BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION **MDL DOCKET NO. 3036**

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

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INTRODUCTION

In its response to Plaintiffs' Motion for Transfer, Merck fails to refute the fact that, among the pending Gardasil cases, "there are [ ] several common and overlapping issues that can likely be handled more efficiently in a consolidated MDL." Ex. 1, *Malloy v. Merck & Co., Inc.*, ECF 9 at 3, No. 6:2021-cv-00506 (E.D. Tex. May 5, 2022). Realizing it cannot prevail on the merits of forming an MDL in these cases, which involve multiple plaintiffs, represented by multiple different attorneys, in multiple jurisdictions, and involving the same or similar injuries, Merck resorts to a disgraceful ad hominem attack on *one* of the attorneys of record in these cases, Robert F. Kennedy, Jr., an attorney who has dedicated the bulk of his career to successfully battling environmental polluters and ensuring our children are not exposed to harmful products. Merck's effort to inject into these proceedings the charged debate concerning vaccines generally, from sensationalized news reports no less, illustrates the weakness of its arguments. These cases are about *one* vaccine, Gardasil. Indeed, the safety concerns regarding Gardasil were not raised by Mr. Kennedy or "anti-vaxxers," but by scientists in the peer reviewed literature.[1] And, to suggest all the involved plaintiffs' lawyers are blindly following

[1] A small sampling of that literature includes, *e.g.*, Svetlana Blitshetyn, *Postural Tachycardia Syndrome After Vaccination with Gardasil*, 17 EUROPEAN J. OF NEUROLOGY e52 (2010); Louise S. Brinth et al., *Orthostatic Intolerance and Postural Tachycardia Syndrome As Suspected Adverse Effects of Vaccination Against Human Papilloma Virus*, 33 VACCINE 2602 (2015); Tom Jefferson et al., *Human Papillomavirus Vaccines, Complex Regional Pain Syndrome, Postural Orthostatic Tachycardia Syndrome, and Autonomic Dysfunction – A Review of the Regulatory Evidence from the European Medicines Agency*, 3 INDIAN J. OF MED. ETHICS 30 (2017); Shu-Ichi Ikeda et al., *Suspected Adverse Effects After Human Papillomavirus Vaccination: A Temporal Relationship*, IMMUNOLOGIC RESEARCH (2019); Lars Jørgensen et al., *Benefits and Harms of the Human Papillomavirus (HPV) Vaccines: Systemic Review with Meta-Analyses of Trial Data from Clinical Study Reports*, 9 SYSTEMATIC REVIEWS 43 (February 2020); Jill R. Schofield et al., *Autoimmunity, Autonomic Neuropathy, and HPV Vaccination, A Vulnerable Subpopulation*, CLINICAL PEDIATRICS (2017); Darja Kanduc et al, *Human Papillomavirus Epitope Mimicry and Autoimmunity: The Molecular Truth of Peptide Sharing*, PATHOBIOLOGY (2019); Shu-ichi 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).

Mr. Kennedy, with their time, money, and resources, ostensibly making up meritless claims, is nonsense. These are legitimate claims that deserve to be heard in a just and efficient manner. Merck's attempt to force hundreds of injured young women and men to litigate their cases on numerous different fronts, and against Merck's significant resources, is nothing more than an attempt to deny justice and efficient representation to hundreds of patients injured by Gardasil. Let us not forget that Merck is the company that claimed its FDA-approved drug, Vioxx, was safe, and continued to do so for several years until it was forced to take Vioxx off the market in one of the biggest medical scandals in history.[2] Plaintiffs allege Merck did the same here.

Plaintiffs' Motion for Transfer established that informal coordination is simply impractical. Besides making ad hominem attacks on Plaintiffs' counsel, Merck primarily argues that: (1) transferring and centralizing cases, which *have been fully exhausted* through the National Vaccine Injury Compensation Program and are *statutorily permitted* to proceed to civil litigation, would be "unprecedented"; (2) (failed) coordination attempts with *one* firm representing less than half of the Plaintiffs subject to transfer somehow shows coordination is practical among all firms representing the remaining plaintiffs; and (3) individualized issues predominate. Merck's arguments are unavailing.

ARGUMENT

A. The National Vaccine Injury Compensation Program Does Not Bar Transfer and Consolidation Pursuant to 28 U.S.C. § 1407

There is nothing unprecedented about consolidating properly exhausted claims, which are pending in federal court, in an MDL, so long as the factors of 28 U.S.C. § 1407 are satisfied.

[2] *See* Topol, *Failing the Public Health – Rofecoxib, Merck, and the FDA*, NEJM (October 31, 2004); *see also* Kesselheim et al, *Role of Litigation in Defining Drug Risks*, 17 JAMA 308 (2007) ("the litigation process revealed new data on the incidence of adverse events, enabled reassessment of drug risks through better evaluation of data, and influenced corporate and regulatory behavior.").

See, e.g., *In re FEMA Trailer Formaldehyde Prod. Liab. Litig.*, MDL No. 07-1873, 2010 WL 323898, at *1 (E.D. La. Jan. 21, 2010) (MDL created in personal injury litigation against United States pursuant to the Federal Torts Claims Act (FTCA), which required each plaintiff to exhaust administrative remedies under the FTCA before filing suit in federal court); *In re Managed Care Litig.*, MDL No. 1334, 595 F. Supp. 2d 1349, 1353 (S.D. Fla. 2009) (MDL created in litigation against administrators of group health plans governed by ERISA, which required the plaintiffs to exhaust administrative remedies prior to filing suit).

The simple fact that Plaintiffs have exhausted their claims through the no-fault compensation program established by The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act") does not alter the analysis under § 1407. The Panel has successfully coordinated other MDLs where administrative remedies were exhausted before the federal actions were filed. It should do the same here.

1. Congress Specifically Contemplated Civil Products Liability Actions Against Vaccine Manufacturers When It Enacted the Vaccine Act

The Vaccine Act (42 U.S.C. § 300aa-1 et seq.) was passed by Congress to "stabilize the vaccine market." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011). Prior to the passage of the Vaccine Act, there were two forces negatively impacting vaccination rates. *Booth v. Bowser*, __ F. Supp. 3d __, 2022 WL 823068, *11 (D.D.C. Mar. 18, 2022) (citing *Bruesewitz*, 562 U.S. at 227). The *first* was a purported risk that tort suits were driving vaccine manufacturers from the market. *Id.* The *second* was due to injuries associated with vaccines and the lack of accessible tort compensation, parents purportedly had become reluctant to vaccinate their children out of fear that, if their children were injured, they would not have access to financial remedies to compensate for the injuries. *Id.* To address these competing forces, in a *quid pro quo*, Congress passed the Vaccine Act which provided for a "[f]ast, informal adjudication" of claims through

the U.S. Court of Federal Claims ("Vaccine Court"). *Bruesewitz*, 562 U.S. at 228.

The Vaccine Act mandates that individuals who have been injured by Gardasil and wish to file a civil action against the vaccine manufacturer first file a claim with the Vaccine Court. 42 U.S.C. § 300aa-11. After the Vaccine Court issues a judgment (or the statutory time by which the Vaccine Court must issue its ruling passes), "a claimant has two options: to accept the [Vaccine Court's] judgment and forgo a traditional tort suit for damages, **or** to reject the judgment and seek tort relief from the vaccine manufacturer." *Bruesewitz*, 562 U.S. at 228 (citing 42 U.S.C. § 300aa-21) (emphasis added). To ensure children from all states injured by vaccines had the ability to bring products liability tort claims against vaccine manufacturers, in passing the Vaccine Act, Congress took the extra step of *preempting* any state laws that would prohibit an injured plaintiff from bringing a civil tort action against a vaccine manufacturer. 42 U.S.C. §300aa–22(e); *see also Booth*, __F.Supp.3d __, 2022 WL 823068, at *8 ("the [Vaccine Act] expressly prohibits states from enacting protections for vaccine manufacturers contrary to the [Vaccine Act].")

Thus, the legislative history of the Vaccine Act confirms that Congress did not intend to preclude state tort law claims against vaccine manufacturers, regardless of the volume of suits filed. H.R. REP. 100-391, 691 (1987); 1987 U.S.C.C.A.N. 2313-1, 2313–365 ("It is not the Committee's intention to preclude court actions under applicable law."). To the contrary, Congress developed the Vaccine Court program specifically to *allow* petitioners to exhaust the administrative process and, if the petitioner chooses, bring a civil action outside of Vaccine Court. *See Bruesewitz*, 562 U.S. at 232 (the Vaccine Act specifically permits claims for failure-to-warn and manufacturing defect). Courts too have held that the text and legislative history of the Vaccine Act confirm Congress intended that tort suits against manufacturers be permitted.

Abbot by Abbot v. Am. Cyanamid Co., 844 F.2d 1108, 1112 (4th Cir. 1988); *Hurley v. Lederle Lab'ys Div. of Am. Cyanamid Co*., 863 F.2d 1173, 1178 (5th Cir. 1988); *Mazur v. Merck & Co*., 742 F. Supp. 239, 246 (E.D. Pa. 1990); *Morris v. Parke, Davis & Co*., 667 F. Supp. 1332, 1340 (C.D. Cal. 1987) *G.M. v. Sanofi Pasteur Inc*., 2016 WL 7638186, *4 (C.D. Cal. Mar. 22, 2016). Importantly, Congress *never* prohibited individuals who exhausted their claims in Vaccine Court from seeking coordination of pre-trial proceedings, pursuant to § 1407.

2. Plaintiffs Have Done Exactly What Congress Contemplated and Exhausted the Requirements of the Vaccine Court Program

Merck postulates that, if the Panel were to establish an MDL "comprised of recycled Vaccine Court claims," the Vaccine Court system would be overwhelmed. Opp. at 8, 12. In doing so, Merck seems to suggest the sole purpose of the Vaccine Act was to limit lawsuits against vaccine manufacturers. To the contrary, the goal of the Vaccine Act was to ensure children get vaccinated. *See Hurley*, 863 F.2d at 1177 (noting that "the absence of products liability may discourage vaccine use by increasing quality uncertainty and forcing users to bear the cost of any adverse reaction to vaccination"); *Bruesewitz*, 562 U.S. at 228; *Booth*, 2022 WL 823068, *11; *see also* 42 U.S.C.A. §§ 300aa-22, 300aa-23.

Merck also suggests that Plaintiffs and their Vaccine Court counsel are gaming the system by filing their claims with the Vaccine Court with the intent to pursue civil litigation, if necessary, and subsequently requesting their statutorily permitted attorneys' fees and costs. These arguments have been rejected by the Vaccine Court itself. *See Thomas on behalf of Z.T. v. Sec'y of Health & Hum. Servs*., 2021 WL 2389837, at *6 (Fed. Cl. May 17, 2021) (explaining the Vaccine Act specifically creates a mechanism for petitioners to withdraw from the program and pursue civil litigation and stating a "petitioner's stated intention to file suit directly against the vaccine manufacturer in a different forum is entirely in keeping with a sincerely held belief

that a vaccine-caused injury has occurred."); *see also* Ex. 2 at 13, 17, May 17, 2022 Order in *Wingerter v. Secretary of HHS*, Case No. 20-1408 (same). Merck's assertions that the Vaccine Court would be overwhelmed by baseless claims, or that Plaintiffs' counsel are gaming the system, are simply unfounded, as evidenced by the Vaccine Court's own rulings as cited *supra*.[3]

Preventing an MDL here, solely because Gardasil is subject to the Vaccine Act compensation program, would not only run afoul of Congress' purpose for establishing the Vaccine Act, but would also run afoul of Congress' intent to promote just and efficient resolution of related proceedings through coordinated pre-trial proceedings.

B. Informal Coordination Efforts Failed

Merck's representation that informal coordination has been successful, that the multiple cases pending in federal courts across the country being handled by numerous different law firms are "manageable," and that the non-Baum Hedlund firms are simply "nominal," is not true. As set forth in Plaintiffs' Motion for Transfer, informal coordination has not been successful. And, with the burgeoning caseload, disparate rulings, and varying scheduling orders, it was not (and still is not) possible to informally coordinate. Lastly, the other plaintiffs' attorneys handling Gardasil cases are not "nominal." Baum Hedlund, standing alone, could not possibly handle the multitude of individual Gardasil cases to be filed in different courts across the country, thus, it is not surprising that other firms are now involved. Further, there is nothing nefarious about attorneys working on the same litigation to communicate with one another.

[3] Merck does not dispute that Plaintiffs fully exhausted their claims in Vaccine Court. Instead, Merck claims that, because they did not receive compensation there, they should not be given an opportunity to pursue their civil claims in a coordinated fashion. Merck fails to point out that most of the claims were voluntarily withdrawn at their statutorily permitted time, with no adjudication on the merits. Even in cases where there was a dismissal on the merits, a decision of dismissal by the Vaccine court is *inadmissible* in civil litigation. 42 U.S.C.A. § 300aa-23(e). And, unlike civil litigation, the Plaintiffs in Vaccine Court are not able to obtain internal company records to provide further evidence of causation.

Merck's suggestion that informal coordination was still possible notwithstanding the *Stratton* court's February 3, 2022 pretrial scheduling order, which called for Plaintiff's expert disclosures to occur within five months, before Plaintiff had the opportunity to complete discovery and long before expert disclosures in other cases, with a trial to begin on New Year's Day, and Merck pouncing on the tactical advantage gained thereby, is disingenuous. That it continues to argue coordination is possible under the circumstances is pure fantasy.

Further evidence of Merck's abandonment of informal coordination is that, a few weeks after the *Stratton* scheduling order, on February 28, 2022, when plaintiff attempted to modify the scheduling orders in other proposed coordinated cases (entirely consistent with what the parties had previously agreed upon), Merck filed an opposition to plaintiff's request to amend the scheduling order.[4] *See* Ex. 3, at 5 & 7-8; Ex. 4. Following Merck's abandonment of the informal coordination efforts, and once the volume of Gardasil cases mushroomed from a handful to 33 (and counting) spread across two dozen different district courts filed by multiple different firms, Baum Hedlund moved for centralization pursuant to 28 U.S.C. Section 1407. Merck's suggestion that Plaintiffs' motion for centralization had anything to do with the *Herlth* court's order dismissing *Herlth's* complaint *with leave to amend*, is non sequitur and untrue.

Merck makes much of the fact that Plaintiffs have not filed a motion to compel in a federal case. But Merck omits crucial context. In *Robi v. Merck & Co., Inc*., No. BC628589—the first filed Gardasil case—prior to Baum Hedlund making an appearance in the case, and despite nearly three years of litigation, Merck had only produced 700 pages of documents. After

[4] Other examples include Merck's refusal to allow use of tens of millions of pages of documents across the Baum Hedlund Gardasil cases. Thus, Merck's suggestion that it has been forthright in its attempts to informally coordinate is disingenuous. Rather, it appears Merck used the coordination attempts to prevent Baum Hedlund from filing motions to compel and now uses Baum Hedlund's agreement to hold off on filing motions to compel to suggest Baum Hedlund has not been diligent.

Baum Hedlund appeared in *Robi* and propounded discovery, Baum Hedlund had to file multiple discovery briefs and attend over a dozen discovery hearings over several months, to get Merck to produce its internal documents, *on a rolling basis* (approximately 24 million pages to date).

Despite the volume of documents produced, Merck's production remains deficient, many of the documents are improperly redacted, and more than 10,000 have been withheld for privilege. Baum Hedlund has sent multiple meet-and-confer letters to Merck concerning these and other deficiencies to which Merck has either failed to respond, tardily responded, or promised to further respond, and asked Plaintiffs to hold off on filing motions to compel. *See, e.g.*, Ex. 5, 6, and 7 (meet and confer letters).

C. Common Issues Predominate

While completely overlooking the common legal claims and factual allegations regarding Merck's general liability, the common procedural postures, and that there is but one corporate Defendant, Merck attempts to differentiate Plaintiffs' injuries by muddying the record with facts alleged throughout the various complaints. Merck claims the Plaintiffs' injuries are so distinct that centralization is improper, but in doing so, Merck splits apart each *individual symptom* the various Plaintiffs experienced, all of which are the resulting sequalae and symptoms of the autoimmune diseases, Postural Orthostatic Tachycardia Syndrome (POTS) and Orthostatic Intolerance (OI), and in some cases, Immune Thrombocytopenic Purpura (ITP). As the medical literature explains, in individuals who are suffering from POTS or OI, the body's autonomic nervous system fails to compensate for the upright posture which, over time, results in a myriad of symptoms associated with the upper extremities not getting enough blood, resulting in, *for example*, fainting, chronic fatigue, chronic headaches, vision issues, cardiovascular issues, gastrointestinal issues and neuropathic pain. *See* Mot. at n. 9. It is unsurprising that certain plaintiffs have alleged they have experienced a variety of symptoms as a result of suffering from

an autoimmune disease. Indeed, Merck itself successfully advocated for creation of an MDL in autoimmune personal injury cases alleged to be caused by its shingles vaccines. *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig*., 330 F. Supp. 3d 1378, 1379 (J.P.M.L. 2018) (creating MDL where plaintiffs alleged they suffered among others, encephalitis, optical nerve damage, kidney and liver damage, Bell's palsy, and Guillain Barre Syndrome due to shingles vaccine).

Plaintiffs allege, and intend to prove, their autoimmune diseases were caused by Gardasil through the unintended process of molecular mimicry. Recently, in a consolidated decision concerning eight petitioners' claims related to Gardasil, the Vaccine Court found the petitioners:

> established by a preponderant standard that POI [primary ovarian insufficiency] can be autoimmune. In those instances, molecular mimicry can occur if there is an immune response triggered by vaccination, and homology between peptides in the reproductive system specifically relating to ovarian function and components of the vaccine. This can lead to cross-reaction, and it is logical that the production of autoantibodies, particularly in an individual already susceptible due to autoimmune comorbidities, could lead to the development of autoimmune POI.

Ex. 8, Aug. 30, 2021 Order in *Brayboy v. Secretary of* HHS, Case No. 15-183V at 23. The commonality among Plaintiffs' injuries further warrants centralization.[5]

D. <u>The District of Connecticut is Not an Appropriate Venue for Centralization</u>

Merck argues that, if an MDL is created, the Subject Actions should be transferred to the District of Connecticut. In support, Merck misrepresents the import of the ruling in *Herlth v. Merck & Co., Inc.* First, the *Herlth* court dismissed the case *with leave to amend*. Plaintiff then filed a motion to reopen the case, which was granted, and thereafter, an amended complaint was filed containing new allegations. *See* Ex. 9 & 10. Second, the District of Connecticut was the

[5] Merck's argument that an individualized assessment of whether each Plaintiff's claims were properly exhausted prevents coordination is a red herring. Courts overseeing MDLs routinely adjudicate whether claims are time barred or properly exhausted. *See, e.g. In re FEMA Trailer Formaldehyde Prod. Liab. Litig*., MDL No. 07-1873, 2010 WL 323898, at *1; *In re Managed Care Litig*., MDL No. 1334, 595 F. Supp. 2d at 1353.

first *and only* court to consider this conflict preemption argument because Merck cherry-picked the forum knowing a circuit-specific preemption decision existed that is at odds with all other circuits and subsequent Supreme Court precedent.

Specifically, the Second Circuit's holding in *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019), on which Merck relied, runs afoul of the Supreme Court's *subsequent* decision in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). Although *Gibbons* placed the burden of pleading around preemption on the plaintiff, *Albrecht* held the reverse, confirming that *Gibbons* is flawed. Other Circuits agree. *See, e.g.*, *Bennett v. Southwest Airlines Co.*, 493 F.3d 762, 763 (7th Cir. 2007); *Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1289 (9th Cir. 2021); *In re Zofran (Ondansetron) Prod. Liab. Litig.*, 541 F. Supp. 3d 164, 197 (D. Mass. 2021) (preemption is an affirmative defense which the defendant has burden to establish). In short, the Second Circuit is an outlier with respect to preemption law, and for this reason, the District of Connecticut is ill-suited to field a Gardasil MDL. Notably, Merck has Answered Gardasil complaints in jurisdictions less favorable to it and has brought other motions to dismiss without making similar conflict preemption challenges. This inconsistent posture confirms centralization is appropriate, but in a venue outside of the Second Circuit.

CONCLUSION

For all the reasons outlined herein and in the opening brief, Plaintiffs respectfully request that the subject Gardasil actions, as well as any subsequent filed Gardasil autoimmune personal injury cases be transferred and centralized in the District of Arizona before the Honorable Judge Douglas L. Rayes.

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Respectfully submitted,

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