**BEFORE THE UNITED STATES**
**JUDICIAL PANEL ON MULTIDISTRICT LITIGATION**

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| **IN RE: GARDASIL PRODUCTS LIABILITY LITIGATION** | **MDL No. 3036** |

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407**

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The Gardasil MDL that Movants seek is unprecedented. Never in this Panel's 54-year history have claims already adjudicated in the Office of the Special Masters in the U.S. Court of Federal Claims ("Vaccine Court") about a routine childhood vaccine covered by the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act") later been consolidated into an MDL. The Panel should not do so for the first time here. The Vaccine Court—created by Congress as part of the Vaccine Act—already provided each of the Plaintiffs in the Subject Actions with a ***no-fault*** forum to receive compensation for their alleged injuries. Yet, ***none*** of these current Plaintiffs mustered causation evidence sufficient to recover ***a single dollar of compensation*** in Vaccine Court for the injuries they attribute to Gardasil. These unanimous failed outcomes come as no surprise; Gardasil is a lifesaving, FDA-approved human papillomavirus ("HPV") vaccine with a 15-year-long safety and efficacy profile confirmed by the Centers for Disease Control and Prevention ("CDC") and lauded by the global medical community. Unable to recover individually under the less demanding legal standard in Vaccine Court, Plaintiffs' hobbled claims should not be given a collective second wind in an MDL.

Creation of a first-of-its-kind Gardasil MDL would have far-reaching consequences. Regardless of the underlying claims' lack of merit, publicity from an MDL would amplify the vaccine misinformation spread by Robert F. Kennedy, Jr. (Movants' co-counsel in nearly a dozen of these Subject Actions), which permeates Plaintiffs' Complaints, at a time when vaccine hesitancy is on the rise as a result of such misinformation. And an MDL would overload the Vaccine Court with superficial and meritless petitions brought by claimants with no intent to meaningfully pursue their claims there, and who instead are simply box-checking en route to an MDL.

These harmful ramifications of such a novel MDL would be for naught. Individualized issues, such as causation and threshold Vaccine Court statutory exhaustion, would predominate,

and many of the perceived benefits of an MDL have already been achieved. Merck's counsel and Baum Hedlund, counsel in virtually all of the cases filed prior to the month leading up to this Motion to Transfer ("Motion"), have efficiently informally coordinated for nearly two years. While Plaintiffs forewarn of "a myriad of discovery disputes," Plaintiffs have not filed a single motion to compel related to Merck's discovery responses in any federal court over the course of nearly two years of litigation. Moreover, these cases remain manageable without consolidation. This Panel has denied petitions involving a similar number of plaintiffs. And, while eight Plaintiffs' firms are nominally involved, all signs suggest that the newcomer firms are working in tandem with Baum Hedlund and belatedly joined the fray as part of Plaintiffs' push to gin up grounds for an MDL.

Yet, if the Panel concludes that consolidation is warranted, efficiency dictates that these actions be transferred to the Honorable Jeffrey Meyer in the District of Connecticut. Judge Meyer is the only judge in the country to have thoroughly analyzed the causation evidence in Plaintiffs' complaints and ruled on implied preemption—a central pretrial issue. No judge is better positioned to efficiently manage this litigation should the Panel deem consolidation necessary.

## I. BACKGROUND

### A. Gardasil is a "Safe and Effective" FDA-Approved Vaccine.

FDA-approved since 2006, Gardasil protects against cervical, vulvar, vaginal, anal, oropharyngeal, and other head and neck cancers and their associated precancerous lesions, as well as genital warts, caused by certain types of HPV. Ex. A, 2020 Gardasil 9 Patient Information; Ex. B, Sample Package Inserts. With limited exceptions inapplicable to these Plaintiffs, the "CDC recommends HPV vaccination for ***everyone through age 26 years***, if not vaccinated already." Ex. C, CDC, HPV Vaccine (emphasis added).

The CDC has stated HPV vaccines like Gardasil "***provide[] safe, effective, and lasting protection against the HPV infections that most commonly cause cancer***." Ex. D, CDC, HPV Vaccination & Cancer Prevention (emphasis added). The CDC estimates that "85% of people will get an HPV infection in their lifetime." Ex. E, CDC, Reasons to Get HPV Vaccine; Ex. D. "HPV is estimated to cause nearly 36,500 cases of cancer in men and women every year in the United States." Ex. E. Those cancers are deadly: the World Health Organization ("WHO") estimates that in 2018 alone, "570,000 women were diagnosed with cervical cancer worldwide and about 311,000 women died from the disease." Ex. F, WHO, Cervical Cancer. This is to say nothing of the millions of precancerous lesions that are diagnosed and must be invasively treated each year.

Multiple independent long-term studies have reaffirmed that Gardasil prevents cancer. *See, e.g.,* Ex. G, Lei 2020 (finding vaccination "was associated with a substantially reduced risk of invasive cervical cancer").[1] According to a recent statement by more than 20 national medical organizations, "HPV vaccines are ***among the most effective vaccines available worldwide***, with unequivocal data demonstrating greater than 99% efficacy for some populations." Ex. M, Joint Statement on the Elimination of HPV (emphasis added).

According to the CDC, Gardasil is "very safe." Ex. N, CDC, HPV Vaccination is Safe and Effective. Both FDA and the CDC today "continue to monitor the safety of [the] vaccine, with the public's health and safety [as] top priority." Ex. O, FDA, Gardasil Vaccine Safety. As the CDC has reported, "[f]indings from many vaccine safety monitoring systems and more than 160 studies

[1] *See also, e.g.,* Ex. H, Kjaer 2021 ("HPV vaccination is associated with a substantial protection against cervical cancer"); Ex. I, Falcaro 2021 ("substantial reduction in cervical cancer" after introduction of HPV immunization program in England); Ex. J, Lehtinen 2021 (100% vaccine efficacy against HPV-positive invasive cancers); Ex. K, Tabibi 2021 ("decreased cervical cancer incidence and mortality among women and girls aged 15 to 24 years after HPV vaccine introduction"); Ex. L, Berenson 2022 (results indicating squamous cell carcinomas of the anus are declining among vaccine-eligible adults, likely as a result of HPV vaccination).

have shown that HPV vaccines have a favorable safety profile—***the body of scientific evidence overwhelmingly supports their safety***." Ex. C (emphasis added).

**B. Plaintiffs' Gardasil Claims Did Not Pass Muster in Vaccine Court.**

HPV vaccines like Gardasil are covered by the Vaccine Act. *See* 42 C.F.R. § 100.3. In the wake of vaccine manufacturers leaving the market due to tort liability thereby creating the risk of shortages, Congress enacted the Vaccine Act in 1986 "[t]o stabilize the vaccine market and facilitate compensation." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011); H.R. Rep. No. 99-908, 7, 1986 U.S.C.C.A.N. 6344, 6348 (describing the "instability and unpredictability of the childhood vaccine market" as one of Congress's "two overriding concerns" in enacting the Vaccine Act). As part of the Act, Congress created the National Vaccine Injury Compensation Program, a "***no-fault*** compensation program designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 562 U.S. at 228 (emphasis added) (internal quotation marks omitted). "The *quid pro quo* for this [no-fault system] was the provision of significant tort liability protections for vaccine manufacturers." *Id.* at 229. Before filing a personal injury lawsuit against a vaccine manufacturer alleging injuries caused by routinely administered childhood vaccines like Gardasil, a claimant or legal guardian must first present those claims to Vaccine Court, where the respondent is the Secretary of Health and Human Services ("HHS"). 42 U.S.C. §§ 300aa-11(a)(2)(A), 300aa-12(b)(1). Vaccine Court claims are adjudicated by special masters, who number no more than eight and are appointed by the U.S. Court of Federal Claims. 42 U.S.C. § 300aa-12(c)(1).

"Unlike in tort suits, claimants under the [Vaccine] Act are not required to show that the administered vaccine was defectively manufactured, labeled, or designed." *Bruesewitz*, 562 U.S. at 229. To receive compensation in Vaccine Court, a claimant must demonstrate by a preponderance of the evidence that she received a covered vaccine and that her injury was either identified

on the Vaccine Injury Table[2] or caused by the vaccine. *Balasco v. Sec'y of Health & Hum. Servs.*, 2020 WL 1240917, at *1 (Fed. Cl. Feb. 14, 2020). In addition to medical records, claimants with non-Table injuries must support their claims with "scientific studies or expert medical testimony." *Id.* at *2 (internal quotation marks omitted). Vaccine Court claimants who wish to file a civil action must exhaust their claims in one of three ways: (1) obtain a final judgment from Vaccine Court rejecting the claim for compensation and then file a timely election to file a civil action, 42 U.S.C. §§ 300aa-11(a)(2)(A)(i), -21(a); (2) reject a final judgment awarding compensation and file a timely election to file a civil action, *id.*; or (3) withdraw the petition and file a lawsuit if 240 days pass from the filing of a complete petition without a decision from Vaccine Court, 42 U.S.C. § 300aa-11(a)(2)(A)(ii).

Notably, ***none*** of the Plaintiffs in the Subject Actions were awarded any compensation in Vaccine Court for the alleged injuries they claim to be caused by Gardasil. *See* App'x C. Instead, every Plaintiff's claim was dismissed as not entitled to compensation, dismissed for insufficient proof, or withdrawn from Vaccine Court before a decision on the merits could be issued. *See id.*

### C. Merck's Counsel and Baum Hedlund, Counsel of Record in Nearly Half of the Subject Actions, Have Successfully Coordinated for Almost Two Years.

Movants' counsel Baum Hedlund is counsel of record in nearly half of the Subject Actions (along with Robert F. Kennedy, Jr.). *See* App'x A. Merck's counsel and Baum Hedlund have informally coordinated these Gardasil matters for nearly two years.

Two key developments appear to have been the impetus for this Motion for Transfer. First, in January 2022, the parties jointly submitted amended schedules "consistent with…their informal

[2] The Table describes the "compensable, adverse side effects" for each covered vaccine. *Bruesewitz*, 562 U.S. at 228. With Table injuries, claimants are "prima facie entitled to compensation" if a "listed injury first manifested itself at the appropriate time." *Id.*

coordination discussion" in two Subject Actions with approaching discovery deadlines, with plans to amend the others. Mot. at 10. While the first court (*Balasco*) entered the parties' joint scheduling submission verbatim, the second court (*Stratton*) rejected the parties' proposal and, in February 2022, instead entered its own schedule. *See* Ex. P, *Balasco v. Merck & Co.*, No. 1:20-CV-00364, Dkt. No. 29; Ex. Q, *Stratton v. Merck & Co.*, No. 2:21-CV-02211, Dkt. No. 29. Contrary to Movants' claim that "Merck [] abandoned informal coordination efforts," Mot. at 11, Merck offered to ***continue*** informally coordinating on all the other pending matters after the order in *Stratton*. But Baum Hedlund abruptly changed course and made any further coordination contingent on Merck's agreement to allow *Stratton* to be voluntarily dismissed without prejudice and either tolled or re-filed in New Jersey state court—thereby, evading the *Stratton* court's schedule.[3] When Merck instead suggested that the parties comply with the *Stratton* order and continue coordinating the other matters, Movants' counsel proceeded to file *ex parte* extension requests in the next two matters (*Gramza*, *Walker*) with upcoming deadlines. Merck never abandoned the promise that informal coordination is achievable.

Second, on March 15, 2022, after a months-long careful review of Plaintiff's 456-paragraph complaint, analysis of the dozens of medical articles and other documents cited therein, and thorough consideration of over 80 pages of briefing and lengthy oral argument on Merck's Motion to Dismiss, Judge Jeffrey Meyer in the District of Connecticut dismissed Plaintiff Korrine Herlth's Amended Complaint in its entirety in a reasoned decision. *Herlth v. Merck & Co., Inc. et al.*, 2022 WL 788669, at *5 (D. Conn. Mar. 15, 2022) (attached as Exhibit R). Judge Meyer concluded that Ms. Herlth's failure-to-warn claim was "preempted by the Food, Drug, and Cosmetics Act"

[3] During negotiations, Baum Hedlund reiterated that they wanted *Stratton* to be the last case in the schedule and specifically referenced the presiding judge's exclusion of all the plaintiffs' general causation experts in the *In re: Lipitor* MDL.

because she "does not plead facts to plausibly establish that there was newly acquired information about the risks of Gardasil that caused [her] injuries." *Id.* at *3–5. This dismissal is problematic for Plaintiffs because the other Subject Actions make allegations similar to the dismissed *Herlth* complaint regarding Gardasil's FDA-approved label and warnings.

Approximately one month after the dismissal of *Herlth* and facing impending expert disclosure deadlines that they are purportedly unprepared to meet, *see* Mot. at 11, Baum Hedlund filed this Motion for Transfer on April 12, 2022. Prior to the *Herlth* dismissal, there were only 15 Gardasil lawsuits pending in federal court, and all but one of them were brought by Baum Hedlund and its co-counsel. *See* App'x A. The remaining 19 Subject Actions were all filed in rapid succession by a handful of firms never previously involved in the litigation. *See id.* That uptick of lawsuits—all but one nominally brought by law firms other than Baum Hedlund—did not begin until after the *Herlth* preemption dismissal. Only one new case has been filed since Movants lodged their MDL petition. Plaintiffs' counsel appear to be working in concert—led by Baum Hedlund. The allegations in the newly filed mirror large swaths of Baum Hedlund's complaints. The same counsel, Andrew Downing, represented 32 of 35 present Plaintiffs in Vaccine Court—all of whom are now represented in federal district court by Baum Hedlund or their colleagues. *See id.* Moreover, several of the supposedly "separate" Plaintiffs' firms will be co-presenting with Baum Hedlund at the May 2022 HarrisMartin's MDL Conference on panels entitled "Gardasil Litigation," "Gardasil and Autoimmune Injury: Diving Into the Science," and "Vaccine Court Primer." Ex. S, Agenda.

### D. Plaintiffs Allege a Disparate Set of Injuries

As the number of cases filed in the weeks leading up to the Motion to Transfer grew, so too did the range of disparate alleged injuries. Contrary to Movants' suggestion that there is a

single autoimmune injury, Plaintiffs allege a cornucopia of over 90 unique conditions ranging from hirsutism (abnormal hair growth), to an inability to talk, to hallucinations. *See* App'x B.

## II. ARGUMENT

Centralization is inappropriate here for three reasons. ***First***, the unfounded vaccine misinformation spread by Plaintiffs' counsel should not be given the national platform afforded by an MDL. ***Second***, the creation of an unprecedented MDL comprised of recycled Vaccine Court claims would overwhelm the congressionally mandated no-fault compensation system. ***Third***, efficiency and convenience would be best served by continuing the parties' informal coordination efforts.

### A. The Panel Should Decline to Give a National Platform to the Vaccine Misinformation Propagated by Plaintiffs' Counsel.

The Panel should reject this petition, which would draw unwarranted attention to the dangerous vaccine misinformation at the core of Plaintiffs' claims and heighten the resulting public harm—at a time when vaccine hesitancy is already on the rise.

Robert F. Kennedy, Jr.—counsel of record in 11 of the Subject Actions—has been widely criticized for spreading misinformation regarding life-saving vaccines. Various institutions have identified Mr. Kennedy as "a major figure in the vaccine resistance movement" who "spread[s] lies" to "sow distrust" in vaccines. *See* Ex. T, The New York Times, A Kennedy's Crusade Against Covid Vaccines Anguishes Family and Friends; Ex. U, McGill, The Anti-Vaccine Propaganda of Robert F. Kennedy, Jr. He has even been banned from Instagram for posting vaccine misinformation. Ex. V, The New York Times, Robert F. Kennedy Jr. is Barred from Instagram Over False Coronavirus Claims. A recent analysis found that one of Mr. Kennedy's advocacy groups was one of two buyers accounting for 54% of anti-vaccine advertising content on Facebook. Ex. W, Jamison 2020. Although Mr. Kennedy has been on Plaintiffs' pleadings for nearly two years, the present Motion omits him entirely. *See* Mot. at 6.

But Plaintiffs' counsel's efforts to now distance themselves from Mr. Kennedy come too late. The debunked misinformation advanced by Mr. Kennedy is already enmeshed in Plaintiffs' complaints. Tracking almost verbatim Mr. Kennedy's Children's Defense Fund website, Plaintiffs' complaints rest on unfounded allegations of a widespread conspiracy between Merck, the FDA, and other offices of the U.S. government, which purportedly led to Gardasil's approval and thus Plaintiffs' claimed injuries. For example, Plaintiffs' complaints allege that federal agencies fast-tracked Gardasil's approval because they "stood to make millions of dollars on [Gardasil] from patent royalties." *Gramza* Compl. ¶¶ 43, 107; *accord* Ex. X, Children's Health Defense, Gardasil: "The Science" Video and Other Facts (claiming that government scientists profit from the sale of Gardasil and referring to the CDC as "an arm of the vaccine industry").

Despite overwhelming evidence of Gardasil's safety and efficacy,[4] *supra* at p.2, anti-vaccine misinformation campaigns like those championed by Mr. Kennedy, and advanced in Plaintiffs' complaints, have already fueled a dangerous trend toward lower vaccination rates. A recent joint statement by 24 national medical associations, including the American Academy of Pediatrics and the American Cancer Society, stated that although "HPV vaccines are among the most effective vaccines available worldwide . . . ***current HPV vaccination rates are unacceptably low***." *See* Ex. M (emphasis added). Vaccine misinformation leads to vaccine hesitancy, which in turn leads

[4] The Motion for Transfer previews Plaintiffs' hypothesized "molecular mimicry" theory—purportedly triggered by Gardasil's aluminum adjuvant and "HPV LI-DNA" fragments—which they allege can cause "autoimmune disorder." Mot. at 4. But FDA and the CDC have already considered the safety of both of these Gardasil components and rejected Plaintiffs' claims that they are unsafe years ago. *See* Ex. Y, CDC, Adjuvants and Vaccines ("Adjuvants have been used safely in vaccines for decades."); Ex. Z, FDA, FDA Information on Gardasil – Presence of DNA Fragments Expected, No Safety Risk (October 2011). And this theory has already been rejected in Vaccine Court. *See, e.g., Humphries v. Sec'y of Health & Hum. Servs.*, 2020 WL 7706965, at *6 n.3 (Fed. Cl. Dec. 4, 2020) (citing 21 cases to support ruling that "HPV/POTS claims" have generally failed "in the Vaccine Program," including those based on a "molecular mimicry" theory).

to lower vaccination rates and greater spread of infectious disease. *See* Ex. AA, National Cancer Institute, Despite Proven Safety of HPV Vaccines, More Parents Have Concerns (noting that "[t]here has been a rise in misinformation about HPV vaccines on social media in recent years" and "research has shown that parents who are exposed to misinformation about HPV vaccines on social media are less likely to vaccinate their children" (cleaned up)); Ex. BB, WHO, Ten Threats to Global Health in 2019 (identifying vaccine hesitancy "as a top ten global threat to public health"). The formation of a Gardasil MDL would threaten public health by worsening this trend toward to under-vaccination.[5] Thus, under these unique circumstances, the Panel should exercise its discretion under 28 U.S.C. § 1407 and decline to create an MDL.

**B. The Creation of a Gardasil MDL Would Be Unprecedented.**

The Panel should decline to take the unprecedented step of creating an MDL for claims subject to—and already adjudicated by—the Vaccine Act's ***no-fault*** compensation system.[6] Such a novel proposition would result in two serious consequences unique to this litigation. ***First***, the

[5] As the MDL Subcommittee reported to the Advisory Committee on Civil Rules in 2018, "publicity about litigation can prompt patients to stop taking their medications or to forgo needed treatment." *See* Ex. CC, Advisory Committee on Civil Rules, Agenda Book, Nov. 1, 2018, p. 145.

[6] Previous vaccine-related MDLs involved claims ***not*** subject to the Vaccine Act. *See In re Swine Flu Immunization Prod. Liab. Litig.*, 464 F. Supp. 949, 950 (J.P.M.L. 1979) (predating Vaccine Act); *In re Sabin Oral Polio Vaccine Products Liability Litigation*, MDL No. 780 (claims not subject to Vaccine Court); *In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig.*, 330 F. Supp. 3d 1378 (J.P.M.L. 2018) (vaccine not covered by Vaccine Act). Plaintiffs make much of the Zostavax MDL, but the facts and figures underlying the creation of that MDL show just how different the two circumstances are. Since Zostavax is not covered by the Vaccine Act, claims for Zostavax-related injuries need not—indeed, ***cannot***—be brought in Vaccine Court. Moreover, at the time that the Zostavax MDL was created, there were 98 federal Zostavax lawsuits. *In re Zostavax*, 330 F. Supp. 3d at 1379. There were also more than 300 Zostavax plaintiffs consolidated in California state court and over 800 in New Jersey state court. *Id.* at 1380 n.4. By comparison, there are only seven Gardasil cases now pending in state courts, with no request for consolidation there. Although multiple of the California state court plaintiffs allege POTS, among other injuries, Movants' counsel represented at a recent case management conference in May 2022 that "these are independent cases" and confirmed no current desire to relate—much less, consolidate them. Ex. DD, 5/12/22 *Shain* Tr. at 5.

creation of a federal MDL risks overrunning the Vaccine Court with baseless Gardasil claims because Plaintiffs' firms will inevitably rush to file more cases there with the sole intent of eventually parking them in the MDL. ***Second***, an MDL would encourage circumvention of the congressionally mandated procedures for bringing vaccine injury claims. *See In re Highway Acc. Near Rockville, Connecticut, on Dec. 30, 1972*, 388 F. Supp. 574, 576 (J.P.M.L. 1975) (denying transfer where "plaintiff's ulterior motive for seeking transfer amount[ed] to an attempted misuse of the statute"). Thus, it is unsurprising that the Panel has never centralized claims subject to the Vaccine Act. It should decline to do so for the first time here.

**1. An MDL Would Overwhelm Vaccine Court with Baseless Claims.**

Recognizing the paramount importance of vaccines to public health and the shrinking number of manufacturers due to tort actions, Congress enacted the Vaccine Act to ensure vaccine availability by "lessen[ing] the number of lawsuits against [vaccine] manufacturers." H.R. Rep. 99-908, 9, 12. To that end, the Vaccine Act established Vaccine Court as a ***no-fault*** alternative to the traditional tort system. *Bruesewitz*, 562 U.S. at 228. In the more than 35 years since the Vaccine Act became law, Vaccine Court has historically been the primary forum for adjudicating (and, where appropriate, compensating) rare cases of injuries related to covered childhood vaccines, like Gardasil.[7] The formation of a Gardasil MDL would create the "'Field of Dreams' problem" twice over—not only in federal court, but also in Vaccine Court. Ex. CC at 142–43 (Advisory Committee on Civil Rules discussing the "'Field of Dreams' problem, or 'If you build it, they will come,' and noting that "a significant number of claimants [in MDLs] ultimately . . . turn out to have unsupportable claims"). The publicity generated by a first-of-its-kind Gardasil MDL (and amplified by

[7] Between 2016 and 2019, out of over ***4 billion doses*** distributed in the U.S. for ***all vaccines*** subject to the Vaccine Act, 8,551 petitions for compensation were filed in Vaccine Court. Of those, 6,086 were compensated. *See* Ex. EE, Health Resources & Services Administration, Data & Statistics.

vaccine misinformation proponents like Mr. Kennedy) would threaten to overwhelm Vaccine Court and its statutorily limited eight Special Masters with a flood of unfounded claims about Gardasil that otherwise would not likely be filed, while simultaneously prompting the increased filing of nonviable and/or unexhausted claims in federal court. At the same time, HHS and the Vaccine Court's time and resources would be wasted on petitions filed with the sole purpose of eventually joining the MDL and diverted away from claimants genuinely pursuing compensation in Vaccine Court. HHS has even expressed concern about "an ever-burgeoning docket with limited resources" and recently argued:

> Each petition that is filed carries transaction costs for both the [National Vaccine Injury Compensation] Program and the court. With a statutorily-limited number of Special Masters, the time and resources that must be devoted to disposing of cases with no reasonable basis that are brought before the court lacking good faith – cases which petitioner never intended to litigate before the court nor completely develop the record – inevitably reduces the court's ability to focus on meritorious claims, and delays compensation in those cases.

*Hoover v. Sec'y of Health & Hum. Servs.*, 2021 WL 5575768, at *5 (Fed. Cl. Nov. 1, 2021).

Not a ***single Plaintiff*** in any of the Subject Actions was found to be entitled to compensation for their claimed injuries even under the lower, no-fault standard in Vaccine Court. *See* App'x C. These Plaintiffs either withdrew their petitions prior to a merits decision to fast-track their path to federal court, or the Special Master rejected their unfounded theories and dismissed their claims as having failed to establish entitlement to compensation or for "insufficient proof." *See id.* In some cases, Plaintiffs even ***admitted*** in the ***no-fault*** context of Vaccine Court that they would "not be able to establish entitlement to compensation." *Vela on behalf of J.V. v. Sec'y of Health & Hum. Servs.*, 2021 WL 4065524, at *1 (Fed. Cl. Aug. 10, 2021). This menagerie of unsuccessful claims, all insufficient to warrant compensation in Vaccine Court's ***no-fault*** system, should not be cobbled together and perpetuated in an MDL.

**2. An MDL Would Incentivize the Manipulation of the Vaccine Court.**

Even more troublingly, the creation of a Gardasil MDL would incentivize Plaintiffs to manipulate the Vaccine Court process mandated by Congress. Movants candidly admit that current Vaccine Court claimants have no intention of meaningfully pursuing their claims through Vaccine Court, instead boldly predicting that the "52 additional Gardasil autoimmune cases currently pending in Vaccine Court…***will proceed*** with filing traditional tort claims." Mot. at 2 (emphasis added). In other words, over 50 claimants who have ***not yet completed*** their Vaccine Court proceedings already have their sights set on parking a federal lawsuit into an MDL.

Meanwhile, attorneys in Vaccine Court lack any incentive to screen claimants since they can seek legal fees from Vaccine Court regardless of outcome. *See* 42 U.S.C. § 300aa-15(e). The Vaccine Court must render a decision on any complete petition within 240 days. Here, certain Plaintiffs in the Subject Actions—represented in Vaccine Court by Baum Hedlund's Gardasil co-counsel Andrew Downing—filed skeletal petitions and then sought serial extensions until the 240-day statutory period had passed. *See, e.g.*, Ex. FF, *Counts v. Sec. of Health & Human Servs.*, No. 1:20-VV-01782, Dkt. Nos. 6, 7, 9, 10, 12, 13, 15, 17, 18 (filing eight motions for extensions of time to complete petition until 240 days elapsed); Ex. GG, *Fetters v. Sec. of Health & Human Servs.*, No. 1:21-VV-00928, Dkt. Nos. 7, 8, 10, 11, 12, 13, 14, 15, 16, 17 (filing nine extension motions). Once the statutory period expired, they quickly withdrew their incomplete petitions and proceeded to file in federal court—having avoided any hearing on the merits of their Vaccine Court claims. *See, e.g.*, Ex. FF, *Counts*, Dkt. Nos. 18, 20 (withdrawn 16 days after 240-day notice); Ex. GG, *Fetters*, Dkt. Nos. 17, 18 (withdrawn same day as 240-day notice). Expending minimal effort en route to federal court, these claimants' counsel Mr. Downing has now moved to collect his attorneys' fees. *See, e.g.*, Ex. FF, *Counts*, Dkt. Nos. 23, 27; Ex. GG, *Fetters*, Dkt. Nos. 21, 26.

The creation of an MDL would only further incentivize Plaintiffs, who never intended to meaningfully pursue their claims through the procedures established by Congress in the first place, and their counsel, who can seek their fees regardless of outcome, to merely go through the proverbial motions in Vaccine Court. The ripple effects could impact all childhood vaccines covered by the Vaccine Act and could frustrate the Vaccine Court system altogether.

### C. An MDL Will Not Serve Efficiency or the Convenience of the Parties.

Movants have "failed to meet their burden of establishing that centralization would be the most efficient path for this litigation," or "serve the convenience of the parties and witnesses." *In re Belviq (Lorcaserin HCl) Prod. Liab. Litig.*, 555 F. Supp. 3d 1369, 1369–70 (J.P.M.L. 2021). Informal coordination is not just feasible at this stage—it has already been achieved with Baum Hedlund, Movants' counsel. And individualized issues far outnumber the commonalities.

#### 1. Ongoing Informal Coordination Would Best Promote Efficiency.

"[C]entralization under Section 1407 should be the last solution after considered review of all other options." *In re: Gerber Probiotic Prods. Mktg. & Sales Pracs. Litig.*, 899 F. Supp. 2d 1378, 1379 (J.P.M.L. 2012) (internal quotation marks omitted). Here, informal coordination remains a preferable and feasible alternative to the "last solution" of consolidation.

##### *a) Nearly Half of the Subject Actions Share Counsel and the Number of Plaintiffs Remain Manageable.*

Informal coordination remains feasible because the Subject Actions involve a limited number of law firms. Merck is represented by national counsel in all U.S. Gardasil litigation.[8] And while Plaintiffs insist that the Subject Actions "involv[e] at least eight different Plaintiffs' law firms," Mot. at 12, any surface-level appearance of diversity among Plaintiffs' counsel appears to

[8] Goldman Ismail Tomaselli Brennan & Baum LLP, Venable LLP, and Morgan Lewis & Bockius LLP collectively represent Merck across the Subject Actions.

be an orchestrated scheme to reverse-engineer grounds for an MDL and dilute Judge Meyer's seminal opinion dismissing the *Herlth* Gardasil complaint in its entirety as preempted:

- Gardasil has been FDA approved since 2006. But prior to the March 15, 2022, *Herlth* decision, there were only 15 federal Gardasil actions. Baum Hedlund was counsel in all but one of those cases.[9]

- After the *Herlth* decision, the number of cases and firms nominally involved rose abruptly. In the month between the *Herlth* decision and the filing of the Motion, 19 new cases were filed by eight firms. This flurry of filings more than doubled the number of Gardasil cases that had been filed in the previous year and a half since the first federal Gardasil case was filed in July 2020.

- In a starkly different trend, Baum Hedlund was counsel of record in just one of the cases filed after the *Herlth* dismissal. And Baum Hedlund hurriedly moved to stay that single case ***before*** they even served Merck with the complaint. *See Thomas v. Merck & Co, Inc.*, No. 9:22-CV-80445 (S.D. Fla.), Dkt. No. 9, 10.

Even with these nominally inflated numbers, the number of involved counsel remains manageable, and there is ample evidence of coordination between Baum Hedlund and the various newcomers who filed complaints in the month leading up to this Motion for Transfer:

- Nineteen of the 34 Subject Actions were filed in the three weeks between March 15 and April 5, 2022, with seven filed by four different firms all within two days. *See* App'x A. Only one new case has been filed since the flurry of activity preceding the MDL petition.

- The complaints filed by other firms copied and pasted hundreds of paragraphs from Baum Hedlund's. *Compare, e.g.*, *Malloy* Complaint ¶¶ 14–343 *with Soileau* Complaint ¶¶ 14–343.

- More than two thirds of the Subject Actions were filed by Movants' counsel, Baum Hedlund or one of Baum Hedlund's co-counsel in another Gardasil matter. *See* App'x A. For

[9] Those 15 actions are now in varied procedural postures, with some cases already in the midst of depositions. *See* App'x A. Centralization is not appropriate where, as here, the Subject Actions are "at substantially different procedural stages," with several filed more than a year after the first few. *In re Cymbalta (Duloxetine) Prod. Liab. Litig. (No. II)*, 138 F. Supp. 3d 1375, 1376 (J.P.M.L. 2015). Four federal courts have dismissed Plaintiffs' claims in full or in part, and five motions to dismiss are currently pending. As the Panel has recognized, such dispositive rulings can "provide useful guidance for the resolution of similar motions" in other cases, obviating the need for centralization in an MDL. *In re: Removal From U.S. Marine Corps Rsrv. Active Status List Litig.*, 787 F. Supp. 2d 1350, 1351 (J.P.M.L. 2011). Further, three trials are set to commence in January and February 2023.

example, Andrew Downing of Van Cott & Talamente—Baum Hedlund's co-counsel in *Gramza*—filed two cases as sole counsel of record within a week after the *Herlth* decision.

- All but three of the Plaintiffs in the 34 Subject Actions were represented by the same attorney in Vaccine Court (Andrew Downing of Van Cott & Talamente).
- Counsel of record for several of the "separate" firms are presenting together as co-panelists at an upcoming May 2022 MDL conference about "Gardasil Litigation." Ex. S, Agenda.

Gamesmanship aside, the number of cases also remains manageable.[10] In fact, the Panel has recently declined to centralize products liability litigation of similar sizes. *See, e.g.*, *In re Cymbalta*, 138 F. Supp. 3d at 1376 (denying transfer of 41 actions); *In re Baby Food Mktg., Sales Pracs. & Prods. Liab. Litig.*, 544 F. Supp. 3d 1375 (J.P.M.L. 2021) (denying transfer of 38 actions). Tellingly, counsel in several of those newly filed actions have not even served Merck, suggesting a disinterest in meaningfully pursuing these claims outside of an MDL.

***b) Ongoing Informal Coordination Has Already Been Achieved.***

Informal coordination is not only feasible for the Subject Actions—it has ***already been achieved***. Contrary to Movants' suggestion, Merck's national counsel and Baum Hedlund have been successfully coordinating in federal court for nearly two years. As part of this coordination, Merck agreed to make its Gardasil document production—over 8 million pages—across all federal cases filed by Baum Hedlund. *See* Ex. HH, *Gramza* Dkt. No. 58. Merck and Baum Hedlund have also agreed to custodial file search terms and the identity of custodial files across the cases, to depose fact witnesses and experts only once, to limit the number of Merck witness depositions,

[10] Although Movants predict there will eventually "be 129 Gardasil autoimmune personal injury cases," Mot. at 3, the Panel "generally does not take into account the mere possibility of future filings when considering centralization." *In re Route 91 Harvest Festival Shootings in Las Vegas, Nevada, on Oct. 1, 2017*, 347 F. Supp. 3d 1355, 1358 (J.P.M.L. 2018) (internal quotation marks omitted). In any event, no deluge of cases is imminent in the absence of the publicity an MDL would bring, and no FDA or CDC action relating to Gardasil has recently occurred that might suggest an oncoming "rush to the courthouse." *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 793 F. Supp. 1098, 1098 (J.P.M.L. 1992).

and to limit the time to conduct depositions. *See* Ex. P, *Balasco* Dkt. No. 29, at p.3. This Panel has previously found that "agreements regarding . . . discovery issues," including defendants' offers to "cross-notice all corporate witness depositions and share generic fact discovery in all actions" is the type of informal coordination preferable to formal centralization. *In re Belviq*, 555 F. Supp. 3d at 1370; *see also In re Eli Lilly & Co. (Cephalexin Monohydrate) Patent Litig.*, 446 F. Supp. 242, 244 (J.P.M.L. 1978). Thus, the chief benefit of consolidation—the coordination of discovery—has already been realized.

Movants' true gripe appears to be not with Merck's coordination efforts to date, but rather with the scheduling order entered by the *Stratton* court, with which Movants' counsel candidly admit they cannot comply. *See* Mot. at 11. While Movants foreshadow "a myriad of discovery disputes," Mot. at 17, the reality is that Plaintiffs have not filed a single motion to compel regarding Merck's discovery responses in any federal court, despite the earliest case being filed in July 2020. Far from "abandon[ing] informal coordination," Mot. at 11, 17, Merck remains willing to continue efficiently cooperating with Baum Hedlund and is willing to extend the arrangements already in place with Baum Hedlund to other Plaintiffs' counsel. The Panel should permit Baum Hedlund and Merck's national counsel to continue their established practice of informal coordination.

**2. Individualized Issues Would Overwhelm Common Ones.**

Centralization is improper because the commonalities among these cases would quickly be overwhelmed by plaintiff-specific, individualized questions of (1) alleged injury and causation and (2) threshold satisfaction of timely Vaccine Court claim exhaustion. *In re Belviq*, 555 F. Supp. 3d at 1370 (denying transfer where "individualized factual issues concerning causation will predominate and diminish the potential to achieve significant efficiencies in an MDL").

Movants' counsel generically refers to the Subject Actions as "Gardasil autoimmune cases" throughout the brief to create a false sense of commonality. In reality, Plaintiffs' complaints allege

injuries comprising a veritable cornucopia of over ***90 unique conditions***, running the gamut from anxiety (alleged by five Plaintiffs) to irritable bowel syndrome (two Plaintiffs), from "severe insomnia" (one Plaintiff) to narcolepsy (two Plaintiffs). *See* App'x B.[11] In fact, ***no*** single, common injury is alleged by all 35 Plaintiffs, and only two-thirds of Plaintiffs allege that they have been diagnosed with the most-claimed syndrome of POTS. *See id.* The causation theories advanced in Plaintiffs' complaints are equally as diffuse. While the Motion articulates a "molecular mimicry" mechanism of causation—again to create the façade of commonality, the kitchen-sink theories in the Complaints are not nearly as harmonized. The Complaints non-exhaustively malign everything from Gardasil's FDA-approved proprietary aluminum adjuvant to its labeled component yeast to "DNA fragments" to purported "PMSF." It is, thus, unclear whether any given Plaintiff is attributing his or her injury to some specific component of Gardasil, some combination of factors, or something else entirely. This would only serve to further complicate and individualize the question of causation for each plaintiff. And even if "molecular mimicry" was the sole causation mechanism at issue, Movants do not explain how their hypothesized mechanism applies to symptoms like hallucinations or anxiety. This Panel has previously denied centralization where, as here, the Subject Actions "allege a broad range of [injuries] without indicating the mechanism by which [defendant's drug] allegedly causes the various [injuries]." *In re Belviq*, 555 F. Supp. 3d at 1370; *see also In re Linear Gadolinium-Based Contrast Agents Prod. Liab. Litig.*, 341 F. Supp. 3d 1381, 1382 (J.P.M.L. 2018) (denying transfer where "the injuries alleged in each case appear[ed] to be highly plaintiff-specific"). Thus, any causation issues—whether Gardasil could generally, or did

[11] Movants cite comments from a December 2020 hearing in one of the Subject Actions to support their claim that Plaintiffs allege common injuries. *See* Mot. at 7. At the time of that hearing, only three of the Subject Actions had been filed—not the 34 now before the Panel. The breadth of injuries alleged by the plaintiffs in those three actions was far more limited than the wide array of allegations now subject to the Motion.

specifically, cause any given plaintiff's alleged injuries and, if so, how—would require an individualized, plaintiff-specific assessment. Given the broad swath of claimed injuries, expert discovery in one matter may have little to no bearing on the next.

Individualized issues will also arise with respect to Plaintiffs' satisfaction of the prerequisites for filing their claims. The Vaccine Act prohibits claims against vaccine manufacturers in federal (or state) court unless the Vaccine Court process has been ***properly*** exhausted (e.g., filing a petition for compensation within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury"). 42 U.S.C. §§ 300aa-11(a)(2)(B), -16(a)(2). A plaintiff-specific, jurisdictional inquiry will thus be required to investigate each plaintiff's satisfaction of the statutory prerequisites for proceeding in federal court. If an MDL were formed improperly exhausted claims would likely be filed.[12]

### D. If the Cases are Centralized, They Should be Transferred to the Hon. Jeffrey Meyer in the District of Connecticut.

While an MDL is unwarranted, if the Panel determines that centralization is appropriate, the Subject Actions should be transferred to the Hon. Jeffrey Meyer in the District of Connecticut. In the alternative, the Eastern District of Michigan (and specifically the Hon. Judith Levy) is also an appropriate transferee forum. Merck opposes centralization in the District of Arizona or Western District of Wisconsin as inefficient forums.[13]

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[12] Adjudication of Plaintiffs' claims will also require individualized inquiries arising from differences in state law. For example, Michigan and Texas state law provide certain protections where, as with Gardasil, a drug and its label were properly approved by the FDA. *See* Mich. Comp. Laws § 600.2946(5); Tex. Civ. Prac. & Rem. Code Ann. § 82.007; *see In re: Narconon Drug Rehab. Mktg., Sales Pracs. & Prods. Liab. Litig.*, 84 F. Supp. 3d 1367, 1368 (J.P.M.L. 2015) (denying transfer where "pretrial practice in each action [would] differ from action to action due to the different state and federal laws asserted in each action").

[13] Transfer to these courts would be inefficient because other courts have already performed a great deal of substantive work regarding Plaintiffs' Gardasil claims.

***Hon. Jeffrey Meyer (D. Conn.)***: With the "just and efficient and [these] actions" in mind, 28 U.S.C. § 1407, Judge Meyer is best positioned to efficiently oversee pretrial proceedings if the Subject Actions are centralized. Should the Panel order centralization, one of the central pretrial issues will be whether Plaintiffs' state law warning-related claims are preempted by federal law. Judge Meyer is the ***first and, so far, only judge in the country*** to perform the requisite substantive analysis and rule on whether a Gardasil plaintiff's failure-to-warn claims are preempted—which, along with proper exhaustion and causation, would be one of the core dispositive pretrial issues in an MDL. *See Herlth*, 2022 WL 788669, at *3. In ruling on Merck's August 2021 motion to dismiss, over a series of months Judge Meyer pored over Plaintiff's 456-paragraph First Amended Complaint, the voluminous literature and other documents cited therein (which are identical in all of the other Subject Actions' complaints), 80 pages of briefing, the pertinent federal statutes and regulations, and entertained lengthy oral argument. Judge Meyer has already thoroughly assessed one of the core dispositive issues and thus is best positioned to efficiently oversee a Gardasil MDL, if one is formed. Additionally, Judge Meyer's chambers are conveniently located a short drive or train ride from several major airports, and near Merck's headquarters.

***Hon. Judith Levy (E.D. Mich.)***: Judge Levy would also be an appropriate transferee judge. Judge Levy's court has reviewed materials substantially similar to those considered by Judge Meyer and is currently considering Merck's preemption-based motion to dismiss in *Dalton*. Her court is centrally located in the Midwest and is easily accessible through major airports.

## III. CONCLUSION

Merck respectfully requests that the Panel deny the Motion for Transfer. If centralization is ordered, Merck respectfully requests, in the alternative, a transfer to Judge Meyer in the District of Connecticut, or alternatively, to Judge Levy in the Eastern District of Michigan.

Date: May 20, 2022

*/s/ Allyson Julien*

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**Appendix A: Table of Subject Actions & Tag-Along Actions (as of May 20, 2022)**

| Date of Filing | Plaintiff | Plaintiff's Counsel | Vaccine Court Counsel | Case Status |
|---|---|---|---|---|
| 7/17/2020 | Gramza | Baum, Hedlund, Aristei & Goldman<br>Van Cott & Talamante | Van Cott & Talamente | Ongoing Discovery; Depositions Ongoing |
| 8/19/2020 | Balasco | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Ongoing Discovery;<br>Stayed Pending JPML Decision |
| 11/18/2020 | Walker | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Ongoing Discovery; Depositions Ongoing |
| 1/21/2021 | Colbath | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Motion to Dismiss Granted in Part |
| 3/30/2021 | Herlth | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Motion to Dismiss Granted;<br>Amended Complaint Filed;<br>Motion to Dismiss Second Amended Complaint Pending. |
| 4/9/2021 | Flores | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Motion to Dismiss Amended Complaint Pending |
| 7/21/2021 | Stratton | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Motion to Dismiss Granted in Part |
| 7/27/2021 | McElerney | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Ongoing Discovery |
| 7/29/2021 | Silver | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Ongoing Discovery |
| 9/21/2021 | Humphries | Siri & Glimstad LLP<br>Spiros Law, PC | Siri & Glimstad LLP | Ongoing Discovery |

| Date of Filing | Plaintiff | Plaintiff's Counsel | Vaccine Court Counsel | Case Status |
|---|---|---|---|---|
| 10/1/2021 | Dalton | Baum, Hedlund, Aristei & Goldman | Van Cott & Talamente | Motion to Dismiss Pending |
| 10/8/2021 | Muller | Baum, Hedlund, Aristei & Goldman | Van Cott & Talamente | Ongoing Discovery |
| 12/1/2021 | Sullivan | Baum, Hedlund, Aristei & Goldman<br>Feldman Pinto P.C. | Van Cott & Talamente<br>Robert J. Krakow | Motion to Remand Pending |
| 12/29/2021 | Malloy | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Motion to Dismiss Pending; Stayed Pending JPML Decision |
| 1/3/2022 | Butler | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Motion to Dismiss Pending |
| | | | | |
| 3/15/2022 | Merino | Van Cott & Talamente | Van Cott & Talamente | Unserved |
| 3/16/2022 | Atjian | A. Liberatore, P.C. | Van Cott & Talamente | Response to Complaint due due June 6 |
| 3/18/2022 | Hilton | Mullins Duncan | Turning Point Litigation | Response to Complaint due June 10 |
| 3/18/2022 | Bergin | Mullins Duncan | Van Cott & Talamente | Response to Complaint due June 10 |
| 3/18/2022 | Derr | Mullins Duncan | Van Cott & Talamente | Response to Complaint due June 10 |
| 3/18/2022 | Vela (J.V.) | Van Cott & Talamente | Van Cott & Talamente | Unserved |
| 3/18/2022 | Fetters | A. Liberatore, P.C. | Van Cott & Talamente | Response to Complaint due due June 6 |
| 3/18/2022 | Thomas (Z.T.) | Baum, Hedlund, Aristei & Goldman<br>Robert F. Kennedy, Jr. | Van Cott & Talamente | Response to Complaint due due July 5 |
| 3/21/2022 | Levy | A. Liberatore, P.C. | Van Cott & Talamente | Response to Complaint due due June 6 |
| 3/23/2022 | Hendrix | Pendley, Baudin & Coffin, LLP | Van Cott & Talamente | Response to Complaint due June 24 |

| Date of Filing | Plaintiff | Plaintiff's Counsel | Vaccine Court Counsel | Case Status |
|---|---|---|---|---|
| 3/24/2022 | Wingerter | Pendley, Baudin & Coffin, LLP | Van Cott & Talamente | Response to Complaint due June 24 |
| 3/29/2022 | Raymer | Pendley, Baudin & Coffin, LLP | Van Cott & Talamente | Response to Complaint due June 27 |
| 3/30/2022 | Soileau | Pendley, Baudin & Coffin, LLP | Van Cott & Talamente | Response to Complaint due June 24 |
| 3/31/2022 | Counts | Morgan & Morgan | Van Cott & Talamente | Unserved |
| 4/1/2022 | Landers, K. | Pendley, Baudin & Coffin, LLP | Law Offices of Chicago Kent (Edward M. Kraus) | Response to Complaint due June 27 |
| 4/1/2022 | Landers, E. | Morgan & Morgan | Van Cott & Talamente | Unserved |
| 4/3/2022 | Wagner | Pendley, Baudin & Coffin, LLP | Van Cott & Talamente | Response to Complaint due June 27 |
| 4/4/2022 | Hoddick | Bronster Fujichaku Robbins | Van Cott & Talamente | Response to Complaint due June 28 |
| 4/5/2022 | Lipscomb | Pendley, Baudin & Coffin, LLP | Van Cott & Talamente | Response to Complaint due June 27 |
| 4/18/2022 | Pennell | Pendley, Baudin & Coffin, LLP | Van Cott & Talamente | Response to Complaint due June 27 |

## Appendix B: Plaintiffs' Alleged Injuries

| Alleged Injury | # of Plaintiffs Alleging Injury |
|---|---|
| **Adjustment disorder** | 1 |
| **Adrenal disfunction** | 1 |
| **Alopecia areata** | 1 |
| **Amnesic spells** | 1 |
| **Amplification pain syndrome (AMPS)** | 2 |
| **Anaphylaxis** | 1 |
| **Anti-ovarian antibodies** | 1 |
| **Anxiety** | 5 |
| **Arthritis** | 1 |
| **Autoimmune Autonomic Neuropathy** | 1 |
| **Autoimmune inflammatory syndrome** | 1 |
| **Autonomic dysfunction** | 12 |
| **Bile acid malabsorption (BAM)** | 1 |
| **Biliary dyskinesia** | 1 |
| **Brain fog** | 1 |
| **Breast cysts** | 1 |
| **Chronic and/or severe headaches** | 2 |
| **Chronic Fatigue and Immune Dysfunction Syndrome** | 1 |
| **Chronic fatigue and tiredness** | 2 |
| **Chronic fatigue syndrome (CFS)** | 7 |
| **Chronic joint pain** | 1 |
| **Chronic pain** | 2 |
| **Complex Regional Pain Syndrome (CRPS)** | 3 |
| **Conversion disorder** | 1 |
| **Depression/major depressive disorder** | 3 |
| **Dietary issues** | 1 |
| **Dizziness** | 3 |
| **Dysautonomia** | 7 |
| **Ehlers-Danlos syndrome** | 1 |
| **Encephalopathy** | 1 |
| **Endometriosis** | 1 |
| **Essential tremor** | 1 |
| **Factor XII deficiency blood disorder** | 1 |
| **Fainting** | 2 |
| **Fibromyalgia** | 4 |
| **Gastritis** | 1 |
| **Gastroesophageal reflux disease (GERD)** | 1 |
| **Gastroparesis** | 2 |

| | |
|---|---|
| **Guillain Barre Syndrome (GBS)** | 1 |
| **Hallucinations** | 1 |
| **Hirsutism** | 1 |
| **Hormonal disturbances** | 1 |
| **Hypoaldosteronism** | 1 |
| **Hypokalemic periodic paralysis (HypoKPP)** | 1 |
| **Idiopathic Hypersomnia (IH)** | 1 |
| **Immune Thrombocytopenia (ITP)** | 1 |
| **Immune-mediated Encephalitis** | 1 |
| **Inability to talk** | 1 |
| **Inability to walk** | 1 |
| **Irlen Syndrome** | 1 |
| **Irregular menstrual cycles** | 1 |
| **Irritable bowel syndrome (IBS)** | 2 |
| **Joint hypermobility** | 1 |
| **Mast cell activation syndrome (MCAS)** | 1 |
| **Median Arcuate Ligament Syndrome (MALS)** | 1 |
| **Memory impairment/short-term memory loss** | 2 |
| **Migraines/chronic migraines** | 7 |
| **Miscarriages** | 1 |
| **Mixed connective tissue disease (MCTD)** | 1 |
| **Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS)** | 3 |
| **Narcolepsy** | 2 |
| **Neurogenic bladder** | 1 |
| **Non-cancerous breast tumors** | 1 |
| **Non-epileptic seizures** | 1 |
| **Orthostatic Hypotension (OH)** | 1 |
| **Orthostatic intolerance (OI)** | 7 |
| **Ovarian cysts** | 1 |
| **Pediatric acute-onset neuropsychiatric syndrome (PANS)** | 1 |
| **Pelvic floor dysfunction** | 1 |
| **Pilonidal cysts** | 1 |
| **Pityriasis rosea** | 1 |
| **Polyarthralgia** | 1 |
| **Polycystic ovarian syndrome (PCOS)** | 1 |
| **Postural orthostatic tachycardia syndrome (POTS)** | 25 |
| **Premature ovarian failure (POF)** | 1 |
| **Progressive vision loss/worsening vision** | 2 |
| **Reduced bone density** | 1 |
| **Scoliosis** | 1 |
| **Seizures** | 2 |

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|---|---|
| **Severe allergies** | 1 |
| **Severe insomnia** | 1 |
| **Sleep apnea** | 1 |
| **Sleeping 15-17 hours/day** | 1 |
| **Small fiber neuropathy (SFN)** | 2 |
| **Small intestinal bacterial overgrowth (SIBO)** | 1 |
| **Spasms** | 1 |
| **Symptoms mimicking Reynard's Syndrome** | 1 |
| **Syncope/near syncope** | 3 |
| **Tachycardia/sinus tachycardia** | 3 |
| **Temporomandibular joint disorder (TMJ)** | 1 |
| **Tonsillitis** | 1 |
| **Uncontrollable shaking** | 1 |
| **Vaginismus** | 1 |
| **Vasovagal allergy** | 1 |
| **Vertigo** | 1 |
| **Worsened hearing loss** | 1 |

## Appendix C: Plaintiffs' Outcomes in Vaccine Court

| Plaintiff | Court | Case No. | Vaccine Court Result |
|---|---|---|---|
| **Gramza, Jasmyne** | D. Ariz. | 2:20-cv-01425 | Petition dismissed after decision denying compensation: "The record does not support Petitioner's contention that the HPV vaccines she received caused her ITP, and/or did so in a medically acceptable timeframe. Petitioner has not established entitlement to a damages award, and therefore I must DISMISS her claim." *Gramza v. Sec'y of Health & Hum. Servs*., No. 15-247V, 2018 WL 1581674, at *1 (Fed. Cl. Feb. 5, 2018). |
| **Merino, Adriana** | D. Ariz. | 2:22-cv-00398 | Petition dismissed on petitioner's motion and "for insufficient proof". *Merino v. Sec'y of Health & Hum. Servs.*, No. 19-1723V, at 2 (Fed. Cl. Aug. 12, 2021). |
| **Vela, Allen OBO J.V.** | D. Ariz. | 2:22-cv-00420 | Petitioner moved to dismiss his petition so he could file a claim in district court. In doing so, he stated that he "feels he will be unable to prove that he is entitled to compensation in the Vaccine Program." *Vela v. Sec'y of Health & Hum. Servs.*, No. 20-1387V, at 2 (Fed. Cl. Aug. 10, 2021). The Vaccine Court dismissed his petition "for insufficient proof". |
| **Atjian, Eduardo II** | C.D. Cal. | 2:22-cv-01739 | Petitioner withdrew his petition before a decision was issued on the merits. *Atjian v. Sec'y of Health & Hum. Servs.*, No. 21-1413V (Fed. Cl. Feb. 14, 2022). |
| **Fetters, Sydney** | C.D. Cal. | 8:22-cv-00422 | Petitioner withdrew his petition before a decision was issued on the merits. *Fetters v. Sec'y of Health & Hum. Servs.*, No. 21-928V (Fed. Cl. Oct. 18, 2021). |
| **Levy, Jacob** | C.D. Cal. | 8:22-cv-00431 | Petitioner withdrew his petition before a decision was issued on the merits. *Levy v. Sec'y of Health & Hum. Servs.*, No. 20-1791V (Fed. Cl. Sept. 8, 2021). |
| **Colbath, Michael** | S.D. Cal. | 3:21-cv-00120 | Petition dismissed on petitioner's motion. *Colbath v. Sec'y of Health & Hum. Servs.*, No. 17-599V, 2020 WL 6703538 (Fed. Cl. Oct. 26, 2020). |
| **Hoddick, Jeffrey** | D. Haw. | 1:22-cv-00144 | Petitioner withdrew his petition before a decision was issued on the merits. *Hoddick v. Sec'y of Health & Hum. Servs.*, No. 20-1028V (Fed. Cl. June 23, 2021). |

| | | | |
|---|---|---|---|
| **Butler, Skylee** | D. Mass. | 3:22-cv-10006 | Petition dismissed after decision denying compensation. The Vaccine Court found no evidence to issue an award because petitioner offered no medical opinion, and "the record does not contain persuasive evidence indicating that petitioner's alleged injury was vaccine-caused or in any way vaccine-related." *Butler v. Sec'y of Health & Hum. Servs*., No. 16-1027V, 2018 WL 6822354, at *1 (Fed. Cl. Nov. 30, 2018). |
| **Sullivan, Emma** | D.N.J. | 3:22-cv-00116 | Petition dismissed for insufficient proof. The Vaccine Court noted that the petitioner had not established her injuries, "[a]nd overall, Petitioner's theories—that the HPV vaccine or flu vaccine can either cause or aggravate (a) dysautonomia and/or POTS, (b) small fiber neuropathies, (c) chronic fatigue syndrome, (d) narcolepsy, or (e) diabetes—reiterate contentions that have rarely been successful in the Program, and are medically and scientifically unreliable based upon the evidence offered in this case." *E.S. v. Sec'y of Health & Hum. Servs.*, No. 17-480V (Fed. Cl. Apr. 7, 2021). |
| **Flores, Savannah Smithson** | D. Nev. | 3:21-cv-00166 | Petition dismissed after decision denying compensation. The Vaccine Court found that despite having "had the opportunity to present reports from numerous experts and treating physicians in support of her claim of compensation. . . the reports submitted have continued to struggle to provide preponderate evidence of an association between Ms. Smithson's vaccinations and the injuries she alleged." *Smithson v. Sec'y of Health & Hum. Servs*., No. 13-735V, 2019 WL 1992636, at *1 (Fed. Cl. Apr. 9, 2019). |

| | | | |
|---|---|---|---|
| **Balasco, Julia** | D. R.I. | 1:20-cv-00364 | Petition dismissed after decision denying compensation. The Vaccine Court found that "[r]ather than suffering either postural orthostatic tachycardia or orthostatic intolerance, the evidence presented preponderates in favor of a finding that petitioner experienced fibromyalgia . . . However, contrary to petitioner's assertion, there is not preponderant evidence that fibromyalgia is an autonomic disorder. Moreover, I did not find preponderant evidence of any HPV-vaccine syndrome that could explain petitioner's alleged post-vaccination symptoms." *Balasco v. Sec'y of Health & Hum. Servs.*, No. 17-215V at 1-2 (Fed. Cl. Mar. 16, 2020). |
| **Stratton, Abigail** | D. S.C. | 2:21-cv-02211 | Petition withdrawn by petitioner prior to entitlement hearing. *Stratton v. Sec'y of Health & Hum. Servs.*, No. 20-1515V (Fed. Cl. Aug. 2, 2021). |
| **McElerney, Corrine** | M.D. Fla. | 8:21-cv-01814 | Dismissed at petitioner's request and on a finding that petitioner did not "present a reliable medical theory causally connecting petitioner's HPV vaccination to autonomic nervous system dysregulation or POTS." *McElerney v. Sec'y of Health & Hum. Servs.*, 16-1540V, 2020 WL 4938429, at *2 (Fed. Cl. July 28, 2020). |
| **Silver, Ruby** | M.D. Fla. | 8:21-cv-02903 | Petitioner withdrew her petition before a decision was issued on the merits. *Silver v. Sec'y of Health & Hum. Servs.*, No. 16-1019V, 2020 WL 4818890 (Fed. Cl. Aug. 4, 2020). |
| **Muller, Ashley** | N.D. Fla. | 3:21-cv-01335 | Petition dismissed and compensation denied because petitioner had "failed to establish that she has sustained a vaccine-related injury by preponderant evidence" in light of expert testimony that her "symptoms are more likely due to an alternative cause" and that she "likely would not have been diagnosed with POTS." *Muller v. Sec'y of Health & Hum. Servs.*, 18-1258V, 2020 WL 6267971, at *2 (Fed. Cl. Oct. 2, 2020). |
| **Thomas, Mark OBO Z.T.** | S.D. Fla. | 9:22-cv-80445 | Petition withdrawn by petitioner prior to entitlement hearing. *Thomas v. Sec'y of Health & Hum. Servs.*, No. 20-886V (Fed. Cl. Apr. 12, 2021). |
| **Hendrix, Darby** | N.D. GA | 1:22-cv-01171 | Petition withdrawn by petitioner prior to entitlement hearing. *Hendrix v. Sec'y of Health & Hum. Servs.*, No. 20-868V (Fed. Cl. Mar. 17, 2021). |

| | | | |
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| **Wingerter, Ken & Shaun OBO H.W.** | N.D. GA | 1:22-cv-01178 | Petition withdrawn by petitioner prior to entitlement hearing. *Wingerter v. Sec'y of Health & Hum. Servs.*, No. 20-1408V (Fed. Cl. July 8, 2021). |
| **Humphries, Cooper** | C.D. Ill. | 4:21-cv-04154 | Petitioner withdrew his petition before a decision was issued on the merits. *Humphries v. Sec'y of Health & Hum. Servs.*, No. 16-1019V, 2020 WL 4818890 (Fed. Cl. Aug. 4, 2020). |
| **Landers, Krista** | N.D. Ill. | 1:22-cv-01696 | Petition withdrawn by petitioner prior to entitlement hearing. In her request to dismiss the petition, she stated that "because of the complex presentation of her illness and paucity of medical literature examining the causal connection between vaccines and dysautonomia and POTS, the expert . . . has been unable to provide a medical opinion to establish the vaccine was more likely than not the cause of [Petitioner's] condition. . . . Petitioner believes she will be unable to prove that she is entitled to compensation in the Vaccine Program." *K.L. v. Sec'y of Health & Hum. Servs.*, No. 16-645V, at 2 (Fed. Cl. May 13, 2020). |
| **Wagner, Tanja & Scott OBO S.W.** | N.D. Ill. | 1:22-cv-01717 | Petition dismissed on petitioner's motion and for insufficient proof. The petitioner's proffered "medical opinion alone did not provide persuasive evidence supporting a finding of entitlement. Nor did petitioners present a reliable medical theory causally connecting [petitioner's] HPV vaccination to POTS." *Wagner v. Sec'y of Health & Hum. Servs.*, No. 19-188V, 2020 WL 6554930, at *2 (Fed. Cl. Oct. 14, 2020). |
| **Raymer, Jessica** | N.D. Ill. | 1:22-cv-01643 | Petition dismissed on petitioner's motion and for insufficient proof. *Raymer v. Sec'y of Health & Hum. Servs.*, No. 18-794V, 2020 WL 4362147 (Fed. Cl. July 6, 2020). |
| **Lipscomb, Madelyn** | N.D. IN | 1:22-cv-00116 | Petition withdrawn by petitioner prior to entitlement hearing. *Lipscomb v. Sec'y of Health & Hum. Servs.*, No. 21-784V (Fed. Cl. Oct. 19, 2021). |
| **Soileau, Nalon** | M.D. LA | 3:22-cv-00210 | Petition withdrawn by petitioner prior to entitlement hearing. *Canning v. Sec'y of Health & Hum. Servs.*, No. 21-1016V (Fed. Cl. Nov. 22, 2021). |
| **Dalton, Ashley** | E.D. Mich. | 2:21-cv-12324 | Petition dismissed on petitioner's motion and for insufficient proof because "the evidence weighs against a finding that Ms. Dalton suffered from POTS." *Dalton v. Sec'y of Health & Hum. Servs.*, No. 15-1465V, 2020 WL 5800716, at *2 (Fed. Cl. July 6, 2020). |

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| **Derr, Maeson** | M.D.N.C. | 1:22-cv-00212 | Petition dismissed on petitioner's motion before a decision was issued on the merits. *Derr v. Sec'y of Health & Hum. Servs.*, No. 18-751V, 2020 WL 5753350 (Fed. Cl. Aug. 10, 2020). |
| **Bergin, Payton** | W.D.N.C. | 3:22-cv-00117 | Petition dismissed for insufficient proof because "the evidence weighs against a finding that Ms. Bergin suffered from idiopathic hypersomnia," the injury alleged in that case. *Bergin v. Sec'y of Health & Hum. Servs.*, No. 17-241V, 2020 WL 5800718, at *3 (Fed. Cl. Sept. 1, 2020). |
| **Hilton, Kameron** | W.D.N.C. | 5:22-cv-00030 | Petition dismissed. Opinion not available. *H. v. Sec'y of Health & Hum. Servs.*, No. 17-1739V. |
| **Malloy, Madelyn** | E.D. Tex. | 6:21-cv-00506 | Petition withdrawn by petitioner prior to entitlement hearing. *Malloy v. Sec'y of Health & Hum. Servs.*, No. 21-1153V, 2021 WL 6622462, at *1 (Fed. Cl. Dec. 29, 2021). |
| **Counts, Madeline** | N.D. Tex. | 4:22-cv-00241 | Petition withdrawn by petitioner prior to entitlement hearing. *Counts v. Sec'y of Health & Hum. Servs.*, No. 20-1782V (Fed. Cl. Sept. 20, 2021). |
| **Walker, Sahara** | W.D. Wis. | 3:20-cv-01048 | Petition dismissed "for insufficient proof." "[T]he evidence weighs against a finding that Ms. Walker suffered from POTS or other injuries alleged. Without a showing that the vaccinee suffered the injury that the vaccine allegedly caused, the remainder of the case becomes moot… Accordingly, the undersigned is not required to evaluate whether the HPV vaccine can cause POTS.". *Walker v. Sec'y of Health & Hum. Servs.*, No. 16-543V, 2020 WL 5641871, at *1 (Fed. Cl. Aug. 25, 2020). |
| **Landers, Elizabeth OBO I.L.** | S.D. W. Va. | 2:22-cv-00160 | Petition withdrawn by petitioner prior to entitlement hearing. *Landers v. Sec'y of Health & Hum. Servs.*, No. 21-1499V (Fed. Cl. Feb. 22, 2022). |
| **Herlth, Korrine** | D. Conn. | 3:21-cv-00438 | Petition dismissed on petitioner's motion and because "the record does not contain persuasive evidence indicating that petitioner's alleged injury was vaccine-caused or in any way vaccine-related." *Herlth v. Sec'y of Health & Hum. Servs.*, No. 16-71V, 2020 WL 4280698, at *1 (Fed. Cl. July 2, 2020). |
| **Pennell, Amy J., guardian of minor, M.L.P.** | N.D. Ohio | 5:22-cv-00619 | Petition dismissed on petitioner's motion and "for insufficient proof". In her request to dismiss the petition, she stated that she wanted to "opt out of the Vaccine Program" and "pursue a third-party action in district court against Merck directly." *Pennell v. Sec'y of Health & Hum. Servs.*, No. 20-257V (Fed. Cl. Oct. 29, 2021). |