BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO. _____

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED PRETRIAL PROCEEDINGS

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I. INTRODUCTION

Pursuant to 28 U.S.C. 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Plaintiffs Sahara K. Walker, Jasmyne Gramza, Michael A. Colbath, Korrine A. Herlth, Mark Thomas on behalf of Z.T., Skylee A. Butler, Emma E. Sullivan, Savannah M. Flores, Julia Balasco, Abigail R. Stratton, Ashley K. Dalton, Madelyn G. Malloy, Corinn McElerney, Ruby D. Silver and Ashley Muller respectfully submit this Memorandum of Law in Support of their Motion for Transfer and request to centralize all currently filed cases (hereinafter referred to as "Subject Actions")[1] as well as any subsequently filed cases involving common issues of fact. For the reasons discussed below, the Subject Actions should be transferred and centralized in either the District of Arizona before the Honorable Judge Douglas L. Rayes or the Western District of Wisconsin before the Honorable Judge James D. Peterson.

Movants are Plaintiffs in 15 civil actions pending in 14 different federal district courts across the U.S. alleging they were injured after receiving Gardasil, Merck's "cervical cancer vaccine," which purportedly prevents a handful of strains of the Human Papillomavirus ("HPV"). Plaintiffs seek to recover under theories of negligence, strict liability (failure to warn and manufacturing defect), breach of warranty, common law fraud and violation of various state laws. The undersigned law firm represents Plaintiffs in their actions against Defendants, Merck & Co., Inc. and Merck Sharpe & Dohme Corp. (collectively "Merck"), for personal injuries, including, but not limited to, autoimmune diseases caused by the Gardasil vaccine.

In addition to the 15 actions described above, there are at least 19 additional actions alleging similar facts and injuries pending in 12 different federal district courts before 18

[1] *See*, Schedule of Subject Actions, attached hereto as Exhibit "A."

different judges.[2] These 19 additional actions are being handled by at least seven different law firms. Accordingly, there are currently a total of at least 34 Gardasil personal injury autoimmune lawsuits pending in 25 different district courts, before 32 different judges being handled by eight different plaintiffs' law firms.

In addition to the aforementioned 34 Gardasil autoimmune cases pending in federal district courts, there are approximately 39 additional Gardasil autoimmune cases that have already gone through the mandatory U.S. Court of Federal Claims ("Vaccine Court") process and will in all likelihood be filed in the coming months in federal courts across the country; and 52 additional Gardasil autoimmune cases currently pending in Vaccine Court, which upon conclusion of the Vaccine Court proceedings, will proceed with filing traditional tort claims, akin to the plaintiffs who currently have Gardasil tort cases pending in various district courts.[3] If

[2] In addition, there are at least five Gardasil-related matters currently pending in state courts (namely, California). The pendency of state court matters supports the creation of an MDL because "an MDL will make it easier to coordinate, as needed, pretrial proceedings in both the state and federal cases, because there will now be just one judge handling the latter." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 997 F. Supp. 2d 1354, 1356 (J.P.M.L. 2014).

[3] For certain vaccines such as Gardasil, federal law, pursuant to Section 300aa-11 of the National Childhood Vaccine Injury Act of 1986 ("the Vaccine Act"), generally does not permit a person to bring a civil action against a vaccine manufacturer until the injured person has first filed a petition in the Vaccine Court (i.e., United States Court of Federal Claims) and has obtained a judgement from the Vaccine Court. 42 U.S.C.A. § 300aa-11. After the Vaccine Court issues its judgment, the petitioner has the option of rejecting the judgment and electing to file a *civil action* against the manufacturer. 42 U.S.C.A. §§ 300aa-11(a)(2) & § 300aa-21(a). The Vaccine Court program is a no-fault system, discovery is generally not permitted (other than obtaining plaintiff's medical records) and monetary caps are placed on damages awarded through the vaccine court program. 42 U.S.C.A. §§ 12(d)(2)(E) (limits on discovery in Vaccine Court); 300aa-15 (damages limitations in Vaccine Court); *see also Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011) (discussing the vaccine court). Generally, the petitioner is required to participate in the program for at least 240 days and if no decision on the substantive merits has been reached by that time, she can decide to opt out of the program to pursue civil remedies against the vaccine manufacturer in either state or federal court. 42 U.S.C.A. § 300aa-21(b)(1) & § 300aa-12(d)(3) & 12(g); *Bruesewitz*, 562 U.S. at 228. Even if a judgment on the merits is issued by the vaccine court, the petitioner has the option to reject the judgment (whether

all of the cases currently in Vaccine Court and those that have recently come out of Vaccine Court are filed in federal courts (which is likely), there will be 129 Gardasil autoimmune personal injury cases in federal district courts. Moreover, undersigned counsel and other firms across the country are investigating many more Gardasil-related cases which will likely result in further litigation.[4] Coordination of pretrial proceedings is necessary to avoid duplicative discovery, unduly burdensome discovery obligations, and inconsistent rulings on pretrial motions. Centralization will preserve resources of the parties, counsel, and the judiciary.

Although the facts pertaining to individual Plaintiffs will vary, the Subject Actions present common, complex factual issues related to the clinical trials, regulatory approval, manufacturing, pharmacovigilance, labeling and marketing of Gardasil and Merck's knowledge of the vaccine's adverse effects. As Merck's counsel recently stated during a status conference in a pending Gardasil lawsuit, "there are certainly some common issues with respect to the injury."[5] Accordingly, transfer will promote the just and efficient conduct of the actions and the Subject Actions are suitable for transfer, coordination, and centralization.

II. GARDASIL FACTUAL BACKGROUND

In June 2006, after the Food and Drug Administration's ("FDA") fast-tracked review, Gardasil was approved for use in females ages 9 through 26 for the purported prevention of cervical cancer. In December 2014, the FDA approved Gardasil 9 (containing the same

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favorable or adverse) and pursue traditional tort remedies under state common law against the vaccine manufacturer. 42 U.S.C.A. § 300aa-21; *Bruesewitz*, 562 U.S. at 228. Should a petitioner elect to pursue tort damages under state common law, neither the judgment nor the findings from the vaccine court are admissible in any future civil action. 42 U.S.C.A. § 300aa-23(e).

[4] As way of example, undersigned counsel is aware of at least 50 additional Gardasil autoimmune cases awaiting to be filed in Vaccine Court.

[5] See, **Exh. 1**, Transcript of December 18, 2020 hearing in *Gramza* at 25:7-8.

ingredients as Gardasil, but in higher quantities)[6] for use in girls ages 9 through 26 and boys ages 9 through 15 for the purported prevention of cervical, vaginal, and anal cancers. This rush to approval left unanswered questions relating to the efficacy and safety of the vaccine. Merck obscured information relating to these issues. Presently, Gardasil 9 has been approved for and is being promoted by Merck to males and females between 9 and 45 years of age, with an emphasis on pre-teens and their parents. In a best-case scenario, Gardasil causes immune hyperactivation and production of anti-HPV antibodies to fend off certain strains of the HPV virus. In a worst-case scenario, it causes the immune system to lose its ability to differentiate human proteins from foreign proteins, causing the immune system to attack the body's own proteins and organs.

To stimulate an enhanced immune response, Merck added adjuvants to the Gardasil vaccine, including (but not limited to) a proprietary aluminum known as amorphous aluminum hydroxyphosphate sulfate (AAHS) and HPV LI-DNA fragments. Because of the peptide commonality between HPV and human proteins, the attack triggered by the Gardasil adjuvants can cause cross-reactions and dangerous attacks against human proteins.[7] This process, which is referred to as "molecular mimicry," can cause autoimmune disorder. Except for the *Gramza* case[8], it is believed that nearly all the other 33 Gardasil cases presently pending in federal court are plaintiffs who allege they sustained neurological autoimmune autonomic injuries known as

[6] After the approval of the Gardasil 9 vaccine, the original Gardasil vaccine was phased out of the U.S. Market and the original Gardasil vaccine is no longer available for sale in the United States.
[7] 82 heptapeptide sequences have been identified that overlap perfectly with the HPV16 proteins. "Based on the need for five or six amino acids to induce a monoclonal antibody response, the 82 heptapeptide overlaps can clearly induce autoimmune reactions." Darja Kanduc, *Quantifying the Possible Cross-Reactivity Risk of an HPV16 Vaccine*, 8 Journal of Experimental Therapeutics and Oncology 65 (2009).
[8] In *Gramza*, the injury at issue Is Immune Thrombocytopenic Purpura (ITP), a blood clotting issue, but as discussed infra, the mechanism of action (i.e., molecular mimicry) for Gardasil causing ITP and POTS are identical and the injury is simply dictated by what cells in the body exhibit the immune intolerance caused by Gardasil.

Postural Orthostatic Tachycardia Syndrome (POTS) or Orthostatic Intolerance[9]. Merck's counsel has admitted the commonality of the injuries involved. During a hearing in *Gramza* (an ITP injury case), Merck's counsel informed the court the injury has common issues with a POTS injury case pending in California. **Exh. 1** at 25.

III. LITIGATION BACKGROUND AND STATUS

As noted above, 34 Gardasil-related civil actions are currently pending in 25 different federal district courts: U.S. District Court for the Western District of Wisconsin; U.S. District Court for the Middle District of Florida; U.S. District Court for the District of Rhode Island; U.S. District Court for the District of Massachusetts; U.S. District Court for the Southern District of California; U.S. District Court for the Eastern District of Michigan; U.S. District Court for the District of Nevada; U.S. District Court for the District of Arizona; U.S. District Court for the District of Connecticut; U.S. District Court for the Central District of Illinois; U.S. District Court for the Eastern District of Texas; U.S. District Court for the Northern District of Florida; U.S. District Court for the District of South Carolina; U.S. District Court for the Central District of California; U.S. District Court for the District of Hawaii; U.S. District Court for the District of New Jersey; U.S. District Court for the Middle District of Louisiana; U.S. District Court for the

[9] In individuals who are suffering from POTS or orthostatic intolerance, the body's autonomic nervous system fails to compensate for the upright posture which over time results in a myriad of injuries and symptoms associated with the upper extremities not getting enough blood, these symptoms and injuries include, among others, fainting, chronic fatigue, chronic headaches, vision issues (blurry vision and in a worst case scenario, blindness), cardiovascular issues, gastrointestinal issues and neuropathic pain. POTS and Orthostatic Intolerance are autoimmune diseases. *See* Li et al., *Autoimmune Basis for Postural Tachycardia Syndrome*, 3 J. AMERICAN HEART ASSOC. e000755 (2014); Ruzieh et al., *The Role of Autoantibodies in the Syndromes of Orthostatic Intolerance: A Systematic Review*, 51 SCANDINAVIAN CARDIOVASCULAR J. 243 (2017); Ikeda et al., *Autoantibodies Against Autonomic Nerve Receptors in Adolescent Japanese Girls after Immunization with Human Papillomavirus Vaccine*, 2 ANNALS OF ARTHRITIS AND CLINICAL RHEUMATOLOGY 1014 (2019); Svetlana Blitshetyn, *Postural Tachycardia Syndrome Following Human Papillomavirus Vaccination*, 21 European J. of Neurology 135 (2014).

Middle District of North Carolina; U.S. District Court for the Northern District of Georgia; U.S. District Court for the Northern District of Illinois, Eastern Division; U.S. District Court for the Northern District of Indiana, Fort Wayne Division; U.S. District Court for the Northern District of Texas; U.S. District Court for the Southern District of Florida; U.S. District Court for the Southern District of West Virginia; and U.S. District Court for the Western District of North Carolina. Plaintiffs in the Subject Actions are represented by the following eight separate law firms: Baum Hedlund Aristei & Goldman, P.C.; Mullins Duncan Harrell & Russell PLLC; Van Cott & Talamante, PLLC; A Liberatore Law Offices PC; Siri & Glimstad; Bronster Fujichaku Robbins; Pendley Baudin & Coffin, LLP; and Morgan & Morgan.

As is demonstrated by the diversity of jurisdictions and respective counsel for the Subject Actions, it will be impossible to informally coordinate this litigation, as is discussed in further detail below. However, aside from the diversity of jurisdictions and counsel, the Subject Actions share many common features which mandate centralization. More specifically, the Subject Actions stem from common factual allegations, involve common Defendants, a common mechanism of injury, and common damages. Furthermore, the current procedural posture and status of discovery also point to centralization as a favorable method for case administration.

A. Common Factual Allegations

Plaintiffs in the Subject Actions allege they were injured by the Gardasil vaccine, which, through the unintended processes of molecular mimicry, caused Plaintiffs to develop autoimmune disorder, POTS/Orthostatic Intolerance and ITP. Plaintiffs allege Merck concealed the known dangers of Gardasil and that Merck's targeted consumers and doctors did not know the true risks. Plaintiffs have universally alleged throughout the Subject Actions that Merck breached its duty of reasonable care and failed to exercise ordinary care in the research,

manufacturing, testing, marketing, pharmacovigilance, promotion, and labeling of Gardasil.

Merck, through its own counsel, has recognized the common issues that predominate the Subject Actions. At a Rule 16 scheduling conference held in one of the Subject Actions, *Gramza v. Merck & Co., Inc.*,[10] Merck's counsel admitted the commonalities between *Gramza* and *Robi v. Merck & Co., Inc.*[11] which predate the Subject Actions, even though the Plaintiffs in those cases have manifested different forms of autoimmune disease (ITP and POTS, respectively) due to the Gardasil vaccine. Merck's counsel and the *Gramza* Court had the following exchange:

> THE COURT: So now what we're talking about is [*Robi v. Merck & Co., Inc., et al.*] a case in California that has the same theory of liability. Right?
> MS. GAARDER: Same theory of liability and not -- while not an identical injury, there are certainly some common issues with respect to the injury.
> THE COURT: And it's your belief that all the documents that are produced in California will be applicable to the case that's going to be tried here, and there won't be a need for production of any additional documents here in addition to what's produced in California, at least as to causation. Is that right?
> MS. GAARDER: That is our -- yes.[12]

Given that Plaintiffs' allegations stem from the same basic facts, involve the same injuries and a common mechanism of injury, centralization is appropriate.

B. Common Defendants.

Merck, as the sole manufacturer of Gardasil, is the Defendant in each of the Subject Actions. As the sole manufacturer, Merck will also be the Defendant in any of the "tag-along" matters that are expected to be filed, accordingly, Merck, centralization is appropriate.

C. Common Alleged Injuries.

The Plaintiffs in the Subject Actions allege they received the Gardasil vaccine and through the mechanism of action known as molecular mimicry, Gardasil resulted in the plaintiffs

[10] *Gramza* (Case No. 2:20-cv-01425-DLR), is pending in the District of Arizona.
[11] *Robi* (Case No. BC628589), is currently pending in state court in California.
[12] *See* **Exh. 1** at 25:4-15, Transcript of December 18, 2020 hearing in *Gramza*.

developing autoimmune disorders. All Plaintiffs likewise allege their injuries were caused by Merck's research, manufacturing, testing, marketing, promotion, and labeling of Gardasil. The factual investigation in all cases will focus on whether Gardasil has unreasonably dangerous side effects, whether Merck adequately warned of side effects and whether Gardasil caused Plaintiffs' injuries. The commonality among Plaintiffs' injuries further warrants centralization.

D. Common Procedural Status.

The First Subject Action was filed on July 17, 2020 (*Gramza*) and the most recent Gardasil autoimmune injury case was filed on or about April 5, 2022. As noted above, at least 91 additional actions are expected to be filed in the coming months (39 have exited Vaccine Court and are expected to be filed soon and 52 are in Vaccine Court and will be filed after the conclusion of the Vaccine Court) and nothing suggests the pace of filings will slow in the future.

While Merck has produced documents in a few of the cases being handled by the undersigned firm, primarily in the *Gramza* case and a state court case, undersigned counsel does not believe Merck has produced documents in any of the cases being handled by the other firms. To date, no depositions of Merck company witnesses have taken place and expert discovery has not yet begun. The only depositions that have occurred to date are the depositions of two plaintiffs (Gramza and Walker) and their respective mothers.

Scheduling Orders have been issued in some of the cases with vastly differing dates. As way of example, in one case, *Stratton*, the court has scheduled plaintiff's expert disclosures for July 1, 2022, while in *Muller*, plaintiff's expert reports are due January 30, 2023. Merck has filed Answers in several cases (without any motion practice) and in other cases it has filed motions to dismiss. The most recent motion to dismiss to be decided was in *Colbath* wherein the court denied Merck's motion as to the negligence, strict liability (failure to warn), fraud

(concealment) and false advertising causes of action and granted with leave to amend as to manufacturing defect, fraud, and express warranty. *Colbath v. Merck*, No. 3:21-CV-120-W (DEB), 2022 WL 935195 (S.D. Cal. Mar. 29, 2022). In another district court in the Ninth Circuit, reviewing a nearly identical complaint as *Colbath* with the same injuries (POTS), the court dismissed all causes of action with leave to amend. *Flores v. Merck & Co.*, No. 321CV00166MMDCLB, 2022 WL 798374 (D. Nev. Mar. 16, 2022). The issuance of conflicting orders on motions to dismiss is further justification for consolidation.

Given the current early stage of the Subject Actions, the fact that no depositions of Merck employees have taken place, expert discovery has yet to initiate, and the earliest trial date is not until next year (2023), the time is ripe to centralize these cases, and reap the maximum benefits from the creation of an MDL in terms of efficiency and preservation of resources. In the absence of centralization, the parties will inevitably face inconsistent rulings, duplicative and burdensome discovery obligations, and conflicting scheduling orders.

E. Informal Coordination is Not Feasible.

Clearly, informal coordination of 34 pending matters in 25 different courts among eight law firms is simply not achievable. This difficulty is demonstrated by prior unsuccessful efforts between the undersigned counsel and Merck's counsel to attempt to informally coordinate.

Beginning on or about January 3, 2022, undersigned counsel's office, along with another plaintiffs' firm, Morgan & Morgan, and two firms representing Merck, including Venable, LLP and Goldman Ismail Tomaselli Brennan & Baum, LLP, began to have multiple detailed discussions to attempt to informally coordinate the Gardasil litigation, which at that time had far fewer cases filed and only approximately six cases that had scheduling orders issued. The coordination discussions spanned many weeks and involved multiple calls, e-mails, text

messages as well as the exchange of various proposals until, on or about January 27, 2022, the parties reached a prospective agreement wherein they agreed, among other things: to coordinate the first five Gardasil POTS cases with an agreed upon staggered pre-trial schedule based upon the order in which the cases were filed and the pre-trial schedule attempted to permit sufficient time for plaintiffs' counsel to complete discovery; allowed for sharing of documents across those cases; allowed for a consistent ESI and Protective Order across the cases; provided a protocol for the number and length of depositions; and agreement that all discovery disputes would be adjudicated in W.D. Wisconsin which was overseeing one of the earliest filed cases (*Walker*) and the *Walker* court's ruling would be applicable to the other five coordinated cases. The pre-trial schedule, which was designed to hopefully provide Plaintiffs with the *minimal* amount of time necessary to complete discovery (assuming Merck was forthcoming with its discovery responses and documents) and disclose expert reports, was a critical component of the informal coordination process.

Once the informal coordination agreement was reached, the parties began the process of informing the respective courts. In that regard, the parties initially sent requests to two of the five proposed coordinated courts, with the intent to eventually inform all five courts. The first two district courts to be notified were *Stratton* (on January 27, 2022) and *Balasco* (on February 3, 2022). *See* **Exh. 2**, Stratton Joint Report at 12 & **Exh. 3**, Balasco Joint Motion at 3. The requests informed the two courts, inter alia, of the informal coordination efforts and asked the courts to adopt a scheduling order that was consistent with what the parties had agreed as part of their information coordination discussion and which allotted plaintiffs' counsel the appropriate minimum time to attempt to complete fact and expert discovery to address the complex issues involved in this litigation. *Id*. On February 4, 2022, the *Balasco* Court in Rhode Island amended

its then existing pre-trial schedule and specifically adopted the parties' proposed pre-trial schedule which was consistent with the informal coordination agreement. *See* **Exh. 4**. Unfortunately, the *Stratton* Court in South Carolina refused to adopt the parties' agreed upon schedule and instead implemented an Order on February 3, 2022, with a far more aggressive pre-trial schedule that as way example called for expert disclosure to occur July 1, 2022 (even the parties per their informal coordination proposal had agreed to and requested November 18, 2022), and called for a January 1, 2023 trial date (even though the parties had proposed an August 31, 2023 trial date). *See* **Exh. 5**, Stratton Order & **Exh. 2**, Joint Request at 11-12. In short, the *Stratton* Court imposed timeframes with which Plaintiffs cannot comply. Realizing the advantage to be gained by Plaintiffs' inability to comply, Merck abandoned informal coordination efforts in favor of pushing *Stratton* toward trial. In a further effort to compromise, Plaintiffs proposed dismissal of *Stratton* without prejudice, tolling deadlines while the parties pursued their original agreed upon case management schedule. Merck rejected this proposal.

Thereafter, on February 28, 2022, when Plaintiff attempted to modify the scheduling orders in the other cases, including for example the *Walker* case, consistent with what the parties had previously agreed in their informal coordination proceedings, Merck filed an opposition to Plaintiff's request to amend the scheduling order. *See* **Exh. 6**, Plaintiff's Ex Parte in *Walker* at 5 & 7-8; and **Exh. 7**, Merck's Opposition. Merck's filing of its opposition in *Walker* and opposing the very same pre-trial deadlines that it had previously agreed upon as part of the informal coordination proceedings, confirmed that Merck had abandoned informal coordination efforts. In addition, thereafter, during a Rule 26(f) meet and confer discussion concerning another Gardasil case, Merck's counsel informed undersigned counsel's office that Merck would no longer agree to apply the ESI and Protective Orders universally across all Gardasil cases and that

instead it would treat each case individually and would want to negotiate new or separate terms for each case.

The collapse of the informal coordination efforts which at that time only involved five cases and only two sets of plaintiffs' firms confirms that coordination across the now 34 Gardasil cases pending in 25 different district courts, involving at least eight different plaintiffs' law firms, is not feasible and centralization is needed to ensure the just, efficient handling of the Subject Actions.

IV. ARGUMENT

A. Centralization Is Warranted For These Cases.

1. Consolidation Is Appropriate Under Section 1407.

Under 28 U.S.C. § 1407, the Panel may consolidate multiple cases if the moving parties sufficiently demonstrate that:

1. the lawsuits involve one or more common questions of fact;
2. consolidation will best serve the convenience of the parties and witnesses; and
3. consolidation will promote the just and efficient conduct of such lawsuits.

28 U.S.C. § 1407(a). As shown herein, the Gardasil lawsuits meet the statutory requirements for centralization, and on this record, centralization in one district court for pre-trial proceedings is the most appropriate course of action for the Panel to take. Thus, centralization and coordination of pretrial proceedings against Merck is clearly warranted. *See, e.g.*, *In re: Taxotere (Doxetaxel) Eye Injury Prods Liab. Litig*., MDL No. 3203, 2022 WL 303562, at *1-*3 (J.P.M.L. Feb. 1, 2022) (recently granting centralization of thirteen lawsuits filed against Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. arising out of eye injuries suffered by Taxotere users); *see also In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig*., 330 F. Supp. 3d 1378, 1379 (J.P.M.L. 2018) (granting Merck's motion for centralization in cases wherein plaintiffs alleged they had suffered various types of injuries, including encephalitis, optical nerve damage, kidney and liver damage,

Bell's palsy, Guillain Barre Syndrome, and other injuries as due to Merck's shingles vaccine).

First, each Gardasil lawsuit alleges nearly identical facts against the same two Merck entities and concerning the same vaccine. Each lawsuit contains almost identical allegations about Gardasil and its propensity to cause neurological injuries and autoimmune diseases. In turn, Merck will deny Plaintiffs' allegations. These defenses will involve common questions of fact on both liability and causation.

Second, centralization before one MDL court will prevent inconsistent judicial rulings, would eliminate duplicative discovery, will be more convenient to the parties, witnesses, and their counsel, and will conserve the resources of the judiciary, the parties, and their counsel. *See, In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig*., 330 F. Supp. 3d at 1379 (highlighting that consolidation will eliminate duplicative discovery, prevent inconsistent pretrial rulings on *Daubert* issues and other pretrial matters, and conserve resources); *In re MLR, LLC, Patent Litig.*, 269 F. Supp. 2d 1380, 1381 (J.P.M.L. 2003) (consolidation before a single transferee judge allows for consideration of "all parties' legitimate discovery needs while ensuring that common parties and witnesses are not subjected to discovery demands which duplicate activity that has already occurred or is occurring in other actions.").[13] A transferee judge can "employ any number of techniques … to manage pretrial proceedings efficiently." *In re Proton Pump Inhibitor Prods. Liab. Litig. (No. II)*, 261 F. Supp. 3d 1351, 1354 (J.P.M.L. 2017). Consequently, "formal centralization under section 1407 is the best course." *Id.*

Indeed, because the lawsuits alleging injuries due to Merck's Gardasil vaccine are based upon substantially similar, if not identical, allegations, the parties will address similar issues in

[13] *See also In re: Farxiga (Dapagliflozin) Prods. Liab. Litig.*, 273 F. Supp. 3d 1380, 1380-83 (J.P.M.L. 2017) (same); *In re: Biomet M2A Magnum Hip Implant Prods. Liab. Litig.*, 896 F. Supp. 2d 1339, 1340 (J.P.M.L. 2012) (same).

discovery, and in some cases identical issues, especially those involving causation, Plaintiffs' injuries, and the misrepresentations on which Plaintiffs relied. *In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 148 F. Supp. 3d 1383, 1385 (J.P.M.L. 2015) (deeming transfer appropriate where related actions shared factual issues related to allegations of injuries from a defective warming system); *see also In re Actos Prods. Liab. Litig.*, 840 F. Supp. 2d 1356 (J.P.M.L. 2011) (granting consolidation where: (1) the actions involved common questions of fact regarding whether the pharmaceutical drug could cause cancer and whether defendants concealed their knowledge of the risk and failed to provide adequate warnings, and (2) centralization would eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel, and the judiciary).

Finally, as noted above, the need for centralization is warranted because there are already 34 Gardasil lawsuits on file in 25 different federal district courts across the country. These lawsuits span nine federal circuits. Taken together, these cases will ultimately result in separate scheduling orders and duplicative discovery and pretrial practices if an MDL is not created. The panel should therefore authorize an MDL so that pretrial proceedings "will be conducted in a manner leading to the just and expeditious resolution of all actions to the overall benefit of the parties." *In re: Prempro Prods. Liab. Litig.*, 254 F. Supp. 2d 1366, 1368 (J.P.M.L. 2003); *see also In re: Taxotere (Doxetaxel) Eye Injury Prods Liab. Litig.*, MDL No. 3203, 2022 WL 303562, at *1 (granting centralization for 13 lawsuits); *In re: Farxiga*, 273 F. Supp. 3d at 1381-82 (granting centralization for 18 lawsuits that involved "allegations that ingestion of the drug Farxiga may cause a variety of injuries").

2. Informal Coordination is Impractical.

Informal coordination is not a practical alternative to centralization for these cases.

"[T]he number of actions, districts, and involved counsel, and the complexity of the litigation, make effective coordination on an informal basis impracticable." *In re Uber Tech., Inc., Data Breach Litig.*, 304 F.Supp.1351, 1354 (J.P.M.L. 2018) (informal coordination was not a practicable alternative to centralization where ten actions, with a potential for seven more, were pending in nine districts). It would be inefficient and uneconomical to engage in informal coordination amongst so many different cases, districts, and involved counsel, and as previously discussed, attempts at informal coordination of the first five filed cases proved to be futile and impractical. *See In re: Roundup Prods Liab. Litig.*, 214 F.Supp. 1346, 1348 (J.P.M.L 2016) (concluding informal coordination of 37 actions pending in 21 districts was not practicable).

a. Discovery will be difficult to informally coordinate within multiple districts with cases at various stages across the country.

"The number of involved districts … pose[s] [a] significant obstacle[] to informal coordination" especially for discovery. *In re Viagra (Sildenafil Citrate) Prods. Liab. Litig.*, 224 F.Supp.3d 1330, 1331 (J.P.M.L 2016). As is common in an MDL proceeding, Plaintiffs anticipate taking the depositions of treating physicians, third-party witnesses, and current and former employees of Merck who worked on Gardasil, many of whom will be deposed in multiple cases or will discuss overlapping issues. It would be very difficult to informally coordinate the timing and scope of this discovery across numerous cases in different stages of litigation. "[A] single court can more effectively manage the discovery disputes … likely to arise, including those relating to discovery from third party witnesses, depositions of apex witnesses, and the scope of relevant discovery, generally." *In re Ahern Rentals, Inc., Trade Secret Litig.*, 481 F.Supp.3d 1355, 1356 (J.P.M.L. 2020) (granting consolidation in lieu of informal coordination for ten actions pending in eight districts). Centralization of these proceedings, rather than informal coordination, would thus be more convenient for the parties and witnesses and would

"promote the just and efficient conduct of such actions." 28 U.S.C. § 1407 (a).

b. Without a centralized process, motion practice will be duplicative, resulting in disparate judicial rulings and a tax on the judiciary.

As previously discussed, while Merck has filed Answers in certain district courts, in others, it has filed Rule 12(b)(6) motions and the parties are already seeing inconsistent rulings. With no centralized process, duplicative staggered motions will result in inconsistent rulings on nearly identical motions and underlying facts. This becomes particularly likely for *Daubert* and summary judgment motions, given the complex medical, scientific, and legal concepts at issue in these actions. A single Court reviewer will achieve far greater consistency than the efforts of multiple judges and parties across the country. "Were this litigation smaller, such duplicative discovery and motion practice might be effectively coordinated on an informal basis by the parties and involved courts." *In re Dollar Gen. Corp. Motor Oil Mktg. & Sales Pracs. Litig.*, 190 F.Supp.3d 1361, 1362 (J.P.M.L. 2016). But "[c]entralization of these … actions before a single judge will yield greater efficiency and cost benefits for both the parties and the courts than informal cooperation and coordination can achieve." *Id.* at 1363 (holding that "centralization [was] the best option" for that litigation involving twenty actions in separate district courts).

Additionally, duplicative motion practice encourages forum shopping and strains judicial resources. As cases are guided by different scheduling orders, motions are filed and ruled upon at different times, which means that unsuccessful matters in one jurisdiction can be re-framed and re-litigated in other jurisdictions. This incentivizes forum shopping (which Merck has already undertaken by filing Answers in jurisdictions in which it feels it would lose a motion to dismiss but filing such motions in other jurisdictions even though the complaints are nearly identical) and places a strain on the judiciary. Informal coordination cannot practically eliminate these risks within so many cases and districts. MDL "[c]entralization will eliminate duplicative

discovery, prevent inconsistent pretrial rulings on *Daubert* and other issues, and conserve the resources of the parties, their counsel, and the judiciary." *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 249 F.Supp.3d 1357, 1361 (J.P.M.L. 2017).

c. Disputes amongst parties have occurred, and will continue to occur, without formal coordination.

As discussed *supra*, attempts at informal coordination have already proven unsuccessful in these actions. For example, in *Stratton*, parties have been unable to resolve scheduling issues. Despite efforts to submit a mutually agreeable calendar that works for all parties, the defendants have abandoned negotiations and are proceeding with preliminary dates that are both unfeasible and detrimental to the plaintiff. The standing order in that case provides for a January 1, 2023 trial date and a very early and impractical July 1, 2022 expert disclosure deadline for plaintiff.

In addition, while Merck has produced some documents in the *Gramza* case and in one state court litigation, it has not produced all relevant and discoverable documents. Indeed, it has not even produced the full regulatory file for Gardasil, nor has it produced all relevant documents and adverse event reports from its clinical trials for Gardasil. Thus, it is anticipated that the parties will have a myriad of discovery disputes (as way of example, in one state court case involving Gardasil, the parties had more than a dozen hearings on various basic discovery issues concerning Merck's internal documents). When "discovery in these actions, including when to begin taking it and its scope, already has been contentious," "voluntary coordination across … dispersed districts appears problematic" and should be abandoned. *In re Ahern Rentals, Inc., Trade Secret Litig.*, 481 F.Supp. at 1356 (ordering centralization of "twelve actions pending in ten districts" after unsuccessful informal coordination).

The *Stratton* case demonstrates the current challenges of informal coordination. As more cases are filed throughout the country and the issues become more complex, informal

coordination will become less practical and unlikely to yield results. Accordingly, based "on this record, informal coordination is not an efficient alternative to centralization." *In re Eliquis (Apixaban) Products Liability Litigation*, 282 F.Supp.3d 1354, 1355 (J.P.M.L 2017) (holding that "[i]n addition to the unsuccessful efforts to coordinate discovery informally, it is clear that the number of involved counsel, the large number of actions and districts, and the complexity of the factual issues pose significant obstacles to informal coordination.")

d. The number of cases and distinct courts warrant centralization over informal coordination.

The Panel has routinely found informal coordination to be unworkable where, as here, multiple cases are on file in several federal courts. *See In re: Onglyza (Saxagliptin) & Kombiglyze XR*, 289 F. Supp. 3d 1357, 1358 (J.P.M.L. 2018) ("Informal coordination among 84 cases across the nation does not seem feasible …"); *In re: Sorin 3T Heater-Cooler Sys. Prods. Liab. Litig. (No. II)*, 289 F. Supp. 3d 1335, 1337 (J.P.M.L. 2018) ("There are now 40 actions pending in 21 districts …"); *In re: Eliquis (Apixaban) Prods. Liab. Litig.*, 282 F. Supp. 3d 1354, 1355 (J.P.M.L. 2017) ("There are now a total of 53 actions pending in 17 districts …")

B. <u>An Appropriate Venue For These Cases is the District of Arizona</u>

As shown above, centralization is appropriate for these cases. The next issue for the Panel to consider is the proper venue for transfer of these cases. Plaintiffs submit that an appropriate venue for this litigation could be the District of Arizona.

The *Gramza* case in front of Judge Douglas L. Rayes and is the earliest filed federal court case. Merck has Answered the Complaint and produced various internal documents in *Gramza* and the court has also adjudicated motions to compel filed by Merck. In addition to *Gramza*, there are two additional Gardasil autoimmune personal injury cases that were recently filed in the District of Arizona (for a total of three cases pending in that Court) and there are nearly a dozen

cases currently pending within the Ninth Circuit. *In Re DePuy Orthopaedics, Inc.*, 753 F. Supp. 2d 1378, 1380 (J.P.M.L. 2010) (transferring to the N.D. of Ohio because, among other things, several potential tag-along actions were already pending there).

The District of Arizona would also be an efficient location for these cases, as that Court currently only has one MDL before it with none of them assigned to Judge Rayes. Accordingly, Judge Rayes more likely has the necessary time to devote to a new MDL. Given Judge Rayes' experience, he would undoubtedly be a legitimate candidate to ably oversee this litigation.

The Panel has previously preferred venues that are geographically convenient, and easily located. The District of Arizona meets each of these criteria. The Court is located in Phoenix which is easily accessible, and this Panel has previously observed that "[t]he District of Arizona is not burdened by many MDLs and has the capacity and resources to successfully guide this litigation." *In re: Bard IVC Filters Prod. Liab. Litig.*, 122 F. Supp. 3d 1375, 1377 (J.P.M.L. 2015). The District of Arizona can serve as an appropriate forum for this MDL.[14]

Dated: April 12, 2022

Respectfully submitted,

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[14] Alternatively, the undersigned counsel proposes the Hon. Judge James D. Peterson in the Western District of Wisconsin where the Walker case, one of the first filed Gardasil cases, is currently pending, and it was in this Court that Merck and undersigned counsel had initially agreed upon to attempt informal coordination (i.e., agreeing that any ruling made by Judge Peterson as to discovery disputes would be binding on the other five Gardasil cases that were part of the informal coordination process), however, as discussed supra, the plans to informally coordinate failed as one of the other courts (*Stratton*).

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