. Gerberding's work as the Director of the CDC, Plaintiffs must obtain an authorization from the head of the Department

of Health and Human Services for any such testimony pursuant to the *Touhy* doctrine and applicable regulations. At this time, Plaintiffs have not obtained this required authorization, but are in the process of obtaining such authorization. Additionally, Merck has objected to Dr. Gerberding's deposition related to her work as a former high-level executive as unduly burdensome, duplicative, and irrelevant. Merck has requested additional information from Plaintiffs and remains willing to confer. While the Parties continue to meet and confer, Plaintiffs have requested that Merck obtain available dates from Dr. Gerberding.

The parties continue to meet and confer and will be prepared to discuss at the July MDL conference.

4. Additional Discovery Items

On June 28, Plaintiffs selected five additional document sources pursuant to the parties' agreement in the Second Case Management Order (D.E. 122). The parties are meeting and conferring regarding whether Merck's forthcoming production of documents from these five document sources exhausts the remaining Merck document sources allotted to Plaintiffs pursuant to the parties' agreement in the Second Case Management Order (D.E. 122). The parties have additional discovery items that they are discussing and hope to have resolved prior to the hearing, but should any items remain, the parties will be prepared to discuss them in their respective supplemental statement on Tuesday and at the July MDL Conference.

B. California State Court Coordination

1. Trial schedules

There are currently seven Gardasil cases pending in California state court. Citing the Court's guidance from the beginning of the MDL and up to and including the May 2024 MDL Conference and the Court's various Orders encouraging coordination, Merck moved to continue

the first California Gardasil trial. Plaintiff Jennifer Robi and her counsel (who also serves as Plaintiff's co-lead counsel in this MDL) opposed Merck's motion. After oral argument, Merck's motion to continue was denied on June 6, 2024. Accordingly, the *Robi* trial is scheduled to commence in Los Angeles County on October 7, 2024.

The next California state court case (*Carillo*) is currently scheduled to commence on January 17, 2025, with additional trials thereafter set to begin on February 7, 2025 and February 26, 2025. Merck previously suggested to Plaintiff's counsel in those cases (who again serves as Plaintiff's co-lead counsel in this MDL) that the parties agree to a short continuance to allow continued coordination with this MDL proceeding. Plaintiff's counsel deferred in answering that request, but is not opposed to a short extension of these January and February 2025 trial dates. In light of the Court's guidance and in the interest of coordination of appropriate pretrial proceedings, Merck submits that these trials should be continued so that general expert discovery can be coordinated and until a reasonable time after briefing is completed on implied preemption and general causation briefing. The parties will be prepared to update the Court about the status of California state court coordination with this MDL at the July MDL Conference.

2. Merck discovery

On May 24, 2024, Plaintiffs served two document requests in the California cases. These are Request for Production 333 ("Please produce all YOUR communications with UpToDate Concerning GARDASIL") and Request for Production 334 ("Please produce all YOUR communications with the American Academy of Pediatrics (AAP) Concerning GARDASIL"). Merck objected to these requests, among other reasons, because they are (1) generic Merck discovery not unique to California, and thus subject to the discovery limits in the Second Case Management Order (D.E. 140) and (2) overly broad under the Court's prior Order on Plaintiffs'

Motion to Compel (D.E. 80, p. 4-5). Plaintiffs maintain these requests are case-specific to the California state court matters based on specific prescriber testimony obtained in those cases. In the interest of coordination, Merck submits that to the extent there is a dispute around these generic requests, that dispute should be resolved in this MDL. The parties will be prepared to discuss at the July MDL conference.

C. Plaintiffs' Third-Party Subpoenas

Plaintiffs have served subpoenas for depositions and documents on multiple third parties. Plaintiffs have served subpoenas *duces tecum* and for oral depositions on four authors of the Chao (2011) study, which is a publication of data from one of Merck's post-marketing commitment studies 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 depositions of the authors subpoenaed in the *Robi* matter are scheduled to occur in July. The authors subpoenaed in the MDL have served objections.

Plaintiffs have also served or informed Merck they intend to serve subpoenas *duces tecum* and for Rule 30(b)(6) deposition testimony on the American Academy of Pediatrics and UpToDate (a clinical resource site). Plaintiffs have also served or informed Merck they intend to serve subpoenas *duces tecum* and for oral depositions on a former chair of the CDC's Advisory Committee on Immunization Practices (ACIP), another member of the ACIP, an UpToDate contributor, and a medical doctor who is a co-inventor of a different vaccine.

D. Bellwether Case Updates

Almost all depositions of bellwether Plaintiffs and, if applicable, their parents have occurred, and the parties are continuing to complete 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, the written discovery deadline, Merck served on the bellwether plaintiffs one set of Requests for Productions, Interrogatories, and Requests for Admissions. Plaintiffs provided responses to the Requests for Admissions on April 19, 2024, and promised to provide supplemental responses to the Interrogatories and Requests for Productions through Plaintiffs' initial expert disclosures, on or before August 19, 2024. 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

With the benefit of the learnings from the Court's *in camera* process (and with the additional learning to be gained from the Court's rulings on the 50 documents submitted on June 28 over which Merck maintains its privilege designations in whole or in part), the parties believe that they can resolve Plaintiffs' remaining challenges to Merck's privilege designations among themselves. Merck has committed to a number of steps to reduce Plaintiffs' burden of reviewing the remainder of the documents over which Merck has claimed privilege in whole or in part. The parties agree that Plaintiffs can seek further Court review of any privilege designation challenges that the parties were not able to resolve, but the parties are hopeful that there will not be any.

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: July 11, 2024.

Respectfully submitted,

/s/ K. Rachel Lanier
K. Rachel Lanier
Co-Lead Counsel for Plaintiffs
THE LANIER LAW FIRM
2829 Townsgate Road, Suite 100
Westlake Village, CA 91361
Telephone: (713) 659-5200
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

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

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

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