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

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION	)	**MDL No. 3036**
	)	**THIS DOCUMENT RELATES TO ALL CASES**

JOINT STATUS REPORT FOR DECEMBER 14, 2022, PRETRIAL CONFERENCE

Pursuant to the Court's Second Pretrial Order, dated October 13, 2022, and the Court's Text Order, dated November 4, 2022, the parties jointly submit the following status report ahead of the Second Pretrial Conference on December 14, 2022, at 11:00 a.m.:

I. Preliminary MDL Orders

a. Proper party order

The parties reached agreement on a Proper Party-Defendant Stipulation and Proposed Order, which was previously attached as Exhibit A to the Joint Status Report for the November 9, 2022, Pretrial Conference. ECF No. 35 at p. 24.

b. Waiver of service

The parties reached agreement on a Waiver of Service Stipulation and Proposed Order, which was previously attached as Exhibit B to the Joint Status Report for the November 9, 2022, Pretrial Conference. ECF No. 35 at p. 27.

c. Direct filing order

The parties reached agreement on a Direct Filing Stipulation and Proposed Order, which was attached as Exhibit C to the Joint Status Report for the November 9, 2022, Pretrial Conference. ECF No. 35 at p. 30.

d. Protective order

The parties continue to negotiate a Protective Order. The parties will provide an update at the December Case Management Conference.

e. ESI order

The parties expect to reach agreement as to an ESI Order, but are still meeting and conferring to finalize. The Parties will provide an update at the December Case Management Conference.

f. Science Day

The parties have met and conferred on a proposed Science Day Order and continue meeting and conferring as to the substance of said Order. The Parties hope to reach agreement prior to the December Case Management Conference.

II. Pleadings

a. Deadline for amending pleadings

The parties have agreed to a December 15, 2022, deadline for amended pleadings.

b. Deadline for filing counterclaims, crossclaims, and third-party complaints

The parties have agreed to a December 22, 2022, deadline for filing counterclaims, crossclaims, and third-party complaints.

c. Deadline for Merck's Federal Rule of Civil Procedure 12 motions

i. Plaintiffs' Position

Plaintiffs' position is that there should not be Rule 12 motion practice in this MDL. Plaintiffs also object to the characterization of these motions as "bellwether" motions. The Defendants have served and filed Answers in a dozen cases rather than file any type of Rule 12 motion. Moreover, as noted in Plaintiffs' initial position statement (see Docket No. 13 at 5-7), many of the arguments Merck made in its prior Rule 12 motions were rejected and, in others, the issues were merely crystalized for re-pleading. Plaintiffs, of course, cannot stop Defendants from filing Rule 12 motions, but believe that the business of this MDL should be to move forward with discovery and address any generally applicable issues following the conclusion of discovery. The Defendants themselves admit the Rule 12 motions will not result in the termination of this MDL. The cases, probably all of them, will continue and will require discovery to ripen other issues. Further, the discovery that will take place will necessarily require discovery on the matters Defendants want dismissed (fraud allegations, marketing issues, and manufacturing lot variation), or the commencement of discovery will need to be delayed for some significant period of time – certainly months. For these reasons, Rule 12 practice is needlessly disruptive to the MDL.

ii. Merck's Position

Merck proposes a January 17, 2023, deadline to file bellwether motions to dismiss on two exemplar Complaints (*Bergin* (W.D.N.C.) and *America* (N.D.N.Y.)). While Plaintiffs oppose Merck's request to file bellwether motions to dismiss, Plaintiffs do not oppose Merck's proposed January 17, 2023, deadline should the Court grant Merck's request. As previewed in Merck's position statement, ECF No. 12 at p. 15, Merck's bellwether motions to dismiss will address common pleading deficiencies that appear across the cases (e.g., direct failure to warn claims and thinly veiled design defect claims barred by the Vaccine Act, inadequately pleaded manufacturing defect claims, and generic fraud claims). In the interest of efficiency in this MDL setting, Merck's

bellwether Rule 12 motions will not focus on case-specific or state-specific failures, and Merck is not seeking a stay pending the Court's ruling on its motions. Prior to transfer, multiple federal courts agreed with Merck and dismissed Gardasil Plaintiffs' complaints, in part or in full, on these very grounds. *See Flores v. Merck & Co.*, No. 3:21-CV-00166, 2022 WL 798374, at *3–9 (D. Nev. Mar. 16, 2022) (dismissing complaint because plaintiff failed to plead a manufacturing defect claim; plaintiff's warning claims based on a failure to warn the plaintiff directly were preempted; plaintiff's allegations regarding Merck's alleged failure to warn her physician, including in her warranty claim, were "conclusory and [did] not yield a facially plausible claim" *id.* at *5; and plaintiff's fraud allegations failed under Rule 9); ECF No. 12-2, *Herlth v. Merck & Co.*, No. 3:21-CV-438, 2022 WL 788669, at *5–10 (D. Conn. Mar. 15, 2022) (dismissing plaintiff's complaint and finding that she "alleges a design-defect claim dressed up as a manufacturing-defect claim" and she failed to state a fraud claim under Rule 9(b)); *Colbath v. Merck & Co., Inc., et al.*, No. 3:21-cv-120-W, 2022 WL 935195 (S.D. Cal. Mar. 29, 2022) (dismissing Gardasil plaintiff's manufacturing defect claims and intentional and negligent misrepresentation claims); *Stratton v. Merck & Co., Inc., et al.*, 2021 WL 5416705 (D.S.C. Nov. 17, 2021) (dismissing Gardasil plaintiff's direct failure to warn claim, manufacturing defect claim, negligence claim to the extent it is "a veiled design defect claim preempted by the Vaccine Act"). Merck submits there is no need to defer the adjudication of these pleading deficiencies, which have been recognized by courts across the country, until a later time.

By filing its proposed bellwether Rule 12(c) motion(s) on a limited, but global, set of deficiencies, Merck asks that the Court's order regarding Merck's Rule 12 motion provide that Merck has not waived any of its Federal Rule of Civil Procedure 12(b) defenses in any current or

future case in this MDL, and that Merck may assert these case-specific defenses by motion at a later date or on remand.

d. Form of Merck's answer (whether Merck's answer shall be filed as a general denial and list of affirmative defenses or answer to individual complaints) and Deadline

i. Plaintiffs' Position

Plaintiffs are agreeable to Merck's proposal as listed below, with the understanding that this list will not be preliminary as to any general affirmative defenses that are broadly applicable to the cases in the MDL, but only preliminary to the extent there are affirmative defenses only applicable to individual cases or are specific to a particular state. As Merck states in the footnote below, and Plaintiffs agree, absent a change in the law broadly applicable to these cases, Merck will not seek to at-will amend general affirmative defenses in this MDL proceeding. However, Plaintiffs propose that, if a case were to be remanded, then within 30 days of any remand order issuing, Plaintiffs may amend their complaint and Defendant may, 30 days thereafter, serve an amended answer and include any affirmative defenses it chooses to assert in that specific case.

ii. Merck's Position

In the interest of efficiency, Merck requests to file—in lieu of individual answers—the following on January 6, 2023: (1) a general denial, (2) a limited set of admissions to certain allegations, and (3) a preliminary list of affirmative defenses (that are not case-specific or state-specific but rather are applicable to all or most cases in the MDL).[1] In cases selected for bellwether workup, Merck will file a case-specific answer within 21 days of bellwether selection. In the event any cases are remanded, Merck will file a case-specific answer within 21 days of remand. This

[1] This list will not be preliminary as to any general affirmative defenses that are broadly applicable to the cases in the MDL, but only preliminary to the extent there are affirmative defenses only applicable to individual cases or are specific to a particular state. Absent a change in the law broadly applicable to these cases, Merck agrees that it will not seek to at-will amend general affirmative defenses in this MDL proceeding.

proposal is far more efficient than clogging the Court's docket with individual answers to Plaintiffs' dozens of nearly identical complaints. This type of order has previously been entered in another MDL where, like in this MDL, no master complaint had been entered. *See* Ex. D to the Joint Status Report for the November 9, 2022, Pretrial Conference. ECF No. 35 at p. 37, *In re: Aqueous Film-Forming Foams Prods. Liab. Litig.,* MDL No. 2:18-mn-2873-RMG, CMO 20 (General Denial and Preliminary Statement of Affirmative Defenses in Lieu of Answers). Further, Merck would still provide a case- and state-specific answer in any cases selected for bellwether workup or on remand, so Plaintiffs would know which defenses are at issue in any cases being actively litigated and discovered.

As with Merck's bellwether motions to dismiss, in filing a general denial and preliminary list of affirmative defenses, Merck asks that the Court's order regarding the form of and deadline for Merck's answer provide that Merck has not waived any state-specific or case-specific defenses in non-bellwether cases (which may be pleaded in a full Answer upon remand or at another appropriate date), has not waived any of its Federal Rule of Civil Procedure 12(b) defenses in any current or future case in this MDL, and that Merck may assert these case-specific defenses by motion at a later date or on remand.

III. Discovery Plan

i. Parties' Position

Since the initial pretrial conference, the parties met and conferred extensively about the discovery plan for this MDL. Despite these efforts, the parties were unable to reach agreement on a joint proposal for a discovery plan. Plaintiffs continue to seek a traditional, bellwether discovery program with full workup of certain cases, and Merck continues to seek a schedule that prioritizes the dispositive issues of general causation and preemption. Although the parties continue to

disagree about whether the Court should enter Merck's prioritized discovery proposal or Plaintiffs' bellwether workup discovery proposal, the parties have worked together to reach agreement on a schedule for both options.

Plaintiffs' statement in support of full bellwether workup proposal is further detailed in their respective section below. *See infra* at p. 10. Should the Court order traditional bellwether workup, as Plaintiffs propose, the parties have reached agreement on the following schedule:

- 12/15/2022 – Amended pleading deadline
- 12/22/2022 – Deadline for counterclaims, crossclaims, and 3rd party complaints
- 1/2023 or 2/2023 – Science Day (or whenever convenient for the Court)
- 1/6/2023 – Merck's General Answer and Preliminary List of Affirmative Defenses due
- 1/17/2023 – Merck's Bellwether Motion to Dismiss due (*Bergin* (W.D.N.C.) and *America* (N.D.N.Y.))
- 1/26/2023 – Parties to simultaneously exchange list of cases in which their client does not waive *Lexecon*
- 3/28/2023[2] – Selection of 16 cases (of alleged injuries agreed to by the parties) for bellwether workup
- 21 days after Selection of Bellwethers – Merck's case-specific answers due
- 2/15/2024 – Deadline for completion of fact discovery
- 2/29/2024 – Selection of 10 bellwethers from 16 for completion of expert workup
- 4/15/2024 – Plaintiffs' expert reports due in bellwether cases
- 5/30/2024 – Merck's expert reports due in bellwether cases
- 7/29/2024 – Deadline for completion of expert discovery
- 8/5/2024 – Selection of 6 trial-ready picks from pool of 10 bellwethers selected for expert workup
- 8/22/2024 – *Daubert* and Summary Judgment motions due in 6 trial-ready picks
- 10/10/2024 – *Daubert* and Summary Judgment oppositions due in 6 trial-ready picks
- 11/11/2024 – *Daubert* and Summary Judgment replies due in 6 trial-ready picks
- Trial Dates and subsequent pretrial deadlines for 6 trial-ready picks to be determined after ruling on *Daubert* and Summary Judgment motions

Merck's statement in support of its prioritized discovery plan is further detailed in its respective section below. *See infra* at p. 14. Should the Court order a discovery plan that prioritizes

[2] The parties have tentatively agreed to this date assuming that any remaining ESI Protocol, Protective Order, and PFS issues are resolved promptly and there are no major issues with authorizations and records collection.

general causation and preemption as Merck requests, the parties have reached agreement on the following schedule:

- 12/15/2022 – Amended pleading deadline
- 12/22/2022 – Deadline for counterclaims, crossclaims, and 3rd party complaints
- 1/2023 or 2/2023 – Science Day (or whenever convenient for Court)
- 1/6/2023 –Merck's General Answer and Preliminary List of Affirmative Defenses due
- 1/26/2023 – Parties to simultaneously exchange list of cases in which their client does not waive *Lexecon*
- 1/17/2023 – Merck's Bellwether Motion to Dismiss due (*Bergin* (W.D.N.C.) and *America* (N.D.N.Y.))
- 3/28/2023[3] – Selection of 16 POTS, CFS, and CRPS (and/or other agreed alleged injuries) bellwethers for core initial workup (comprised of Plaintiff, parents, vaccinating doctor(s), one treater of each party's choosing)
- 21 days after Selection of Bellwethers – Merck's case-specific answers due
- 2/15/2024 – Deadline for completion of fact discovery

GENERAL CAUSATION EXPERT DISCOVERY AND *DAUBERT* BRIEFING AND GENERAL CAUSATION AND PREEMPTION MOTION FOR SUMMARY JUDGMENT

- 3/14/2024 – Plaintiffs' general causation expert reports due
- 4/11/2024 – Merck's general causation expert reports due
- 5/23/2024 – Deadline for general causation expert discovery
- 7/8/2024 – *Daubert* and Summary Judgment motions due
- 8/22/2024 – Oppositions to *Daubert* and Summary Judgment due
- 9/23/2024 – Replies ISO *Daubert* and Summary Judgment motions due
    - *Daubert* focused solely on general causation and Summary Judgment focused solely on general causation and preemption related to POTS, CFS, and CRPS

STAY OF FURTHER CASE-SPECIFIC BELLWETHER DISCOVERY PENDING RULING ON MERCK'S *DAUBERT* MOTIONS AND MOTION FOR SUMMARY JUDGMENT

- Only if Motion for Summary Judgment Denied:
    - 4 months after Motion for Summary Judgment ruling– Complete remaining fact discovery in 16 bellwether cases

[3] The parties have tentatively agreed to this date assuming that any remaining ESI Protocol, Protective Order, and PFS issues are resolved promptly and there are no major issues with authorizations and records collection.

- 7 days after completion of fact discovery – Selection of 10 cases for expert discovery
- 30 days after selection – Plaintiffs' case-specific (and other non-general causation) expert reports due in 10 cases
- 30 days after Plaintiffs' reports due – Merck's case-specific expert reports due in 10 cases
- 60 days after Merck's expert reports – Deadline for completion of remaining case-specific expert discovery in 10 cases
- 7 days after expert discovery deadline – Selection of 6 trial-ready picks
- 30 days after selection – Case-specific *Daubert* (and other non-general causation) and Summary Judgment motions (other than general causation and preemption) due in 6 trial-ready cases
- 30 days after *Daubert* and Summary Judgment Motions – Oppositions due
- 30 days after *Daubert* and Summary Judgment Motion Oppositions – Replies due

Under both proposals, the parties have also agreed to the following:

- The parties agree that bellwether selection should be made from a select pool of alleged injuries. The parties are meeting and conferring on the alleged injury pool from which the parties will select bellwether cases.
- The parties also agree that the bellwether pool should be comprised of 16 cases, with 5 of those cases to be selected by Plaintiffs, 5 of those cases to be selected by Merck, 2 of those cases to be currently pending suits originally filed in the W.D.N.C. (*Hilton* and *Bergin*), and 4 additional random picks chosen from select agreed categories of alleged injuries.
- The parties agree to negotiate a proposed bellwether discovery order, which will include, among other things, the agreements on bellwether selection detailed above and assumed limits on the number of depositions.
- The parties agree to exchange a list of cases in which their clients do not consent to waive *Lexecon* venue objections on January 26, 2023. Within one week of this exchange (on or by February 2, 2023), the parties will determine whether bellwether selection will be limited to cases where both parties waive *Lexecon*. The parties hope to reach agreement

that bellwether selection of any cases not originally filed in the W.D.N.C. will be limited to cases where both parties have agreed to waive *Lexecon*.

ii. Plaintiffs' Position

Plaintiffs propose a traditional Bellwether selection and discovery program with full workup of certain Bellwether cases. The contours of this proposal are highlighted *supra* and Plaintiffs' position is set forth below:

The cases selected shall have one of the injuries on an agreed-to list of injury categories. (Plaintiffs have agreed that the Bellwether cases, whether Limited Core or Traditional, will be selected from categories of injuries but have asked Defendants to meet and confer on categories, and Plaintiffs have expressed the objection that one of Defendants' categories (Chronic Fatigue Syndrome alone) is not in fact extant in this MDL.) Plaintiffs will immediately provide to Defendants all medical records in their possession and Defendants will do the same. Plaintiffs will serve a fact sheet (that must be substantially complete) and authorizations on all filed cases as soon as possible and no later than December 29, 2022.[4] Plaintiffs shall immediately provide all medical records in Plaintiffs' possession and shall continuously and immediately provide any newly received records on all filed cases through the selection date, and Defendants shall do the same. From this pool of cases, on **March 28, 2023**:

- Plaintiffs pick five cases,
- Defendants pick five cases,
- Two cases from North Carolina are automatically selected,
- Four additional cases picked by randomizer,

[4] This date assumes that any remaining ESI Protocol, Protective Order, and PFS issues are resolved promptly.

- The selections for each side are blinded to the other when the selections are made. If there is a selection of the same case by both sides, that case remains and another case is selected by a randomizer.
- All 16 cases are fully discovered factually, but the pool is reduced for general and case specific expert disclosure and discovery.

On January 26, 2022, the parties shall simultaneously exchange a list of eligible cases in which their client does not consent to "waive *Lexecon.*" Both sides agree that the goal is to have 100% participation but recognize that, especially with the individual plaintiffs, agreement to try their case in North Carolina might not be achieved for a number of reasons.

This Bellwether selection program will give us a motion/trial pool of six fully worked up cases by August 2024. Plaintiffs believe this proposal is not only superior to Merck's proposal because all issues, including case specific causation and other case specific issues, will be ripe for determination on the same time-table, rather than stacking a second time-table on top of the first, but a second time-table as proposed by Merck will certainly take an additional year. Furthermore, this approach has been repeatedly used in MDLs of this nature with great success and efficiency for 30 years.

Indeed, Plaintiff's bellwether selection and discovery program is superior to Merck's proposal for several reasons.

First, it is efficient. Under Plaintiffs' proposal, all dispositive and *Daubert* motions will be fully briefed by **November 11, 2024**, at which point the Court will have six trial-ready cases. Merck's proposal, though, requires multiple rounds of dispositive and *Daubert* motions, with the first round, focusing only on general causation and preemption, ending on September 23, 2024, and the second round, focusing on all other issues, ending almost a ***full year*** after the parties

receive the Court's ruling on Merck's first set of motions for summary judgment. If, for example, the Court were to deny Merck's first round of dispositive and *Daubert* motions on September 24, 2024—one day after it receives Merck's replies—then the earliest the Court would receive all briefing on the next round of dispositive and *Daubert* motions, under this unlikely hypothetical, would be sometime in **August 2025**.

Practically speaking, under Merck's proposal, the Court likely will not receive all briefing on the dispositive and Daubert motions in this litigation until ***2026***. Merck touts its proposal as efficient, but it assumes Merck will prevail on general causation and preemption in the first round. In reality, Merck's truncated discovery plan promotes a delay of over one year, contrary to the guiding principles set forth in the Manual for Complex Litigation, and it assumes Merck's preemption and general causation defenses must be prioritized over all else. Plaintiffs' proposal is straightforward, time-saving, cost-saving, logical, and fair.

Second, Plaintiffs' proposed Bellwether program tracks the approach that has repeatedly been used in MDLs of this nature with great success for 30 years. For as long as there have been civil liability actions, there has existed an ordinary pattern of developing the evidence necessary for both sides to prove the elements of their case: discovery is exchanged that is relevant to both liability and causation, expert discovery on both general and specific causation commences, then defendants may choose to move for summary judgment. While mass tort litigation is an extension of the traditional civil action, it still adopts this standard pretrial protocol. Thus, Courts presiding over coordinated mass tort actions overwhelmingly follow this traditional and sensible protocol to this day.

Examples from several pharmaceutical mass tort litigations which did not place abnormal restrictions on the parties' case specific workup are instructive:

See In Re: Baycol Products Liability Litigation, MDL No. 1431, Judge Michael J. Davis (D. Minn.); *In Re: Seroquel Products Liability Litigation,* MDL No. 1769, Judge Anne Conway (M.D. Fla.); *In Re: Avandia Marketing, Sales Practices And Products Liability Litigation*, MDL No. 1871, Judge Cynthia M. Rufe (E.D. Pa.); *In Re: Yasmin and Yaz (Drospirenone) Marketing, Sales Practices And Products Liability Litigation,* MDL No. 2100, Judge David R. Herndon (S.D. Ill.); *In Re: Depuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation,* MDL No. 2224, Judge James E. Kinkeade (N.D. Tex.); *In Re: Alendronate Sodium Products Liability Litigation,* MDL No. 2243, Judge Joel Pisano (D. N.J.); *In Re: 3m Combat Arms Earplug Products Liability Litigation,* MDL No. 2285, Judge M. Casey Rodgers (N.D. Fla.); *In Re: Actos (Pioglitazone) Products Liability Litigation,* MDL No. 2299, Judge Rebecca F. Doherty (W.D. La.); *In Re: Testosterone Replacement Therapy Products Liability Litigation*, MDL No. 2545, Judge Matthew F. Kennelly (N.D. Ill.); *In Re: Power Morcellator Products Liability Litigation,* MDL No. 2652, Judge Kathryn H. Vratil (D. Kan.); *In Re: Proton-Pump Inhibitor Products Liability Litigation (No. II),* MDL No. 2789, Judge Claire C. Cecchi (D. N.J.); and *In Re: Elmiron (Pentosan Polysulfate Sodium) Products Liability Litigation,* MDL No. 2973, Judge Brian R. Martinotti (D. N.J.).

Merck does not explain why this case should operate any differently from countless other pharmaceutical mass torts that have similarly addressed general causation issues and preemption defenses. It is Merck's proposal, not Plaintiffs', that goes against the grain.

Third, as discussed in the previous hearing, Plaintiffs' proposal will also facilitate superior scientific evaluation of the issues in these cases, as general causation experts will be able to assess and rely upon specific causation evidence, e.g., individual plaintiffs' medical histories, when drafting reports and giving testimony. While Merck is anxious to present only part of the story with its truncated discovery plan, Plaintiffs' proposed plan is the type most favored by MDL Courts in pharmaceutical litigations. It does not favor one side. It does not ask Plaintiffs to put forth only half of their case-in-chief. It requires that the parties to efficiently and economically discover and litigate all causation issues at once. In short, Plaintiffs' proposal is efficient, battle-tested, and fully evaluates the entire causation case.

iii. Merck's Position

A. Early Prioritized Resolution of the Threshold Issues of General Causation and Preemption Best Promotes Efficiency

As previewed in its Position Statement (ECF No. 12), Merck's proposed discovery plan promotes efficiency by prioritizing the dispositive, threshold issues of general causation and implied preemption for early consideration and resolution. The Manual for Complex Litigation ("MCL") endorses this approach. MCL §§ 22.634 ("Issues to be taken up early in the litigation may include . . . whether the facts and expert evidence support a finding that the products or acts in question have the capacity to cause the type of injuries alleged . . . [and] whether plaintiffs' claims are barred by statutes of limitations or other legal bars"), 22.87. And numerous MDL courts have agreed that general causation and preemption are globally dispositive issues—dismissing entire MDLs with many more litigants on one of these two independent bases.[5]

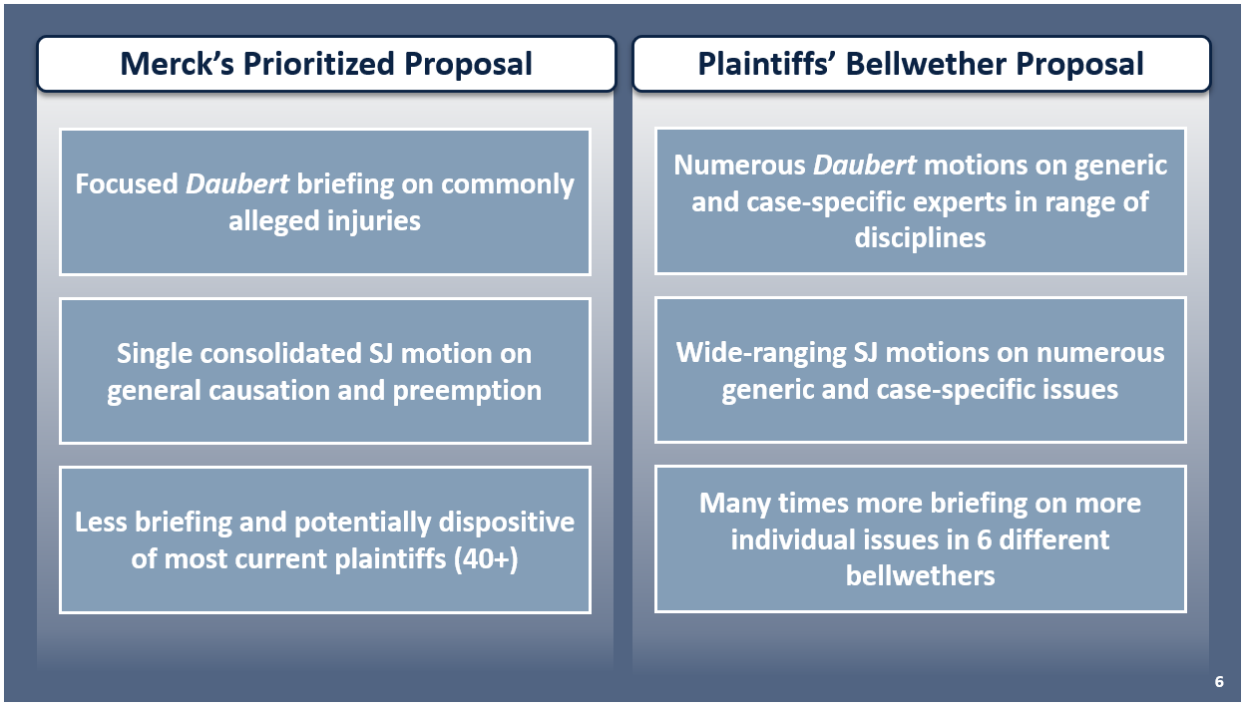
Because Plaintiffs in this MDL allege a broad range of injuries, there is no hallmark alleged harm claimed by all Plaintiffs. *See* ECF No. 12, at p. 20-23 (App'x A); *see also* Ex. E to the Joint Status Report for the November 9, 2022, Pretrial Conference. ECF No. 35 at p. 40. To efficiently and systematically address this range of alleged injuries, Merck requests that the Court structure this MDL to first address two threshold, dispositive issues regarding three of the most commonly alleged injuries (Postural Orthostatic Tachycardia Syndrome ("POTS")—alleged by 37 Plaintiffs,

[5] *See, e.g., In re Zofran (Ondansetron) Prod. Liab. Litig.*, 541 F. Supp. 3d 164 (D. Mass. 2021) (granting defendants' summary judgment motion on preemption grounds); *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d 1007 (S.D. Cal. 2021) (granting defendants' summary judgment motion on both preemption and lack of general causation evidence grounds*); In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213 (S.D.N.Y. 2018) (granted manufacturer defendant's Daubert motions to exclude all seven of Plaintiffs' general causation experts), 387 F. Supp. 3d 323 (S.D.N.Y. June 11, 2019) (granting summary judgment), *aff'd*, 982 F.3d 113 (2d Cir. 2020); *In re Zoloft (Sertralinehydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 501 (E.D. Pa. April 5, 2016) (granting summary judgment after excluding plaintiffs' general causation experts because "Plaintiffs have failed to raise a jury question on the necessary predicate to success in any case: that Zoloft was capable of causing their injuries"), *aff'd*, 858 F.3d 787 (3d Cir. 2017).

Chronic Fatigue Syndrome ("CFS")—alleged by 15 Plaintiffs,[6] and Chronic Regional Pain Syndrome ("CRPS")—alleged by 4 Plaintiffs): (1) whether there is any reliable evidence that Gardasil can cause POTS, CFS, or CRPS—general causation; and (2) whether Plaintiffs' central claim that Merck failed to warn of POTS, CFS, and CRPS in the Gardasil label is preempted by federal law—implied preemption.

Merck's prioritized discovery proposal and the underlying bases in support are detailed in their entirety in the Joint Status Report for the November 9, 2022, Pretrial Conference. ECF No. 35 at pp. 9-20. Merck continues to believe that significant efficiencies would be gained by adopting Merck's prioritized discovery plan, particularly when compared to Plaintiffs' individual bellwether workup proposal:

[6] The basis for Plaintiffs' blanket objection to "Chronic Fatigue Syndrome" being an alleged injury in this MDL is unclear as numerous Plaintiffs in this litigation (currently 11) allege that Gardasil caused them to develop "Chronic Fatigue Syndrome" in their Complaints. *See e.g., America v. Merck & Co. Inc., et al.*, Case No. 3:22-cv-00585, ECF No. 1, Complaint at p. 52 ("Gardasil and Its Ingredients Caused Plaintiff's Injuries, Including…Chronic Fatigue Syndrome"); *Reddicks v. Merck & Co. Inc., et al*., Case No. 3:22-cv-00438, ECF No. 1, Complaint at 52 ("Arriana Reddicks Sustained Autoimmune Disease and Other Serious Injuries, Including but Not Limited to…Chronic Fatigue Syndrome"). Chronic Fatigue Syndrome is a recognized medical condition characterized by extreme exhaustion lasting for at least six months. *See* Cleveland Clinic, Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), available at https://my.clevelandclinic.org/health/diseases/17720-myalgic-encephalomyelitischronicfatigue-syndrome-mecfs.



Fewer Daubert Motions on Fewer Experts: Under Plaintiffs' proposal, Merck and Plaintiffs would disclose expert reports on all general and case-specific experts and then submit motions to exclude some or all of the testimony of each of those experts in 6 different cases. The number of *Daubert* motions submitted to this Court, should it adopt Plaintiffs' proposed individual bellwether structure, could quickly number in the dozens. For example, Merck expects to disclose at least five case-specific experts in one of the California matters. Scaling that assumption to the MDL, that number could grow to more than 30 defense expert reports across 6 cases, not including general causation and other generic expert reports. Should Plaintiffs disclose a similar number of experts, the number of *Daubert* motions submitted to this Court on case-specific experts alone could become unwieldy. By contrast, under Merck's proposal, both parties would first only designate and complete expert discovery on a far more limited number of generic general causation experts opining solely on the common issue of whether Gardasil can cause POTS, CFS, or CRPS. No resources would need to be expended and no briefing would need to be submitted on case-

specific experts without a predicate finding that Plaintiffs' general causation expert evidence satisfies Rule 702.

Fewer Summary Judgment Motions on Fewer Issues: In addition to potentially dozens of *Daubert* motions on case-specific issues, Plaintiffs' proposal also calls for the parties to submit summary judgment briefing in 6 different bellwethers on a wide range of generic and case-specific issues. Plaintiffs do not propose limiting summary judgment briefing to causation or preemption; rather the floodgates would be open to state-law and case-specific arguments. By contrast, Merck proposes that the parties first submit a single round of generic summary judgment briefing applicable to all cases alleging POTS, CFS, and CRPS on the narrower, but dispositive, issues of general causation and preemption.

Impact on > 40 Plaintiffs: Merck's proposal has the benefit of efficiently adjudicating the claims of more than 40 Plaintiffs—most of the currently-filed cases—while preserving the parties' and the Court's resources and requiring the submission of far fewer briefs to the Court.

Accordingly, Merck respectfully requests that the Court enter a schedule prioritizing the threshold issues of general causation and preemption.

IV. Discovery Disputes and Coordination of CA State Court Litigation with MDL

Consistent with the Court's recommendations during the last hearing, the parties reached a resolution concerning the discovery disputes that had a pending November 4, 2002, adjudication/hearing in California state court. After meeting and conferring, the parties have agreed to have the disputes that were the subject of the California motion, adjudicated by the MDL. Specifically, counsel for the California plaintiff agreed to vacate the November 4, 2022, discovery hearing in California and the disputed discovery issues will now be filed in the MDL. Plaintiffs filed their motion to compel concerning the interrogatories and document request responses that

Plaintiffs believe are deficient on November 18, 2022. ECF No. 36. The parties agreed that Merck's opposition is due on December 16, 2022, and Plaintiffs' reply is due on December 30, 2022. The parties filed a joint motion for an extension of time memorializing their agreement on November 22, 2022. ECF No. 38. The joint motion was granted on November 29, 2022.

Consistent with the Court's Pretrial Order 2, the parties are meeting and conferring about the trial dates and related discovery schedules for the seven matters pending in California state court in order to maximize coordination and minimize duplication between these California state court proceedings and the MDL. Those California matters currently have the following trial dates:

- *Robi v. Merck & Co., Inc., et al.* – May 1, 2023
- *Carrillo v. Merck & Co., Inc., et al.* – July 7, 2023
- *Otto v. Merck & Co., Inc., et al.* – August 4, 2023
- *Shain v. Merck & Co., Inc., et al.* – September 25, 2023
- *Brunker v. Merck & Co., Inc., et al.* – not scheduled
- *Rizi v. Merck & Co., Inc., et al.* – not scheduled
- *Trevisan v. Merck & Co., Inc., et al.* – not scheduled

Merck has proposed that the parties jointly move for continuances of the current trial dates in these California matters (of approx. 13 – 14 months) to be more consistent with the agreed MDL schedule. Plaintiffs are conferring with their clients about this offer.

Finally, Merck filed a Motion for a Protective Order to Retain Confidentiality ("*Robi* Confidentiality Motion") on October 3, 2022, in response to California plaintiff Jennifer Robi's January 14, 2022, and August 1, 2022, requests to de-designate dozens of Merck documents that had previously been produced with a confidential designation in California Gardasil litigation. That motion was scheduled to be heard in the *Robi* matter in February 2023. Merck met and conferred with Ms. Robi's counsel, who also serves as co-lead counsel in this MDL, to determine whether Plaintiffs opposed Merck's request that the *Robi* Confidentiality Motion be heard in the MDL in the interest of efficiency, since it involves documents that soon will be produced in the

MDL. The parties agreed that the *Robi* Confidentiality Motion then-pending in California state court would be withdrawn and that the February 2023 hearing on the motion would be vacated with each side preserving all of their respective rights and arguments related thereto. The parties further agreed that Merck's withdrawal of the *Robi* Confidentiality Motion does not constitute a failure to timely address Plaintiff's objections to the disputed documents that were the subject of the motion. The parties also agreed that the disputed documents in the *Robi* Confidentiality Motion will retain their "Confidential" status and all protections afforded documents marked "Confidential" will remain in effect for the documents at issue in the *Robi* Confidentiality Motion, unless and until a motion, if any, is heard and ruled upon by this MDL court. The parties are in the process of filing a stipulation before the *Robi* court memorializing their agreement.

V. Fact Sheets

The parties are meeting and conferring regarding a proposed Plaintiff Fact Sheet ("PFS"), Parent/Guardian Fact Sheet ("P/GFS"), Defendants' Fact Sheet ("DFS"), a PFS and P/GFS Order, and a DFS Order.

PFS:

The parties have met and conferred extensively on the PFS and have agreed on dozens of points. However, there are currently three major areas of disagreement that the parties are prepared to raise with the Court at the December 14, 2022, conference and submit briefing if useful to the Court. The parties have submitted competing proposals on the following issues:

A. ***Vaccine Court File*:**

i. Plaintiffs' Position

Congress and the courts are clear that the substance of proceedings in the Vaccine Injury Compensation Program ("VICP" or the "Program") has no bearing on civil suits filed in district

court. *See* 42 U.S.C. § 300aa-23(e) ("any finding of fact or conclusion of law" from the Vaccine Program "shall not be admissible" at "any stage of a civil action"); *see, e.g.*, *Case v. Merck & Co.*, No. 02-1779, 2002 WL 31478219, at *7 (E.D. La. Nov. 5, 2002) (holding the resolution of causation in the Vaccine Program "does not control the resolution of this issue in this Court"); *John & Jane Doe 2 v. OrthoClinical Diagnostics, Inc.*, 335 F, Supp. 2d 614, 635-36 (M.D.N.C. 2004) (the Vaccine Program's inquiry on causation "is independent of this Court's inquiry" and the Vaccine Program's resolution of a matter cannot bind the district court). The United States Supreme Court noted that a civil action filed after the VICP claim is a 'de novo" action. *Shalala v. Whitecotton*, 524 U.S. 268, 270 (1995) (noting that a "claimant…must exhaust the Act's procedures and refuse to accept the resulting judgment before filing any *de novo* civil action in state or federal court.") The only potential bearing Vaccine Program materials could have on this Court's proceedings is for confirmation that a particular plaintiff complied with the VICP prerequisites before filing a civil action. *See Guillot v. Aventis Pasteur, Inc.*, No. 02-3373, 2013 WL 4508003, at *4 (E.D. La. Aug. 22, 2013) (noting that proceedings in the Vaccine Program may not be used for substantive purposes but could be considered "to determine whether plaintiffs complied with the … prerequisites to filing a civil tort suit"). Moreover, as can be explained more fully in briefing or other presentation to the Court, unique aspects of the VICP make production of VICP materials burdensome and inappropriate. Thus, any production in non-bellwether cases should be limited to documents that show the plaintiff satisfied the VICP prerequisite prior to filing in federal court, which involves two or three documents, depending on how the petitioner exited the Program. Nonetheless, Plaintiffs agree to provide the following from the Vaccine Court File: (1) the Petition (without attachments), demonstrating appropriate VICP filing; (2) Sworn statements/affidavits from Plaintiff, parent(s), and treating physicians, (3) medical records

(excluding mental health records) in Plaintiff's possession, (4) the public decision/order concluding the VICP action; and, in cases that did not exit at the 240-day window, (5) an Election to file civil action, which likewise rejects the VICP decision. In bellwether cases, Plaintiffs would agree to provide the prerequisite documents and, in addition, other sworn statements that were filed in the VICP of those who are witnesses or likely to be witnesses in the bellwether case (e.g., friends, teachers, coaches, and similar). In addition, to the extent that an expert from a plaintiff's VICP matter is designated as a testifying expert in that same plaintiff's bellwether case, reports from any such expert (both Plaintiff and Defendant (which would additionally require the Government's consent)) could be appropriate for provision.

ii. Merck's Position

Merck proposes the following RFP and authorization related to Plaintiffs' Vaccine Court files:

- *Any documents or filings made on your behalf in Vaccine Court, except that attorney billing records submitted to the Vaccine Court may be excluded.*
- *Exhibit 1 is: an authorization for the release of Plaintiff's Vaccine Court file. Plaintiff must also attach to this authorization a copy of a government-issued ID (e.g., a driver's license or U.S. passport). Attorney billing records will be screened from any production of the Vaccine Court file prior to Merck receiving a copy.*

Merck is entitled to the entire Vaccine Court file (with the exception of attorney billing records) for every Plaintiff in this MDL, and its production poses only a minimal burden. Each plaintiff's Vaccine Court file is squarely relevant, discoverable, and includes a wealth of probative material. *See* Fed. R. Civ. P. 26(b)(1). Plaintiffs' Vaccine Court files vary from case-to-case but, collectively, include: (1) the Department of Health and Human Services' ("HHS" – the respondent

in Vaccine Court) and the plaintiffs' Vaccine Court experts' reports, (2) medical literature, (3) education records, (4) plaintiff's Vaccine Adverse Event Reporting System ("VAERS") Report/VAERS-related analyses, (5) case reports detailing the plaintiff's symptoms, signs, diagnosis, treatment, and follow-up of an individual patient, (6) letters from treating physicians, (7) letters/timelines created by the plaintiff and/or their parents, (8) photographs, (9) phone records, (10) statements of completion, and (11) merits hearing-related submissions and transcripts.

Importantly, Vaccine Court filings are generally restricted and accessible only to court personnel and counsel of record. Merck is not a party to the Vaccine Court proceedings. Thus, absent Plaintiffs' production of the file or an authorization process to collect the file directly, Merck cannot access this information. As a result, Plaintiffs' proposal creates a substantial information asymmetry: Plaintiffs' and their experts would have the benefit of Plaintiffs' complete Vaccine Court files to develop their case, while Merck would receive only documents hand-picked by Plaintiffs. Plaintiffs' proposal directly interferes with Merck's ability to defend itself in this litigation, including its implied preemption defenses and its timeliness and exhaustion challenges.

Plaintiffs' argument conflates admissibility with discoverability. Although "any finding of fact or conclusion of law" and "the final judgment" of the Vaccine Court or the special master are not "admissible," the Vaccine Court file is still highly relevant, probative, and discoverable. Every plaintiff in this MDL, after all, had to timely file a petition and exhaust his or her Gardasil-related claims in Vaccine Court regarding the very injuries at issue in his or her federal lawsuit.

Finally, Plaintiffs' objections ignore the history of this litigation. Since July of 2021, Merck and co-lead MDL Plaintiffs' counsel Bijan Esfandiari agreed upon and implemented a process to collect Vaccine Court files. In the process—which the Vaccine Court clerk approved—a plaintiff

signed a form and provided a scanned ID card authorizing the production of their file. A representative for HHS then signed an authorization, and the entire file was produced to both Merck and the plaintiff via a shared records vendor. In fact, Merck has already collected the entire Vaccine Court files of eight plaintiffs in this MDL and two plaintiffs in California state court by agreement. There is no legally sound basis for the parties now to change course.

B. *Mental Health Records*:

i. Plaintiffs' Position

Plaintiffs have agreed to provide mental health records if the Plaintiff is making a claim for mental or psychological injury (excluding claims solely based on pain and suffering, emotional distress, and/or mental anguish). Merck, however, seeks to obtain the most sensitive and private records of one's life, simply based on a "symptoms" test: if you claim a particular symptom, you must divulge these most private records. Merck seeks this despite the fact that these symptoms are all medically recognized symptoms of autoimmune injury and are in fact part of the clinical diagnostic symptoms of certain autoimmune disorders. Specifically, if the Plaintiff claims in her tort action, or even in the prior vaccine proceeding, that she has POTS, orthostatic intolerance, diminished cognitive concentration and focus, chronic fatigue, hypotension, hallucinations, severe insomnia, excessive sleep (more than 15 hours per day), non-epileptic seizures, movement disorder, or functional neurologic disorder, then, as Merck would have it, Merck receives all mental health records. *See* Merck's Proposal in PFS, III.1, Ex. XX. It is Plaintiffs' understanding that this is a broad stroke effort at alleging that Plaintiffs' injuries in this MDL are nothing more than "psychosomatic" injuries and/or symptoms. Merck does not want to be put to a showing, through the extensive *medical* records Plaintiffs agree to fully provide, that there is some compelling basis to obtain the mental health records. Merck simply wants all mental health records

to see what they can make of them. The ascription of a woman's medical symptoms to mental health issue finds its genesis in a stereotype that the world of medicine has relegated to the dustbin. It has been a studied and documented fact, for decades, that this type of shunting of women's complaints to mental health status and gender bias is finally being put to an end. In 2018, a study found that doctors are more likely to view women with a chronic pain condition as "emotional" or "hysterical."[7] The study also found that doctors were more likely to treat women's pain as a product of a mental health condition, rather than a physical condition.[8] A separate 2018 survey arrived at a similar conclusion, finding that many healthcare professionals believed that women exaggerate their pain.[9] The bottom line is that proper medical treatments were for years not dispensed because of such an endemic attitude. It is no longer countenanced in medicine and should not be countenanced here. If the medical records provide a basis for implicating "psychosomatic" origin and a proper showing can be made, then this issue can ripen for a review of the appropriate disclosure. To urge, however, that across the board these plaintiffs are not really injured but are just mentally or emotionally ill is entirely without basis and should be flatly rejected.

ii. Merck's Position

Merck proposes the following RFP: *Plaintiff's medical records obtained from any source. This request does not seek Plaintiff's Mental Health Records, unless (a) mental health records were submitted in Plaintiff's Vaccine Court proceeding, (b) Plaintiff is making, or made in Vaccine Court, a claim for mental or psychological injury (excluding a claim solely based on pain and*

[7] Samulowitz et al., *"Brave Men" and "Emotional Women:" A Theory-Guided Literature Review on Gender Bias in Health Care and Gendered Norms towards Patients with Chronic Pain*, Pain Research and Management, vol. 2018, Article ID 6358654, 14 pages, 2018.
[8] *Id*.
[9] Wesolowicz et al., *The Roles of Gender and Profession on Gender Role Expectations of Pain in Health Care Professionals*, Journal of Pain Research, vol. 2018, pages 1121-1128 (2018).

suffering, emotional distress, and/or mental anguish), (c) Plaintiff is claiming, or claimed in Vaccine Court, that she/he/they have POTS, orthostatic intolerance, brain fog, chronic fatigue syndrome, hypotension, hallucinations, severe insomnia, excessive sleep (more than 15 hours per day), non-epileptic seizures, movement disorder, or functional neurologic disorder (FND), (d) Counsel for Plaintiff and Counsel for Merck agree that the Mental Health Records of the Plaintiff are discoverable or (e) the Court so orders.

Merck has requested Plaintiffs' mental-health records in three situations in which those records are plainly relevant:

1. Where those records were submitted to the Vaccine Court;
2. Where the plaintiff claimed mental or psychological injury in the Vaccine Court; and
3. Where the plaintiff is claiming, or claimed in Vaccine Court, to have certain medical conditions—in particular, POTS, orthostatic intolerance, brain fog, chronic fatigue syndrome, hypotension, hallucinations, severe insomnia, excessive sleep (more than 15 hours per day), non-epileptic seizures, movement disorder, or functional neurologic disorder (FND).

As to the first two categories, mental health and/or psychiatric conditions appear to have been at issue in at least 19 current MDL plaintiffs' Vaccine Court proceedings—proceedings where they ostensibly exhausted the very injuries alleged in this MDL. In these cases, between one and seven mental health care providers (e.g., psychiatrists, psychologists, counselors, and social workers) are identified as having provided medical records and/or other evidence. In short, plaintiffs who put their own mental health at issue in Vaccine Court cannot now disclaim the relevance of their mental-health records in their federal lawsuits.

As to the third category, mental-health records are directly relevant to Merck's defense of alternative causation. Reputable medical authorities recognize that psychological conditions can involve physical symptoms. This recognition is a medical reality, not an attack on any plaintiff or other person. *See* Psychosomatic Disorder, Cleveland Clinic, available at https://my.clevelandclinic.org/health/diseases/21521-psychosomatic-disorder. In addition, significant overlap exists between Plaintiffs' alleged injuries and various mental-health conditions. Consider, for example, the overlapping symptoms of POTS and anxiety.[10]

POTS	Anxiety
Heart palpitations or racing heart	Heart palpitations
Brain fog	Difficulty concentrating
Exhaustion/Fatigue	Being easily fatigued
Headaches	Headaches, muscle aches, stomachaches or unexplained pains
Feeling nervous or anxious	

Medical records from mental healthcare providers that reflect alternative explanations for Plaintiffs' claimed conditions and alleged symptoms are therefore highly relevant—and therefore discoverable.

Plaintiffs have no answers to these substantive points. Instead, Plaintiffs accuse Merck of making a gender-based attack. Merck deeply disagrees with and is troubled by this unfounded accusation. That accusation's premise is also factually untrue: this MDL includes both female and male plaintiffs.

C. *Plaintiffs' Pictures, Videos, and Social Media Content*:

[10] *Compare* POTS, Cleveland Clinic, available at https://my.clevelandclinic.org/health/diseases/16560-postural-orthostatic-tachycardia-syndrome-pots *with* Generalized Anxiety Disorder, Cleveland Clinic, available at https://my.clevelandclinic.org/health/diseases/23940-generalized-anxiety-disorder-gad.

i. Plaintiffs' Position

The Plaintiffs agree that if a Plaintiff has used social media platforms to share information about Gardasil or the conditions they allege in their lawsuit (for the period three years prior to vaccination with Gardasil to two years after any injuries resolved), Plaintiffs will identify which social media platforms they use. (*See* PFS Part II - Section I.F.3). And, with respect to Merck's proposed RFPs, Plaintiffs would agree that if a Plaintiff posted on their social media platforms any pictures, content, text, comments, or other information about Gardasil or Plaintiff's conditions caused by Gardasil, all Plaintiffs with responsive documents *would produce such documents.* (*See* PFS Part III – Request No. 13). Merck insists, however, that every single Plaintiff identify which social media platforms each Plaintiff has used and provide "all pictures, content, text, comments … about Plaintiff's health, social activities, family activities, vacations, trips, school-related activities, sports, holidays, life events (including, but not limited to, graduations, birthdays, weddings, and religious celebrations), work, diet, or fitness posted on any social media platforms, internet chat rooms, social media groups, or other online media." This unbridled foray into everything from religious events to chat rooms should be rejected. Social media posts do not capture the mundane day-to-day activities that one does, or does not do, but instead such posts are used to share personal highlights of happiness and fun that one wishes to share with a select audience. However hard or difficult or painful the rest of your hour, day or week was, you might still post pictures at your niece's First Communion, your grandfather's birthday party, going on a beach walk, or persevering through a vacation. Merck it seems needs to be reminded that disabled people and people who are in chronic pain still try to live their lives to the fullest extent possible and usually with far greater perseverance and fortitude than those more fortunate. Indeed, there is, thankfully, an entire body of law in this country to help ensure that they can do this with as few

barriers as possible. Furthermore, Plaintiffs' position is Merck has taken some facts and circumstances out of context regarding plaintiffs who have suffered debilitating injuries shortly after receiving doses of Gardasil in order to justify document/photo requests that are premature for all plaintiffs, over-broad, and unduly burdensome.

ii. Merck's Position

Merck proposes the following RFPs regarding relevant social media content and Plaintiffs' pictures and videos:

- *For the period from the date of Plaintiff's vaccination with Gardasil to two (2) years after Plaintiff's claimed injury(ies) resolved, all pictures, content, text, comments, or any other information about Gardasil or Plaintiff's conditions caused by Gardasil posted on any social media platforms, internet "chat rooms," social media groups, or other online media. If Plaintiff claims that the injuries allegedly caused by Gardasil impaired Plaintiff's ability to engage in normal activities or that Gardasil caused severe and permanent or debilitating injuries, for the same time period, all pictures, content, text, comments or any other information about Plaintiff's health, social activities, family activities, vacations, trips, school-related activities, sports, holidays, milestone life events (including, but not limited to, graduations, birthdays, weddings, and religious celebrations), work, diet, or fitness posted on any social media platforms, internet "chat rooms," social media groups, or other online media.*
- *For the period from the date of Plaintiff's vaccination with Gardasil to two (2) years after Plaintiff's claimed injury(ies) resolved, all photographs or videos of Plaintiff (with or without other people) that relate to Gardasil or other vaccines or that concern or evidence Plaintiff's health or Plaintiff's claimed injuries. If Plaintiff claims that the injuries*

allegedly caused by Gardasil impaired Plaintiff's ability to engage in normal activities or that Gardasil caused severe and permanent or debilitating injuries, for the same time period, all photographs or videos of Plaintiff (with or without other people) that relate to Plaintiff's ability to engage in exercise, sports, celebrations (including but not limited to, graduations, birthdays, weddings, and religious celebrations), vacations, or recreational activities.

Plaintiffs in this MDL have universally placed their quality of life at issue. They allege that Gardasil caused them to develop debilitating injuries and prevented them from engaging in "normal" life activities. While Merck appreciates Plaintiffs' offer to provide their pictures, videos, and social media content specifically about Gardasil and Plaintiffs' alleged injuries, that only provides a portion of the story. Merck is entitled to the production of pictures, videos, and social media content that reveal the *full* scope of Plaintiffs' quality of life. Merck has reasonably requested portions of Plaintiffs' pictures, videos, and social media content showing them engaging in activities that potentially can serve to disprove their alleged injuries and/or mitigate their claimed damages. Responsive material reflecting capabilities inconsistent with Plaintiffs' claims are relevant to Merck's defenses and will shape bellwether selection strategy.

To offer just one example, one plaintiff in this MDL alleges that she was "bedridden" for "several years" after her Gardasil dose. At her deposition, however, Merck learned that she spent those same years riding four-wheelers and mountain biking. That plaintiff failed to produce dozens of pictures and videos depicting herself engaging in those and other recreational activities until *after* her deposition, despite an RFP similar to the one at issue here pending for several months. In another instance, a now-dismissed plaintiff alleged in her complaint that Gardasil caused her to suffer from "severe, debilitating, disabling, and painful chronic injuries" and that she was "unable

to engage in normal activities that a young adult would enjoy." But her social media presence revealed another perspective on the story—one of international travel and frequent socializing with friends. Just as Plaintiffs are entitled to present evidence of their claimed injuries and limitations, Merck is entitled to develop evidence that may rebut Plaintiffs' allegations.

Merck's requests for certain of Plaintiffs' pictures, videos, and social media are critical to bellwether case assessment and informed selection of these cases for trial workup. Merck's request is not burdensome and could be implemented through Plaintiffs' e-discovery vendor. Under Plaintiffs' proposal, Merck would be required to select a handful of cases for discovery workup and trial without accessing this probative information. Meanwhile, Plaintiffs would have the benefit of informed selection with unfettered access to this information. Merck's requests have been reasonably tailored by time and scope and should be included in the PFS.

DFS and PFS and DFS Orders:

The parties are meeting and conferring on the DFS and the related PFS and DFS Orders, and anticipate submitting those proposed orders to the Court prior to the January pretrial conference.

P/GFS:

Although Merck continues to believe that a Parent/Guardian Fact Sheet would be the most efficient means to collect discovery from Plaintiffs' parents or guardians, the parties are conferring about alternative means to efficiently gather relevant materials from Plaintiffs' parents or guardians, for instance, where parents or guardians consented to a minor plaintiff receiving the Gardasil vaccine or filed claims in the Office of the Special Masters in the U.S. Court of Federal Claims ("Vaccine Court") on behalf of the plaintiff related to Gardasil.

Date: December 2, 2022

Respectfully submitted,

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