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SENT VIA ECF

September 20, 2022

Honorable Robert J. Conrad
United States District Judge
Western District of North Carolina
6200 Charles R. Jonas Federal Building
401 West Trade Street
Charlotte, NC 28202

Re: In re Gardasil Products Liability Litigation, Case No. 3:22-md-03036-RJC-DCK

Dear Judge Conrad:

Pursuant to the Court's First Pretrial Order, dated August 10, 2022, Defendants Merck & Co., Inc. and Merck Sharp & Dohme LLC (collectively, "Merck") respectfully submit this Position Statement:

I. Brief Statement of the Facts in this Litigation and the Critical Factual and Legal Issues

This novel litigation, in which Plaintiffs allege that the long-standing Food & Drug Administration-approved Gardasil human papillomavirus ("HPV") vaccine[1] caused them to develop Postural Orthostatic Tachycardia Syndrome ("POTS"), Chronic Fatigue Syndrome ("CFS"), Complex Regional Pain Syndrome ("CRPS"), and a host of other generic conditions and symptoms, is an MDL unlike any other. Plaintiffs' attempt to impugn Gardasil—a cancer-preventing, life-saving vaccine—is fundamentally flawed for numerous reasons:

- Gardasil is a routine childhood vaccine covered by the National Childhood Vaccine Injury Act ("Vaccine Act") and currently recommended by the Advisory Committee on Immunization Practices ("ACIP") and the Centers for Disease Control and Prevention ("CDC") "***for everyone through age 26 years***, if they are not vaccinated already" (with very limited exceptions not alleged to be applicable to anyone before this Court). CDC, What Can I Do to Reduce My Risk of Cervical Cancer, available at https://www.cdc.gov/cancer/cervical/basic_info/prevention.htm

[1] There are two Gardasil vaccines—a 4-valent vaccine approved in June 2006, and a 9-valent vaccine approved in December 2014. *See infra* n.3. Throughout this brief, unless otherwise noted, 4-valent Gardasil and 9-valent Gardasil 9 are collectively referred to as "Gardasil."

(emphasis added).[2] Because Gardasil is subject to the Vaccine Act, all of the plaintiffs in this MDL were required to first present their claims in the Office of the Special Masters in the U.S. Court of Federal Claims ("Vaccine Court")—created by Congress as part of the Vaccine Act—before filing their federal lawsuit against Merck. ***None*** of the 49 plaintiffs in this MDL were awarded any compensation in the Vaccine Court's no-fault system for any of their claims. This MDL is unprecedented because it is the first comprised of former Vaccine Court claims for a routine childhood vaccine covered by the Vaccine Act.

- The Gardasil vaccine remains FDA-approved and has never been withdrawn. To the contrary, Gardasil has been FDA-approved since 2006, and its approved indications have only expanded over the years. *See* FDA, Gardasil 9, available at https://www.fda.gov/vaccines-blood-biologics/vaccines/gardasil-9; FDA, Gardasil, available at https://www.fda.gov/vaccines-blood-biologics/vaccines/gardasil.

- Despite continuous safety monitoring of Gardasil, the FDA and CDC have not identified any safety issues related to this vaccine. To the contrary, the "FDA and CDC continue to find that Gardasil is a safe and effective vaccine," find that Gardasil's "benefits continue to outweigh its risks," and "monitor the safety of this vaccine, with the public's health and safety" serving as those federal agencies' "top priority." *See* FDA, Gardasil Vaccine Safety, available at https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/gardasil-vaccine-safety.

- There has been no seminal literature publication regarding a potential safety or efficacy issue with Gardasil. To the contrary, countless reliable scientific publications and reputable medical organizations continue to confirm the safety and efficacy of this vaccine.

    - According to a recent statement of more than 20 national medical associations, including the American Academy of Pediatrics and the American Cancer Society, "HPV vaccines [including Gardasil] are among the most effective vaccines available worldwide, with unequivocal data demonstrating greater than 99% efficacy for some populations." Joint Statement on the Elimination of HPV, available at https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/news/joint-statement_hpv-012121-v1.pdf.

    - The American Autonomic Society, whose members include physicians who treat patients with POTS and other conditions of the autonomic nervous system, recently published a position statement finding "the data do not support a causal relationship between HPV vaccination and CRPS, POTS, or other forms of dysautonomia." Ex. 1, Barboi, A., et al., Human papillomavirus (HPV) vaccine and autonomic disorders: a position statement from the American Autonomic Society, Clin. Auton. Res. (2019).

In short, there is no reliable scientific evidence that Gardasil causes POTS, CFS, CRPS, or other of Plaintiffs' alleged injuries. Not only is there no reliable evidence of general causation, Plaintiffs' failure-to-warn-based claims are preempted by federal law. The FDA has repeatedly approved the Gardasil label without warnings related to POTS, CFS, CRPS, or other claimed injuries (including as recently as August of 2020), and there is no evidence of "newly acquired information" suggesting a causal association between Gardasil and Plaintiffs' alleged harms to warrant a unilateral change to the Gardasil label by Merck, as would be required for Plaintiffs to avoid a preemption defense. *See infra* p. 9–10. Indeed, earlier this year, a federal district court confirmed these points and dismissed a Gardasil plaintiff's warnings-based claims as preempted by federal law. *See Herlth v. Merck & Co.*, No. 3:21-CV-438, 2022 WL 788669, at *3–5 (D. Conn. Mar. 15, 2022) (dismissing plaintiff's claims without prejudice as preempted and for failure to state a claim) (attached as Ex. 2).

[2] Merck would be pleased to submit literature and/or documents supporting the statements in this letter at the Court's request.

In light of the unprecedented nature of this MDL and the paramount importance of continued public trust in safe and effective routine childhood vaccines, Merck respectfully requests that the Court prioritize the dispositive issues of implied preemption and general causation—with an initial focus on three of the most commonly alleged injuries: POTS, CFS, and CRPS (and three additional alleged injuries of Plaintiffs' choosing if they view other injuries as higher priority). Merck submits that an early resolution of these sweeping issues would best promote efficiency and judicial economy, and a *Daubert* and summary judgment ruling would serve as a lodestar in resolving what few claims, if any, may remain. In addition, and for the reasons detailed below, Merck also respectfully requests the following:

- The early submission of bellwether motion(s) to dismiss addressing Plaintiffs' global pleading deficiencies, including direct failure-to-warn claims and thinly veiled design defect claims as expressly barred by the Vaccine Act, manufacturing defect claims as inadequately pled, and Plaintiffs' fraud claims for failure to satisfy Federal Rule of Civil Procedure 9(b);

- Simultaneous limited workup of core discovery in cases alleging POTS, CFS, CRPS, and any of the three additional alleged injuries chosen by Plaintiffs;

- Defendant Fact Sheets and Plaintiff Fact Sheets, and a procedure for promptly dismissing Plaintiffs' Complaints where he or she has failed to (1) timely submit a complete Plaintiff Fact Sheet and/or (2) demonstrate that he or she timely filed and exhausted her or his claims in Vaccine Court in the manner required by the Vaccine Act; and

- Coordination before this MDL Court of all continued pretrial discovery and discovery motions now pending in the California state court Gardasil cases and any future state court proceedings.

A. Gardasil

Gardasil[3] is an FDA-approved vaccine that protects against cervical, vulvar, vaginal, penile, anal, and oropharyngeal cancers and their associated precancerous lesions, as well as genital warts, caused by certain types of HPV. First approved in the U.S. in 2006, 4-valent Gardasil prevents infection with HPV types 16 and 18, "two high-risk HPVs that cause about 70% of cervical cancers and an even higher percentage of some of the other HPV-caused cancers," and types 6 and 11, "which cause 90% of genital warts." National Institutes of Health ("NIH"), National Cancer Institute, HPV Vaccines, available at https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-vaccine-fact-sheet. In 2014, the FDA approved Gardasil 9, which protects against HPV infection from the same four HPV types as 4-valent Gardasil but adds protection for five other oncogenic HPV types that account for an additional 10 to 20% of cervical cancers. With very limited exceptions, CDC recommends HPV vaccination for all persons between 9 and 26 years old and for some adults through 45 years.[4] Depending on age at the time

[3] There are two Gardasil vaccines—a 4-valent vaccine approved in June 2006, and a 9-valent vaccine approved in December 2014. *See* FDA, Gardasil 9, available at https://www.fda.gov/vaccines-blood-biologics/vaccines/gardasil-9; FDA, Gardasil, available at https://www.fda.gov/vaccines-blood-biologics/vaccines/gardasil. The FDA approved Gardasil for use in children and young adults aged 9-26 for the prevention of cervical, vulvar, vaginal, and anal cancers as well as for the prevention of genital warts. The FDA extended Gardasil's approvals for Gardasil 9 to include men and women ages 27-45, and approved Gardasil 9's additional indications for the prevention of anal intraepithelial neoplasia (AIN) as well as oropharyngeal and other head and neck cancers. Because of the additional HPV type-protections provided by Gardasil 9, Merck has only distributed the 9-valent Gardasil 9 vaccine (and not the 4-valent vaccine) in the U.S since approximately 2016. The CDC has noted that "[w]hile only Gardasil 9 has been available for use in the United States since late 2016, safety studies of Gardasil have provided important safety information relevant for Gardasil 9…." CDC, HPV Vaccine Safety and Effectiveness Data, available at https://www.cdc.gov/hpv/hcp/vaccine-safety-data.html. Throughout this brief, unless otherwise noted, 4-valent Gardasil and 9-valent Gardasil 9 are collectively referred to as "Gardasil."

[4] The timing of vaccination is critical: "Although HPV vaccines have been found to be safe when given to

of vaccination and various other considerations, Gardasil is administered in a 2-dose or 3-dose schedule. Gardasil has been the only HPV vaccine available in the United States since approximately late 2016.

HPV is a viral infection that affects millions of Americans; in fact, "85% of people will get an HPV infection in their lifetime." CDC, Reasons to Get Vaccinated, available at https://www.cdc.gov/hpv/parents/vaccine/six-reasons.html. HPV is a known cause of cervical cancer, as well as cancers of the vulva, vagina, penis, anus, and oropharynx. Although HPV infections can go away on their own, "infections that don't go away can cause certain types of cancer." *Id.* HPV can lead to cancer "[w]hen the body's immune system can't get rid of an HPV infection with oncogenic HPV types." CDC, HPV and Cancer, Basic Information, available at https://www.cdc.gov/cancer/hpv/basic_info/index.htm. "There is no way to know which people who get HPV now will develop cancer . . . ." CDC, HPV Fact Sheet, available at https://www.cdc.gov/std/hpv/stdfact-hpv.htm.

"HPV is estimated to cause nearly 36,500 cases of cancer in men and women every year in the United States." CDC, Reasons to Get Vaccinated, *see supra*. According to the CDC, approximately 4,000 women die each year of cervical cancer nationwide. CDC, Cancers Caused by HPV are Preventable, *see supra*. Of the cancers caused by HPV, "[o]nly cervical cancer can be detected early with a screening test [known as a Pap test]. The other cancers caused by HPV may not be detected until they are more serious." CDC, Reasons to Get Vaccinated, *see supra*. As a diagnostic method, the effectiveness of the Pap test depends on routine and timely screening. To be effective, Pap tests should be repeated every 3 to 5 years. CDC, What Should I Know About Screening?, available at https://www.cdc.gov/cancer/cervical/basic_info/screening.htm.

In addition to cervical cancer diagnoses, there are approximately "196,000 cervical precancer cases" annually according to the CDC. Treatment for cervical lesions is invasive and can "limit a person's ability to have children." CDC, Cancers Caused by HPV are Preventable, *see supra*. The CDC estimates that "[p]rior to HPV vaccines, genital warts caused by HPV affected roughly 340,000 to 360,000 people yearly." CDC, HPV Fact Sheet, *see supra*. Genital warts can be painful or pruritic (itchy), and the CDC notes that "[t]he appearance of warts also can result in significant psychosocial distress." CDC, 2015 STD Treatment Guidelines, available at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm. According to the CDC, the available treatments for genital warts "probably do not eradicate[ ] HPV infectivity," which means that the condition may be transmitted to others. *Id.*

Gardasil vaccination helps prevent HPV infections that cause these HPV-associated cancers, pre-cancerous growths, and genital warts. The CDC has noted that 4-valent and 9-valent Gardasil were both found be "safe and effective in clinical trials." CDC, HPV Vaccine Safety and Effectiveness Data, available at https://www.cdc.gov/hpv/hcp/vaccine-safety-data.html. The National Cancer Institute reports that, during clinical trials, Gardasil was found to provide nearly 100% protection against persistent cervical infections with HPV types 16 and 18. NIH, National Cancer Institute, HPV Vaccines, *see supra*. Additionally, "[t]he trials that led to approval of Gardasil 9 found it to be nearly 100% effective in preventing cervical, vulvar, and vaginal infections and precancers caused by the five additional HPV types . . . it targets." *Id.* Since HPV vaccines like Gardasil have been in use in the U.S.,[5] "HPV infections, genital warts, and cervical precancers

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people who are already infected with HPV, the vaccines provide maximum benefit if a person receives them before he or she is sexually active." NIH, National Cancer Institute, HPV Vaccines, *see supra*; *see also* Falcaro M, et al., *The effects of the national HPV vaccination programme in England, UK, on cervical cancer and grade 3 cervical intraepithelial neoplasia incidence: a register-based observational study*, Lancet 2021 Dec 4;398(10316):2084-2092 (finding HPV vaccination campaigns "can lead to a substantial reduction in cervical cancer incidence, especially if vaccination coverage is high and women are offered the vaccine at a younger age."). Despite early theoretical questions raised by some, scientific research has shown the timing of HPV vaccination is not associated with sexual debut or risky sexual behavior. *See, e.g.*, Liddon NC, Leichliter JS, Markowitz LE, *Human papillomavirus vaccine and sexual behavior among adolescent and young women*, Am J Prev. Med. 2012 Jan;42(1):44-52; Marchand E, Glenn BA, Bastani R, *HPV vaccination and sexual behavior in a community college sample*, J Comm. Health 2013 Dec;38(6):1010–4.

[5] In addition to 4-valent and 9-valent Gardasil, a 2-valent HPV vaccine by a different manufacturer—Cervarix—has also been approved by the FDA. However, as noted, only 9-valent Gardasil 9 has been

. . . have dropped." CDC, Reasons to Get Vaccinated*, see supra*. For example, "[i]nfections with HPV types that cause most HPV cancers and genital warts have dropped 88% among teen girls and 81% among young adult women" and "[a]mong vaccinated women, the percentage of cervical precancers caused by the HPV types most often linked to cervical cancer have dropped by 40 percent." *Id*.

To this day, public health authorities including the FDA, CDC, NIH, and the World Health Organization ("WHO") as well as reputable medical and scientific organizations and ever accumulating reliable peer-reviewed studies[6] continue to find that Gardasil is both safe and effective. According to the WHO, with more than a decade of real-world data available, "[t]o date no safety concerns have arisen during the pre-licensure clinical trials or in post-licensure surveillance." WHO, Safety of HPV vaccines, available at https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/human-papillomavirus-vaccines/safety. The CDC has confirmed the overall safety and effectiveness of Gardasil, writing that "[t]he safety of HPV vaccine has been well studied," and that "[a]ll three HPV vaccines," including 4-valent Gardasil and 9-valent Gardasil 9, "went through years of extensive safety testing before [they were] licensed by the FDA, which only licenses a vaccine if it is safe, effective, and the benefits outweigh any risks." CDC, Questions about HPV Vaccine Safety – General HPV Vaccine Safety, available at https://www.cdc.gov/vaccinesafety/vaccines/hpv/hpv-safety-faqs.html.

B. Plaintiffs' Alleged Injuries

Plaintiffs in the 49 federal cases allege a broad range of medical conditions and generic symptoms under a purported umbrella of "autoimmune" conditions. *See* App'x A, Plaintiffs' Alleged Injuries. Three of the most commonly alleged injuries (alleged by 40 of the 49 current Gardasil Plaintiffs) are POTS, CFS, and CRPS. These conditions are not uncommon in adolescents and occur in the general population in the absence of vaccination.

- POTS is a condition that affects circulation. It involves the autonomic nervous system (which automatically controls and regulates a variety of vital bodily functions) and the sympathetic nervous system (which activates the fight or flight response). The most frequent symptoms of POTS are lightheadedness, fainting, and a rapid increase in heartbeat that develop when standing up from a reclining position. The majority of POTS patients are women aged 13 to 50. Between one and three million people suffer from POTS in the United States. *See* Cleveland Clinic, Postural Orthostatic Tachycardia Syndrome (POTS), available at https://my.clevelandclinic.org/health/diseases/16560-postural-orthostatic-tachycardia-syndrome-pots.

- CFS is a condition characterized by extreme exhaustion lasting for at least six months. *See* Cleveland Clinic, Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), available at https://my.clevelandclinic.org/health/diseases/17720-myalgic-encephalomyelitischronic-fatigue-syndrome-mecfs.

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distributed in the United States since around 2016.

[6] *See, e.g.*, Berenson AB, Guo F, Chang M, *Association of Human Papillomavirus Vaccination With the Incidence of Squamous Cell Carcinomas of the Anus in the US*, JAMA Oncol. 2022;8(4):1–3; Lehtinen M, et al., *Human papillomavirus vaccine efficacy against invasive, HPV-positive cancers: population-based follow-up of a cluster-randomised trial*, BMJ Open, 2021 Dec 30; Falcaro M, et al., *The effects of the national HPV vaccination programme in England, UK, on cervical cancer and grade 3 cervical intraepithelial neoplasia incidence: a register-based observational study*, Lancet 2021 Dec 4;398(10316):2084–2092; Kjaer SK, Dehlendorff C, Belmonte F, Baandrup L, *Real-World Effectiveness of Human Papillomavirus Vaccination Against Cervical Cancer*, J Natl Cancer Inst. 2021 Oct 1;113(10):1329–1335; Lei J, et al., *HPV Vaccination and the Risk of Invasive Cervical Cancer*, N. Engl. J. Med. 2020 Oct 1;383(14):1340–1348; Drolet M, Bénard É, Pérez N, Brisson M, *Population-level impact and herd effects following the introduction of human papillomavirus vaccination programmes: updated systematic review and meta-analysis*, Lancet 2019 Aug 10;394(10197). These publications also make clear that vaccination at a younger age confers greater protection.

- CRPS is a condition that causes pain, swelling, and changes in skin color and texture and usually affects the extremities. *See* Cleveland Clinic, Complex Regional Pain Syndrome (CRPS), available at https://my.clevelandclinic.org/health/diseases/12085-complex-regional-pain-syndrome-crps. CRPS is generally defined as continuing pain that is disproportionate to the inciting event, may be associated with dysautonomic signs and symptoms, and is usually confined to a single limb.

Departing from the varied allegations in their complaints, Plaintiffs' sworn testimony thus far has revealed a much narrower universe of injuries. Three of the 49 federal plaintiffs have been deposed to date, and all three testified to far fewer claimed injuries than they alleged in their complaints. For example, at Plaintiff Sahara Walker's deposition, her long list of alleged injuries and "symptoms" in her Complaint and written interrogatories was reduced to one condition—POTS—in response to questions by Merck's counsel:

Injuries Alleged in Sahara Walker's Complaint[7]	**Injuries Claimed in Response to Merck's Questioning at Deposition**
• Neurocardiogenic syncope • POTS • Orthostatic hypotension • Autoimmune autonomic neuropathy • Small fiber neuropathy • Additional symptoms including vomiting, headaches, severe body aches, fever, dizziness, weakness, daily migraines, sensitivity to light, lightheadedness, nausea, fainting, pallor, dark circles under her eyes, constant abdominal pain, constant stomach upset, decreased appetite, severe joint, muscle, and bone pain, leg weakness, tingling, numbness, and legs giving out, vision impairment and occasional blurry vision, cognitive processing impairment where she would become easily confused, problems with concentration, short-term memory loss, chest pain, shortness of breath, occasional lower back pain, extreme fatigue, altered sense of taste, pins and needles in the extremities, always feeling cold and having chills, low-grade fevers, trouble hearing and tinnitus, becoming easily agitated, and hypersomnia	• POTS

Further, while these three Plaintiffs uniformly alleged in their Complaints that they continue to suffer "debilitating" injuries, their sworn testimony again tells a different story. For example, Ms. Walker's Complaint alleges that she was "bedridden" for "several years" following her vaccination with Gardasil, *see* Walker Compl. ¶ 352, but according to her deposition testimony she spent those same years riding four-wheelers and mountain biking.

* * *

As will be described more fully below, significant efficiencies will be gained by continuing limited case workup of the 40 Plaintiffs alleging POTS, CFS, CRPS (and any of the three alleged injuries of Plaintiffs' choosing) through the early stages of this litigation. Although Merck requests prioritization of certain key issues as described below, Merck also asks that the parties be permitted to simultaneously continue—in the cases of injuries described above—deposing Plaintiffs, their parents (if appropriate), their vaccinating physicians, and one treating physician of each party's choosing. *See In re Zoloft Prods. Liab. Litig.*, MDL No. 2342, PTO 15 (permitting general causation *Daubert* briefing while allowing "Threshold Plaintiff Discovery" for the "Initial Discovery Group," including Plaintiff Fact Sheets, and depositions of plaintiffs, their parents, physicians and certain treating physicians (attached as Ex. 3). Merck submits that

[7] *See Walker v. Merck & Co, Inc. et al.*, No. 3:22-cv-00388 (W.D.N.C.), Dkt. No. 1, Compl. ¶¶ 349–50, 353–54.

continuing with limited case work in this fashion will streamline the *Daubert* and preemption issues while greatly assisting the parties in making informed bellwether trial selections and avoiding any prolonged delay in this MDL.

C. Vaccine Act and Vaccine Court

Recognizing the paramount importance of vaccines to public health, 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, 1986 U.S.C.C.A.N. 6344, 6353. At the time, lawsuits were causing manufacturers of lifesaving childhood vaccines to withdraw from the vaccine market. The Vaccine Act thus had two goals: "[t]o stabilize the vaccine market and facilitate compensation." *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011). As noted, Gardasil is a routine childhood vaccine covered by the Vaccine Act. *See* 42 C.F.R. § 100.3.

The Vaccine Act created the National Vaccine Injury Compensation Program ("VICP"), a "no-fault compensation program designed to work faster and with greater ease than the civil tort system." *Bruesewitz*, 562 U.S. at 228. Pursuant to the Act, claimants, or their legal guardians, must file a petition before a special master in the U.S. Court of Federal Claims, often referred to as Vaccine Court, before they can pursue a claim for compensation in state or federal court. 42 U.S.C.A. § 300aa-11(a)(2)(A). Notably, the respondent in Vaccine Court is the Secretary of Health and Human Services.[8] Vaccine manufacturers like Merck are not parties to the Vaccine Court process.

Vaccine Court is a "***no-fault***" compensation system. This means that "[u]nlike 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[9] or that her injuries were caused by the vaccine. *See 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). Claimants must prove causation by a preponderance of the evidence by showing "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Unlike *Daubert* in federal court, *Althen* does not provide special masters with a basis to exclude expert testimony; rather, special masters are left to exercise their own discretion to decide how to weigh expert testimony. Special masters in Vaccine Court are not required to apply Federal Rule of Evidence 702 or *Daubert* principles to expert evidence. *See* Vaccine R. 8(b)(1) (2009) ("In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.").

"The *quid pro quo* for this [no-fault system] was the provision of significant tort liability protections for vaccine manufacturers." *Bruesewitz*, 562 U.S. at 229. The Act offers at least six significant protections

[8] The FDA is an agency of the U.S. Department of Health & Human Services ("HHS"). *See* HHS, Food & Drug Administration, available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/fda/index.html.

[9] The Vaccine Injury Table "lists the vaccines covered under the Act; describes each vaccine's compensable, adverse side effects; and indicates how soon after vaccination those side effects should first manifest themselves." *Bruesewitz*, 562 U.S. at 228. The Vaccine Injury Table currently lists three compensable injuries for HPV vaccines: anaphylaxis (within 4 hours of administration), shoulder injury related to vaccine administration (within 48 hours of administration), and vasovagal syncope (within 1 hour of administration). Vaccine Injury Table, available at https://www.hrsa.gov/sites/default/files/hrsa/vicp/vaccine-injury-table-01-03-2022.pdf. Claimants that have a "Table" injury are "prima facie entitled to compensation" if a "listed injury first manifested itself at the appropriate time." *Id.*

directly impacting the adjudication of this MDL:

- ***Express preemption of design defect claims***: Design defect claims are expressly preempted by the Vaccine Act. Claimants cannot sue for any "unavoidable side effects," or "design defects" in a vaccine. *Id.* at 232.

- ***Prohibition of direct failure to warn claims:*** Claims based on a supposed failure to warn the patient directly—as opposed to his or her vaccinating physician—are prohibited entirely. *Id.;* 42 U.S.C.A. § 300aa-22(c).

- ***Vaccine Court exhaustion:*** The Vaccine Act prohibits lawsuits against vaccine manufacturers in federal or state court unless those claims have been properly exhausted in Vaccine Court. *See Powers v. Merck & Co., Inc.*, No. 2:17-CV-268, 2018 WL 8899566, at *3 (S.D. Ohio Sept. 13, 2018), *aff'd*, 773 F. App'x 304 (6th Cir. 2019) ("[A] party cannot file a civil action against a vaccine manufacturer for a 'vaccine-related injury' unless the party first filed a timely petition in accordance with the Vaccine Act's requirements."); *see also* 42 U.S.C.A. § 300aa-11(a)(2).

- ***Presumption of adequate warnings:*** "Manufacturers are generally immunized from liability for failure to warn if they have complied with all regulatory requirements . . . and have given the warning either to the claimant or the claimant's physician." *Bruesewitz*, 562 U.S. at 229. The Act "imposes a presumption that compliance with Food and Drug Administration requirements means the manufacturer provided proper directions and warnings." *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, *3 (1st 1994) (citing 42 U.S.C.A. § 300aa-22(b)(2)).

- ***Trifurcation of trial:*** The Vaccine Act requires that civil actions against vaccine manufacturers for injuries alleged to be vaccine-related must be tried in three stages: (1) the first stage of trial "shall be held to determine if a vaccine manufacturer is liable under section 300aa-22" of the Act; (2) the second stage "shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found liable under section 300aa-22…shall be required to pay"; and (3) "[i]f sought by the plaintiff, the third stage "shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa-22..shall be required to pay." 42 U.S.C.A. § 300aa-23.

- ***Limitations on punitive damages:*** Punitive damages are not available in the third phase of a trifurcated vaccine-injury trial except in cases of "fraud," "intentional and wrongful withholding of information," or "criminal or illegal activity." *Bruesewitz*, 562 U.S. at 229 (quoting 42 U.S.C.A. § 300aa-23(d)(2)).

Despite the relaxed standards for recovery in Vaccine Court, ***no*** Plaintiffs in this MDL have been awarded any compensation for their alleged Gardasil-related injuries in Vaccine Court. *See* App'x. B, Vaccine Court Summary. Every single Plaintiff's claim was either dismissed as not entitled to compensation, dismissed for insufficient proof, or the claim was withdrawn from Vaccine Court before a decision on the merits could be issued.[10] In some cases, Plaintiffs even admitted, again in the no-fault context of Vaccine

[10] After a string of Gardasil-related losses in Vaccine Court, Vaccine Court claimants and their counsel deployed a new tactic and began exploiting the Vaccine Court's 240-day withdrawal provision. Rather than withdrawing the petition after 240 days because the Vaccine Court process was taking too much time, here Plaintiffs are simply filing skeletal petitions and then seeking serial extensions of their statutory filing deadlines until the 240-day statutory period has passed with no demonstrable intent to have their claims adjudicated in Vaccine Court. *See, e.g.*, Ex. 4, *Fetters v. Sec. of Health & Human Servs.*, No. 1:21-VV-00928, Dkt. Nos. 7, 8, 10, 11, 12, 13, 14, 16, (filing eight extension motions until 240 days elapsed). Once the 240-day statutory period has expired, these Plaintiffs have quickly withdrawn their ***incomplete*** petitions and proceeded to file suit against Merck. Having never submitted completed petitions, these claimants-turned-plaintiffs all assured that the Vaccine Court would be unable to rule on the merits of their Vaccine Court claims within 240 days. *See, e.g.*, Ex. 4, *Fetters*, Dkt. Nos. 17, 18 (withdrawn same day as 240-day notice). Merck submits that this strategy—employed by multiple plaintiffs in this MDL—is not what Congress

Court, that they would "not be able to establish entitlement to compensation." *E.g., Vela on behalf of J.V. v. Sec'y of Health & Hum. Servs.*, 2021 WL 4065524, at *1 (Fed. Cl. Aug. 10, 2021). Because Plaintiffs were unable to show causation and recover even in a no-fault system, Merck submits that this MDL should be structured to focus on preemption and general causation.

D. Critical Legal Issues

1. *Preemption*

In addition to the express preemption protections described above, implied preemption of Plaintiffs' failure to warn-based claims is a critical and dispositive legal issue presented by this litigation that warrants priority. Plaintiffs' failure-to-warn-based claims—the central claims in this litigation—are preempted by federal law. The ***only court*** to have considered and ruled on this issue "agree[d]" with Merck's preemption argument and "dismiss[ed]" the plaintiff's case "to the extent that it relie[d] on a failure-to-warn theory of liability." Ex. 2, *Herlth,* 2022 WL 788669, at *3–5. That stands to reason: not only do Plaintiffs lack evidence that Merck could have unilaterally added Plaintiffs' desired warnings to Gardasil's labeling consistent with federal law, but "the FDA has continued to approve labels" at odds with Plaintiffs' claims and has specifically rejected the scientific theories Plaintiffs present in this litigation. *See Knight v. Boehringer Ingelheim Pharms., Inc.*, 984 F.3d 329, 339 (4th Cir. 2021) (holding failure-to-warn claims against FDA-approved medicine impliedly preempted). Because the deficiencies identified in *Herlth* apply equally here, warnings-based claims in this litigation, including those related to POTS, CFS, and CRPS, are preempted and therefore fail.

A. Plaintiffs must show Merck could have changed Gardasil's label using the CBE regulation

The FDA's approval process for vaccines like Gardasil places "onerous and lengthy" requirements upon the company seeking approval. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013) (discussing approval process for prescription medicines); *see Bruesewitz,* 562 U.S. at 226 ("vaccines have been subject to the same federal premarket approval process as prescription drugs"). When the FDA grants approval, the "vaccine's license spells out the . . . warnings that must" appear in the label that "accompan[ies] the product." *Bruesewitz*, 562 U.S. at 237.

After approval, the manufacturer is generally prohibited from unilaterally changing its vaccine's warnings. "Manufacturers ordinarily must obtain the Food and Drug Administration's . . . approval ***before*** modifying" the warnings that accompany a vaccine.[11] *Bruesewitz*, 562 U.S. at 237 (emphasis added) (citing 21 C.F.R. § 601.12). More specifically, "FDA approval must be obtained before distribution of the product with [a] labeling change" ***unless*** a change is permitted under 21 C.F.R. § 601.12(f)(2), the "Changes Being Effected," or "CBE," regulation for vaccines.[12] *See* 21 C.F.R. § 601.12(f)(1).

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intended when it required exhaustion in Vaccine Court.

[11] Vaccines are considered "biologics" or "biological products." 42 U.S.C. § 262(i) ("The term 'biological product' means a . . . vaccine [among other substances]."). As explained in 21 C.F.R. § 201.57 (first paragraph) and 21 C.F.R. § 201.56(b)(1), and based on Gardasil's 2006 initial approval date, Gardasil's labeling is governed by Section 201.57. As noted in 21 C.F.R. § 201.57(c)(6)(i), labeling ***changes*** for biological products such as Gardasil are governed by 21 C.F.R. § 601.12. And the standard for labeling changes under 21 C.F.R. § 601.12(f)(2), the provision relevant to the preemption analysis, incorporates the labeling criteria in 21 C.F.R. § 201.57(c)(6)(i).

[12] The regulation also permits manufacturers to make very specific label changes without prior FDA approval or a "CBE" supplement under 21 C.F.R. § 601.12(f)(3), but these narrow categories of changes are not relevant to any of Plaintiffs' claims. *See* 21 C.F.R. § 601.12(f)(3) (allowing, *e.g.*, changes to the manufacturer's address).

"[W]hen a party cannot satisfy its state duties without the [FDA's] special permission and assistance," those state duties "are preempted." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623–24 (2011). That means "[a] state law challenge to FDA-approved warnings, including a tort action under state law, can . . . proceed only when the defendant had the unilateral ability to change that labeling; otherwise, the claim is preempted." *Knight*, 984 F.3d at 337. And because manufacturers may ***only*** change a vaccine's label unilaterally under the CBE regulation, a plaintiff's claims may only escape preemption when they show that the manufacturer could have used the CBE regulation to make a certain label change at a relevant time. *See id.* at 338 (noting that "the heart of this case" regarding preemption was whether defendant could have satisfied "the CBE regulation" and made "a unilateral change in the . . . label").

B. *Herlth v. Merck*: Failure-to-warn claims against Gardasil held preempted

In *Herlth*, the court held the plaintiff's failure-to-warn claims preempted because she offered nothing to show that Merck could have unilaterally changed Gardasil's labeling using the CBE regulation to warn of the injuries she alleged, which were "a variety of severe medical conditions, including [POTS] and chronic fatigue syndrome." *See* Ex. 2, *Herlth*, 2022 WL 788669, at *2. The court explained that, "[u]nder the terms of the CBE regulation, a manufacturer may unilaterally change its label only if it has 'newly acquired information.'" *Id.* at *3 (citing 21 C.F.R. § 601.12(f)(2)(i)). That "newly acquired information" must "provide reasonable evidence of a causal association of a clinically significant adverse reaction linked to a drug." *Id.* at *4. Further, the information must "reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." *Id.* at *3.

The court held that the plaintiff "d[id] not allege newly acquired information containing 'reasonable evidence' . . . of a causal association between Gardasil" and her alleged injuries, including POTS. *Id.* at *4. The court reviewed all of the articles cited in the Plaintiff's complaint, noting that "some describe no more than a theoretical relationship between Gardasil and POTS, while others consist of case reports from individual patients." *Id.* Others were even further afield, as they "[did] not specifically relate to POTS or [the plaintiff's] other injuries, and others [did] not appear to specifically relate to the Gardasil vaccine." *Id.* The court cited numerous articles it reviewed in reaching these conclusions. *Id.* at *4 n.27.

Although the decision was a dismissal at the pleadings stage without prejudice, the deficiencies highlighted in the *Herlth* decision pervade this litigation. The same articles the *Herlth* court analyzed, and rejected, appear in nearly every Plaintiff's complaint. *See id.* at *4 n.27. Further, for many of Plaintiffs alleged injuries—such as irritable bowel syndrome, temporomandibular joint disorder, and others—Plaintiffs do not even ***claim*** they are linked to Gardasil by any scientific evidence satisfying the CBE regulation. Ms. Herlth amended her complaint after dismissal, but Merck moved to dismiss again because the additional information in her amended pleadings did nothing to alter the *Herlth* court's analysis and conclusion. In sum, Merck's preemption arguments will show that Plaintiffs' failure-to-warn-based claims—including those regarding POTS, CFS, and CRFS—fail.[13] The goals of efficiency and judicial economy would best be served by prioritizing this dispositive issue.

[13] Merck will also show that Plaintiffs' claims are independently preempted because "clear evidence" demonstrates "that the FDA would not have approved [Plaintiffs' desired] change to [Gardasil's] label." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019). The CDC and FDA have repeatedly considered, and rejected, the medical theories Plaintiffs present in these cases. Further, the CDC, FDA, and other federal health authorities have made numerous statements inconsistent with Plaintiffs' medical claims. For example, as noted above, the Department of Health and Human Services, the FDA's parent agency, has stated in the Federal Register that "there is ***no medical or scientific evidence*** that the HPV vaccine causes POTS and safety monitoring ***has not shown any other problems***." National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6294, 6298 (Jan. 19, 2017) (emphasis added). *See also* Final Rule, National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 86 Fed. Reg. 6249-01, 6251 (Jan. 21, 2021).

2. General Causation

In addition to federal implied preemption, general causation is a dispositive issue that warrants priority in this MDL. "In cases that require medical evidence to establish causation, courts have typically drawn a distinction between 'general causation' and 'specific causation.'" *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 676 (M.D.N.C. 2003) (citing Reference Manual on Scientific Evidence 444 (2d.ed. 2000)). "General causation 'is established by demonstrating ... that exposure to a substance can cause a particular disease.' Specific, 'or individual, causation, however is established by demonstrating that a given exposure is the cause' of a particular individual's disease." *Id.* (internal citations omitted). "To succeed on their claims, Plaintiffs must prove both general causation and specific causation." *Rhyne v. United States Steel Corp.*, 474 F. Supp. 3d 733, 743 (W.D.N.C. 2020) (internal citations omitted). "Typically, expert testimony is necessary to prove general and specific causation." *Id.* "If [a] plaintiff is not able to establish general causation, it is unnecessary to consider whether the plaintiff can establish specific causation." *Dunn*, 275 F. Supp. 2d at 676 (internal citations omitted).

The Manual for Complex Litigation ("MCL") urges that "[i]dentifying the issues . . . is critical to developing a plan for efficiently resolving complex tort litigation." MCL § 22.634. The very first issue that the MCL encourages "to be taken up early in the litigation" is "whether the facts and expert evidence support a finding that the products or acts in question have the capacity to cause the type of injuries alleged." *Id.* (emphasis added). The MCL further states that "courts should consider whether and to what extent…scientific or technical issues are central to the claims and defenses and whether resolution of the admissibility of such evidence will as a practical matter be dispositive of the litigation." MCL § 22.87. To this end, MDL courts have routinely entered discovery schedules prioritizing the central and globally dispositive issue of general causation. *See, e.g., In re Onglyza and Kombiglyze XR Prods. Liab. Litig.*, MDL No. 2809, CMOs 1, 3 (E.D. Ky. Oct. 24, 2018) (ordering phased discovery "with the first phase addressing 'general causation,' *i.e.,* whether Onglyza or Kombiglyze XR is capable of causing any person to develop heart failure or other conditions alleged by the plaintiffs such as congestive heart failure, myocardial infarction and/or cardiovascular injury") (attached as Exs. 5 and 6 respectively); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, MDL No. 2767, CMO 9 (S.D.N.Y. July 28, 2017) (entering phased discovery and briefing schedule on "the issue of general causation") (attached as Ex. 7); *In re Viagra Prods. Liab. Litig.*, MDL No. 2691, PTO 6 (N.D. Cal. Sept. 26, 2016) (ordering phased discovery on general causation) (attached as Ex. 8); *In re Incretin Mimetics Prods. Liab. Litig.*, MDL 2452, Initial Case Management Scheduling Order Regarding General Causation (S.D. Cal. Feb. 18, 2014) (ordering that "Plaintiffs will narrow all discovery related requests to issues involving general causation" and prioritizing general causation discovery) (attached as Ex. 9); *In re Nexium Prods. Liab. Litig.*, MDL No. 2404, PTO 1 at 7 (C.D. Cal. Mar. 11, 2013) (prioritizing general causation expert disclosures and related briefing) (attached as Ex. 10); *In re Bextra & Celebrex Mktg. Sales Practices & Prods. Liab. Litig.*, MDL No. 1699, slip op. at 1–4 (N.D. Cal. Mar. 16, 2007) (ordering early expert discovery and *Daubert* hearings on general causation) (attached as Ex. 11); *In re Viagra Prods. Liab. Litig.*, MDL No. 1724, slip op. at 1 (D. Minn. June 30, 2006) (limiting first phase of discovery to general causation and holding early *Daubert* hearing) (attached as Ex. 12); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, MDL No. 1407, slip op. at 1 (W.D. Wash. Mar. 22, 2002) (ordering expert discovery within a few months of MDL formation) (attached as Ex. 13).

Here, there is no reliable scientific evidence that Gardasil can cause POTS, CFS, CRPS, or other of Plaintiffs' alleged injuries. Leading U.S. and global health authorities, respected medical societies, and a voluminous set of peer-reviewed medical studies have investigated this very causation question, considered the evidence cited in Plaintiffs' complaints, and found no causal link between POTS, CFS, CRPS, or other of Plaintiffs' claimed injuries. To name just a few:

- The CDC, which continuously monitors the safety of Gardasil along with the FDA, describes Gardasil as "very safe." CDC, HPV Vaccine Safety and Effectiveness Data, *see supra*. According to the CDC, "[f]indings from many vaccine safety monitoring systems and more than 160 studies have shown that HPV vaccines have a favorable safety profile—the body of scientific evidence overwhelmingly supports their safety." *Id.* With respect to POTS, the CDC states that "[o]ngoing safety monitoring through [the Vaccine Adverse Event Reporting System] VAERS has not detected any safety concerns related to POTS following HPV vaccination." CDC, "Questions about HPV Vaccine Safety," available at https://www.cdc.gov/vaccinesafety/vaccines/hpv/hpv-safety-faqs.html. Similarly, the CDC states that a review of VAERS reports found "[n]o unusual or unexpected patterns of reports of CFS following HPV vaccine were detected." *Id.*

- The World Health Organization ("WHO") concluded in 2016 and 2017 that "there is still no evidence to suggest a causal association between HPV vaccine and CRPS, POTS or the diverse symptoms that include pain and motor dysfunction." WHO, Meeting of the Global Advisory Committee on Vaccine Safety (June 7-8, 2017), at 399–400, available at https://cdn.who.int/media/docs/default-source/a-future-for-children/wer9228_2017_vol92-28.pdf?sfvrsn=346867b_1&download=true

- After reviewing the available data, the American Autonomic Society, whose members treat patients with POTS and other conditions of the autonomic nervous system, published a position statement that "there are no data to support a causal relationship between HPV vaccination and CRPS, chronic fatigue, and postural tachycardia syndrome to other forms of dysautonomia." Ex. 1, Barboi et al., *Human papillomavirus (HPV) vaccine and autonomic disorders: a position statement from the American Autonomic Society*, Clinical Autonomic Research (Sept. 2, 2019).

- FDA and CDC researchers, in a comprehensive review of reported adverse events from 2009 through 2015 "evaluated several diagnoses of interest that have emerged in the public health and medical communities and in the media since the initial 4vHPV VAERS review of the first 2.5 years of use, which included POTS [and] CRPS," and "did not detect any safety concerns for these conditions or for other reproductive problems in females." Ex. 14, Arana et al., *Post-licensure safety monitoring of quadrivalent human papillomavirus vaccine in the Vaccine Adverse Event Reporting System (VAERS), 2009–2015*, Vaccine (Feb. 21, 2018), at 1786.

As even this brief review reveals, the overwhelming medical consensus, based on years of study covering hundreds of millions of administered HPV vaccine doses, is that there is no causal link between Gardasil and POTS, CFS, CRPS, or other injuries alleged by Plaintiffs. Against this backdrop, the most efficient use of the Court's and the parties' time would be to require a threshold determination of whether Gardasil has "the capacity to cause the type of injuries alleged"—and in the first instance, three of the most commonly alleged injuries (POTS, CFS, and CRPS). MCL § 22.634.

Merck further submits that the Court might find it useful to schedule a "Science Day" during which the parties can present pertinent information in an objective, scientific fashion to further familiarize the Court with the medical and scientific issues at the heart of this case, including issues regarding general causation. *See* American Bar Association Civil Trial Practice Standards § 7 (2007) ("In cases involving complex technology or other complex subject matter which may be especially difficult for nonspecialists to comprehend, the court may permit or require the use of tutorials to educate the court."). Courts overseeing similar pharmaceutical or medical MDL proceedings have hosted a "Science Day" early in the litigation to learn about the key scientific and medical issues. *See In re: Elmiron (Pentosan Polysulfate Sodium) Prods. Liability Litig.*, Case No. 2:20-md-02973-BRM-ESK (D.N.J. July 16, 2021), Dkt. 61 at 1 (scheduling a "Science Day," "[t]he purpose of [which] is to provide the Court with an overview of certain medical and scientific issues associated with the medicine Elmiron® and the injuries being alleged by the plaintiffs"); *In Re: Taxotere (Docetaxel) Prods. Liab. Litig.*, Case No. 2:16-md-02740-JTM-MBN (E.D. La. June 6, 2018),

Dkt. 2778 at 1 (scheduling "a 'Science Day' for the Parties to provide the Court with an overview of general medical and scientific issues in this litigation, presented in an objective direct examination lecture format without advocacy"); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, Case No. 1:17-mc-02767-PAE-JLC (S.D.N.Y Mar. 30, 2018), Dkt. No. 179 at 1 ("[T]he Court will hold 'Science Day' to provide the Court with an overview of the medical, scientific, and epidemiological issues associated with the Mirena® intrauterine device and intracranial hypertension in an objective format without advocacy.").

* * *

Significant efficiencies would be gained by prioritizing implied preemption and general causation. The MCL supports early prioritization and resolution of potential globally dispositive issues, MCL § 22.634; *id.* at § 22.87, and numerous MDLs have been dismissed on implied preemption grounds or for lack of reliable evidence of general causation. *See, e.g., In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624 (4th Cir. 2018) (affirming MDL court's exclusion of plaintiffs' general and specific causation experts and summary judgment dismissal); *In re Zofran (Ondansetron) Prod. Liab. Litig.*, 541 F. Supp. 3d 164 (D. Mass. 2021) (granting defendants' summary judgment motion on preemption grounds); *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d 1007 (S.D. Cal. 2021) (granting defendants' summary judgment motion on both preemption and lack of general causation evidence grounds); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213 (S.D.N.Y. 2018) (granted manufacturer defendant's *Daubert* motions to exclude all seven of Plaintiffs' general causation experts), 387 F. Supp. 3d 323 (S.D.N.Y. June 11, 2019) (granting summary judgment), *aff'd*, 982 F.3d 113 (2d Cir. 2020); *In re Zoloft (Sertralinehydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 501 (E.D. Pa. April 5, 2016) (granting summary judgment after excluding plaintiffs' general causation experts because "Plaintiffs have failed to raise a jury question on the necessary predicate to success in any case: that Zoloft was capable of causing their injuries"), *aff'd*, 858 F.3d 787 (3d Cir. 2017). Moreover, there is likely to be significant overlap between the issues of implied preemption and general causation in this case. For example, the very evidence Plaintiffs may cite as "newly acquired evidence" warranting a change to Gardasil's label may also be cited as evidence of causation in a *Daubert* context. Addressing both issues simultaneously would be the most efficient use of the Court's and the parties' time.

3. *Vaccine Court Timeliness and Exhaustion*

A third key, threshold issue in this novel litigation is whether each Plaintiff has satisfied the Vaccine Act's jurisdictional prerequisites for filing a civil lawsuit against Merck. The Vaccine Act prohibits lawsuits against vaccine manufacturers in federal or state court unless those claims have been timely filed and properly exhausted in Vaccine Court. *See Powers,* 2018 WL 8899566 ("[A] party cannot file a civil action against a vaccine manufacturer for a 'vaccine-related injury' unless the party first filed a timely petition in accordance with the Vaccine Act's requirements."); *see also* 42 U.S.C.A. § 300aa-11(a)(2). Since this Court lacks jurisdiction over any claim that has not been timely filed and properly exhausted in Vaccine Court and the underlying Vaccine Court proceedings are sealed and not publicly available, each Plaintiff should promptly provide a signed Vaccine Court authorization form thereby permitting Merck to collect Plaintiffs' complete Vaccine Court file from the Court of Federal Claims. Plaintiffs' immediate production of an executed Vaccine Court authorization form would allow Merck to assess the following statutory requirements:

- **Whether Plaintiffs Vaccine Court petitions were *timely.*** Vaccine Court claimants must file a petition 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). There is no tolling for minors. This Court lacks jurisdiction over any claim that was filed in Vaccine Court outside of the 36-month hard-cap limitations period. *See Goetz v. N.C. Dept. of Health &*

Human Servs., 692 S.E.2d 395, 400 (N.C. Ct. App. 2010) (dismissing civil action of plaintiffs who filed untimely Vaccine Court petition, because "it is clear from the text of the Federal Vaccine Act, and its legislative history, that a claimant must file a ***timely*** petition and exhaust all of the Federal Vaccine Act's requirements as a precondition to the maintenance of a valid state action") (emphasis added).

- **Whether Plaintiffs pursued *all* injuries currently alleged in their Complaints first in Vaccine Court.** This Court lacks jurisdiction over any claims for injuries a Plaintiff failed to raise in Vaccine Court. *See Price v. Am. Cyanamid Co.*, No. 2:04-CV-242 PS, 2006 WL 694747, at *6 (N.D. Ind. Mar. 14, 2006) (barring plaintiff from pursuing claim he had not pursued in Vaccine Court), *aff'd sub nom. Price v. Wyeth Holdings Corp.*, 505 F.3d 624 (7th Cir. 2007); *see also* 42 U.S.C.A. § 300aa-11(a)(2)(A) ("No person may bring a civil action for damages . . . against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the [National Vaccine Injury Compensation] Program for ***such injury*** or death[.]") (emphasis added).

- **Whether Plaintiffs *fully* exhausted the mandatory Vaccine Court process.** 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). This Court lacks jurisdiction over any claim that was not fully exhausted through one of these three paths.

* * *

Plaintiffs' compliance with these Vaccine Court requirements is a gatekeeping, threshold matter that Merck presents should be addressed early in the litigation. Merck proposes that, in lieu of interrogatories in the first instance, all plaintiffs be required to complete questionnaires, known as Plaintiff Fact Sheets ("PFS"), that include at least the following:

- Signed authorization for collection of Plaintiff's complete Vaccine Court file, as required to obtain sealed records from Vaccine Court proceedings;
- Key dates relating to Plaintiff's Gardasil vaccination(s), including date(s) of vaccination, date of the first symptom or manifestation of onset of injury, and date of first treatment consistent with his or her Vaccine Court file;
- Proof of use of Gardasil or Gardasil 9 vaccine via the Vaccine Court file;
- Key dates relating to Plaintiff's Vaccine Court petition, including date of filing, date of Statement of Completion, date of withdrawal (if applicable), and date of election to file a civil action (if applicable); and
- A list of injuries alleged in Vaccine Court as reflected in Plaintiff's Vaccine Court petition.

See MCL § 22.84; 40.42 Mass Tort Case-Management Order at para. 11. Prior to transfer, Merck and Plaintiffs' counsel negotiated a procedure with a third-party medical records collection vendor for Plaintiffs' prompt production of signed Vaccine Court authorizations to allow Merck to collect the files from the Vaccine Court. Merck's request is reasonable because Plaintiffs are routinely required to time provide complete Plaintiff Fact Sheets in MDL settings that include, among other things, medical records authorizations. *See In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, Case No. 1:17-cv-06299-

PAE-JLC (S.D.N.Y.), CMO 12 (attached as Ex. 15); *In re Lipitor (Atorvastatin Calcium Marketing, Sales Practices and Prods. Liab. Litig.*, Case No. 2:14-cv-01786-RMG (D.S.C.), CMO 5 (attached as Ex. 16). This procedure will assist in quickly and efficiently identifying and weeding out Plaintiffs who have failed to complete the Congressionally-required Vaccine Court process. Merck is prepared to negotiate a proposed Plaintiff Fact Sheet Order with Plaintiffs' counsel to be submitted 30 days after the initial MDL conference on October 11. Merck will likewise negotiate a proposed Defendants' Fact Sheet Order, in which Merck provides certain information regarding each Plaintiff, again in lieu of additional interrogatories in the first instance. Merck additionally requests that the Court create a pathway to efficiently dispose of cases when a Plaintiff fails to timely provide a complete Plaintiff Fact Sheet, including a signed Vaccine Court authorization.

II. Status of All Related Cases

A. Federal Litigation

Currently, there are 49 active federal actions pending in this MDL with 14 of those cases remaining unserved. Prior to transfer, there were 16 pending motions to dismiss. Case-specific depositions of the plaintiff and her or his mother were completed in three federal cases. Depositions of one of the plaintiff's treating physicians had occurred in two of those federal cases. Although the first federal Gardasil case was filed in July 2020, no federal plaintiff ever issued a notice of deposition for any Merck witness, no expert disclosures have been exchanged to date, and none of the cases have proceeded to summary judgment or trial. *See* App'x. C at p. 1, Federal Litigation Status Summary.

There are common pleading deficiencies in Plaintiffs' 400+ paragraph complaints that appear across the cases and warrant the early dismissal of certain claims. Prior to transfer, federal courts across the country have consistently concluded that individual Gardasil Plaintiffs' direct failure to warn claims and veiled design defect claims are expressly barred by the Vaccine Act, and that Plaintiffs' fraud claims as alleged fall far short of Federal Rule of Civil Procedure 9(b)'s particularity requirements. *See Flores v. Merck & Co.*, No. 3:21-CV-00166, 2022 WL 798374, at *3–9 (D. Nev. Mar. 16, 2022) (dismissing complaint because plaintiff failed to plead a manufacturing defect claim; plaintiff's warning claims based on a failure to warn the plaintiff directly were preempted; plaintiff's allegations regarding Merck's alleged failure to warn her physician, including in her warranty claim, were "conclusory and [did] not yield a facially plausible claim" (*id.* at *5); and plaintiff's fraud allegations failed under Rule 9); Ex. 2, *Herlth*, 2022 WL 788669, at *5–10 (dismissing plaintiff's complaint and finding that she "alleges a design-defect claim dressed up as a manufacturing-defect claim" and she failed to state a fraud claim under Rule 9(b)); *Colbath v. Merck & Co., Inc., et al.*, No. 3:21-cv-120-W, 2022 WL 935195 (S.D. Cal. Mar. 29, 2022) (dismissing Gardasil plaintiff's manufacturing defect claims and intentional and negligent misrepresentation claims); *Stratton v. Merck & Co., Inc., et al.*, 2021 WL 5416705 (D.S.C. Nov. 17, 2021) (dismissing Gardasil plaintiff's direct failure to warn claim, manufacturing defect claim, negligence claim to the extent it is "a veiled design defect claim preempted by the Vaccine Act").

In the interest of promoting efficiency (and without waiving its defenses), Merck proposes submitting bellwether motion(s) to dismiss focused on addressing common pleading deficiencies discussed above that appear across the cases (*e.g.*, direct failure to warn claims and thinly veiled design defect claims barred by the Vaccine Act, inadequately pled manufacturing defect claims, and generic fraud claims). Under Merck's proposal, the Court's ruling on Merck's bellwether motion(s) would be exemplar opinions applicable in all currently pending or future filed Gardasil cases. *See* MCL § 22.632 ("Rulings on motions under Federal Rules of Civil Procedure 12 and 56 may be deemed to apply in the newly filed cases unless an objecting party can show good cause."). The approach would streamline the causes of action and reduce the burden on this Court by avoiding the serial submission of duplicative motions on individualized issues. Merck respectfully requests to submit its bellwether motion(s) to dismiss within 45 days of the amended

pleading deadline.

B. State Court Litigation

There are currently seven individual state court Gardasil cases pending in Los Angeles County, Orange County, or Ventura County, California. The Baum Hedlund law firm represents 19 plaintiffs in the MDL and is counsel of record in all seven state court cases. *See* App'x C at p. 10, State Court Litigation Status Summary. In each case, the plaintiff's alleged injuries overlap with those alleged in the federal cases pending in this MDL. In addition to Merck, these cases include various claims against the respective plaintiffs' prescribing physicians and medical groups for battery and malpractice in providing the vaccine to the Plaintiff. Claims against these non-diverse defendants were voluntarily dismissed last week in one California action (*Otto*). The earliest filed Gardasil state court action, *Jennifer Robi v. Merck & Co., Inc., et al.,* was filed in 2016. But the remaining California state court cases were filed and served on a similar timeline as the federal cases (*e.g.*, within the last two years). In three of these cases, motions challenging the pleadings are pending, and in one case, the complaint has not been served.

Although the *Robi* case has been pending since 2016, all of these California state actions are in virtually the same procedural posture as the cases in this MDL. In *Robi*, a partial deposition of the plaintiff and her mother have occurred, as well as a deposition of Plaintiff's father. No fact depositions have occurred in any of the other cases. And, like the cases in the MDL, no depositions of any Merck witnesses have occurred. Indeed, the parties agreed to postpone all Merck depositions previously on calendar until after this Court's upcoming October 11 hearing. Expert disclosures have not been exchanged in any of these matters, and no case has proceeded to summary judgment or trial.

Given the overlap of counsel and in the interest of maximizing efficiency and avoiding duplication, Merck submits that pretrial discovery in the California state court litigation should be coordinated with this MDL. *See* MCL § 10.225 ("If related litigation is pending in other federal or state courts, consider the feasibility of coordination among counsel in the various cases."); *id.* § 20.14 ("Even when related cases pending in different districts cannot be transferred to a single district, judges can coordinate proceedings in their respective courts to avoid or minimize duplicative activity and conflicts."). Consistent with the Manual for Complex Litigation, numerous MDL courts have called for coordination between MDL and state court litigation, particularly where, as here, there is overlapping counsel. *See* Ex. 17, *In re Lipitor (Atorvastatin Calcium Marketing, Sales Practices and Prods. Liab. Litig.*, Case No. 2:14-cv-2502-RMG (D.S.C.), CMO 4 at para. 26–27 ("In order to achieve the full benefits of the MDL proceedings, this Court intends to coordinate with state courts presiding over related cases, and the parties will similarly coordinate discovery and other appropriate pretrial proceedings with any related state court litigations to the greatest extent possible," including *inter alia*, "cross-noticing…of depositions of defense witnesses" and "making reasonable efforts to ensure that, absent agreements, no witness will have to give more than a single deposition"); Ex. 6, *In re Onglyza*, CMO 3 at p. 3. Merck submits that the same should be done in this Gardasil litigation. Depositions should occur once and be cross noticed. As detailed below, Merck document productions have been and should continue to be shared across the federal and state court cases. And, in turn, global discovery disputes if any should be heard once in this MDL, not in serial individual state court cases.

C. Status of Discovery to Date

1. Merck's Extensive Discovery to Date

As part of the parties' previous informal coordination efforts, Merck has produced a staggering volume of documents to Plaintiffs applicable to both federal and state Gardasil litigation to date:

- Merck has produced more than 8.9 million pages of documents (exclusive of native files) – totaling approximately 1.2 TB of data.

- Merck's production includes, but is not limited to, the following categories:
  - Gardasil and Gardasil 9 Regulatory files,[14] including Investigational New Drug Applications, Biologics License Applications, patient-level clinical trial data and correspondence files
  - Gardasil and Gardasil 9 – 15-Day Reports
  - Gardasil and Gardasil 9 – Periodic Safety Update Reports
  - Gardasil and Gardasil 9 Clinical Study Reports
  - Gardasil and Gardasil 9 Non-Clinical Study Reports
  - Extract of Gardasil and Gardasil 9 POTS-related adverse events from Merck's global safety database in *Robi*
  - Extract of Gardasil and Gardasil 9 Immune Thrombocytopenia-related adverse events from Merck's global safety database in *Gramza*
  - Gardasil and Gardasil 9 Vaccine Adverse Event Reporting System and Counsel for International Organizations of Medical Sciences forms for adverse events extracted from Merck's global safety database
  - Gardasil and Gardasil 9 Package Inserts
  - Gardasil and Gardasil 9 Publication Plans
  - Gardasil and Gardasil 9 Physician Information Request responses
  - Gardasil and Gardasil 9 Promotional/Marketing Materials
  - LEAD/LAST committee (Merck's labeling committee) meeting minutes
  - Risk Management Safety Team committee materials
  - Merck Organizational Charts

- In addition to these productions, Merck ran more than 16,000 distinct searches (selected by Plaintiffs' counsel Baum Hedlund)[15] and produced responsive documents from the custodial files of 51 current and former Merck employees (nearly all of which were selected by Plaintiffs' counsel Baum Hedlund). Those custodians included current and former Merck employees spanning a range of departments, including Clinical Research, Regulatory Affairs, Epidemiology, Statistics, Medical Affairs, Basic Research, and Pharmacovigilance.

The depth and breadth of Merck's extensive production has been briefly summarized in Appendix D, Merck Document Production Summary.

Further and by way of background, as part of the parties' previous informal coordination efforts earlier this year, Merck and Plaintiffs' firms Baum Hedlund and Morgan and Morgan agreed to share this expansive document discovery across the cases—state and federal. In addition to sharing document productions, Merck and Plaintiffs' firms Baum Hedlund and Morgan and Morgan also agreed as part of informal coordination efforts that, absent good cause, no additional Merck custodial files would be produced, no additional search terms would be run, and absent agreement or good cause, Plaintiffs would take a maximum of 20 depositions of Merck current and former employees, those depositions would occur once, and each of those depositions would be limited to 7 hours. *See, e.g., Balasco v. Merck & Co., Inc., et al.*, Case No. 1:20-cv-00364-MSM-PAS (D.R.I.), Joint Motion to Amend the Court's Scheduling Order, Dkt. No. 29 ("[A]s this is one of a number of Gardasil-related cases that have been filed by the same Plaintiff's firm, Merck and Plaintiff's counsel have been negotiating and communicating about ways to conserve resources and reduce costs. To that end, the parties have agreed to custodial file search terms,

[14] Merck produced indices for the Chemistry Manufacturing and Controls ("CMC") in lieu of producing those sections in their entirety. Merck has objected to the production of the complete Gardasil CMC because, among other reasons, it is irrelevant in light of the Vaccine Act's express preemption of design defect claims and because it contains proprietary, trade secret information.
[15] If the Court desires, Merck can provide a complete list of these distinct searches.

the identity of custodial files that Merck has/will produce, and the sharing of documents across the cases. Additionally, the parties have agreed to depose fact witnesses and experts only once, limit the number of Merck witness depositions, and limit the time to conduct depositions.").

Consistent with Section 20.14 of the Manual for Complex Litigation, Merck is prepared to immediately share this expansive production across the MDL with newly involved counsel. With more than 1.2 TB of production data and the critical data related to the safety and efficacy of Gardasil already in Plaintiffs' counsel's hands, Merck submits that its generic document production is essentially complete. Given the depth and breadth of Merck's production, Merck believes that further requests bear tangential relevance to this case and submits that, particularly in light of Merck's expansive productions to date, discovery should remain properly proportional under Federal Rule of Civil Procedure 26.

Merck submits, in the interest of avoiding duplication and conflicting rulings, that any remaining general discovery disputes in both state and federal court involving counsel before this MDL should be globally resolved by this Court. This sort of cross-jurisdictional coordination of common discovery is encouraged by the Manual for Complex Litigation. *See* MCL § 20.14 ("Even when related cases pending in different districts cannot be transferred to a single district, judges can coordinate proceedings in their respective courts to avoid or minimize duplicative activity and conflicts."); *id.* ("Judges should encourage techniques that coordinate discovery and avoid duplication….The resolution of discovery disputes can also be coordinated to some degree (e.g., by referring them to a single magistrate judge or special master).").

Plaintiffs' counsel Baum Hedlund, on the other hand, recently raised a number of discovery disputes in different California state courts shortly after this MDL was created and the federal cases were transferred to this Court. Just last month, after this MDL was formed, they filed a sweeping motion to compel the production of additional documents in the *Otto* California state court case even though that case has been pending since September of 2020. Their motion directly impacts documents that have been produced in federal litigation and will be shared in this MDL. For example, Baum Hedlund moved in this individual state court case to compel Merck's entire adverse event database and the CMC section of the Gardasil and Gardasil 9 regulatory files. Additionally and despite the fact that Merck produced vast categories and numbers of documents relying on the confidentiality of those productions, Baum Hedlund recently sent a letter in the *Robi* California state court case now requesting that dozens of documents (that will soon be produced en masse in this MDL) be de-designated so that Baum Hedlund and other Plaintiffs' counsel can share Merck's documents with the press and publish them on firm websites and other places. *See* App'x C at p. 10, State Court Litigation Summary. Because Baum Hedlund was unwilling to postpone their de-designation request until the parties could appear before this MDL Court, Merck, in the interim, will be left with no choice other than to move for protection out of an abundance of caution pursuant to the protective order in that *Robi* case.

Given the expansive productions to date that Merck is prepared to share across the MDL, little to no written discovery is currently outstanding. Therefore, Merck submits that the parties should (1) promptly resolve what few global discovery disputes remain once and before this MDL Court, (2) proceed with completing fact depositions, and (3) prioritize the issues of general causation and preemption in order to expedite a global resolution of these claims.

III. Conclusion

In light of the key legal and factual issues described above, Merck proposes the following trajectory for the efficient resolution of this litigation:

- Bellwether motion(s) to dismiss addressing Plaintiffs' global pleading failures, including direct failure-to-warn claims and thinly veiled design defect claims as expressly barred by the Vaccine

Act, manufacturing defect claims for failure to state a claim, and Plaintiffs' fraud claims for failure to satisfy Federal Rule of Civil Procedure 9(b);

- Prioritization of the dispositive issues of implied preemption and the absence of reliable evidence of general causation with an initial focus on POTS, CFS, and CRPS—three of the most commonly alleged injuries (and three additional alleged injuries of Plaintiffs' choosing, if necessary);

- Simultaneous workup of core discovery in cases alleging the injuries above;

- Defendant Fact Sheets and Plaintiff Fact Sheets, and a procedure for dismissing Plaintiffs' complaints for failure to provide complete Plaintiff Fact Sheets demonstrating, among other things, Vaccine Court timeliness and exhaustion; and

- Coordination before this MDL Court of all continued pretrial discovery and discovery motions now pending in the California state court Gardasil cases and any other future state court Gardasil proceedings.

Respectfully submitted,

/s/ Allyson M. Julien

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Appendix A

Appendix A – Plaintiffs' Alleged Injuries

Injury Alleged in Complaint	Number of MDL Plaintiffs Alleging Injury
Acquired cognitive dysfunction	1
Adjustment disorder	1
Adrenal dysfunction	1
Alopecia areata	2
Amnesic spells	1
Amplification pain syndrome (AMPS)	2
Anaphylaxis	2
Anti-ovarian antibodies	1
Anxiety	5
Aplastic anemia	1
Arthritis	1
Autoimmune autonomic neuropathy	1
Autoimmune disease	1
Autoimmune encephalopathy	1
Autoimmune inflammatory syndrome	1
Autonomic dysfunction	19
Bile acid malabsorption (BAM)	1
Biliary dyskinesia	1
Brain fog	2
Breast cysts	1
Central and vestibular abnormalities	1
Chronic and/or severe headaches	4
Chronic autoimmune demyelinating illness	1
Chronic fatigue and immune dysfunction syndrome	1
Chronic fatigue and tiredness	4
Chronic fatigue syndrome (CFS)	10
Chronic joint pain	1
Chronic pain	4
Complex Regional Pain Syndrome (CRPS)	4
Cyanosis	1
Depression/major depressive disorder	4
Dietary issues	1
Dizziness	3
Dysautonomia	10
Ehlers-Danlos syndrome	2
Encephalopathy	1
Endometriosis	1
Essential tremor	1
Factor XII deficiency blood disorder	1
Fainting	2
Fibromyalgia	4

Functional limb weakness	1
Functional movement disorder	1
Functional neurological disorder	1
Functional speech symptoms	1
Functional vision disorder	1
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
Hypoxia	1
Idiopathic hypersomnia (IH)	1
Immune thrombocytopenia (ITP)	2
Immune-mediated encephalitis	1
Inability to talk	1
Inability to walk	2
Irlen Syndrome	1
Irregular menstrual cycles	1
Irritable bowel syndrome (IBS)	2
Joint hypermobility	1
Major disruptive disorder	1
Mast cell activation syndrome (MCAS)	2
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)	4
Myoclonus	1
Narcolepsy	2
Neurocardiogenic syncope	1
Neurogenic bladder	1
Neuropathy	1
Neutropenia	1
Nonrheumatic mitral insufficiency	1
Nonrheumatic mitral valve prolapse	1
Non-cancerous breast tumors	1

Appendix A – Plaintiffs' Alleged Injuries

Non-epileptic seizures	1
Orthostatic hypotension (OH)	1
Orthostatic intolerance (OI)	7
Osteonecrosis	1
Ovarian cysts	1
Pancytopenia	1
Pediatric acute-onset neuropsychiatric syndrome (PANS)	1
Pelvic floor dysfunction	1
Pilonidal cysts	1
Polyarthralgia	1
Polycystic ovarian syndrome (PCOS)	1
Post-transplant lymphoproliferative disease	1
Postural orthostatic tachycardia syndrome (POTS)	35
Premature ovarian failure (POF)	1
Progressive vision loss/worsening vision	2
Reduced bone density	1
Reticulocytopenia	1
Scoliosis	1
Seizures	3
Severe allergies	1
Severe gastric/abdominal issues or stomachaches	2
Severe insomnia	1
Sleep apnea	1
Sleeping 15-17 hours/day	1
Small fiber neuropathy (SFN)	4
Small intestinal bacterial overgrowth (SIBO)	1
Spasms	1
Staring spells	1
Symptoms mimicking Reynard's Syndrome	1
Syncope/near syncope	4
Tachycardia/sinus tachycardia	3
Temporomandibular joint disorder (TMJ)	1
Tonsillitis	1
Uncontrollable shaking	1
Vaginismus	1
Vasovagal allergy	1
Worsened hearing loss	1

Appendix B

Appendix B –Vaccine Court Summary

Plaintiff	W.D.N.C. Case No.	Vaccine Court Result
Atjian, Eduardo II	3:22-cv-00404	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).
Balasco, Julia	3:22-cv-00386	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).
Bergin, Payton	3:22-cv-00117	Petition dismissed on petitioner's motion and 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).
Butler, Skylee	3:22-cv-00406	Petition dismissed on petitioner's motion and after 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).
Canitz, Shannon	3:22-cv-00435	Petition withdrawn by petitioner prior to entitlement hearing. *Canitz v. Sec'y of Health & Hum. Servs.*, No. 21-1860V (Fed. Cl. June 14, 2022).

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Colbath, Michael	3:22-cv-00398	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).
Counts, Madeline	3:22-cv-00443	Petition withdrawn by petitioner prior to entitlement hearing. *Counts v. Sec'y of Health & Hum. Servs.*, No. 20-1782V (Fed. Cl. Sept. 20, 2021).
Dalton, Ashley	3:22-cv-00387	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).
Derr, Maeson	3:22-cv-00381	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).
Eshelman, Avery	3:22-cv-00424	Petition withdrawn by petitioner prior to entitlement hearing. *Eshelman v. Sec'y of Health & Hum. Servs.*, No. 20-1576V (Fed. Cl. Oct. 12, 2021).
Fetters, Sydney	3:22-cv-00403	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).
Flores, Savannah Smithson	3:22-cv-00397	Petition dismissed on petitioner's motion and because 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).

Appendix B –Vaccine Court Summary

Gramza, Jasmyne	3:22-cv-00377	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).
Graves, Paige	3:22-cv-00445	Petition withdrawn by petitioner prior to entitlement hearing. *Graves v. Sec'y of Health & Hum. Servs.*, No. 21-1734V (Fed. Cl. May 17, 2022).
Hartle, Ethan	3:22-cv-00427	Petition withdrawn by petitioner prior to entitlement hearing. *Hartle v. Sec'y of Health & Hum. Servs.*, No. 21-1470V (Fed. Cl. Mar. 24, 2022).
Hendrix, Darby	3:22-cv-00401	Petition withdrawn by petitioner prior to entitlement hearing. *Hendrix v. Sec'y of Health & Hum. Servs.*, No. 20-868V (Fed. Cl. Mar. 17, 2021).
Herlth, Korrine	3:22-cv-00444	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).
Hilton, Kameron	5:22-cv-00030	Petition dismissed on petitioner's motion and because "there is insufficient evidence in the record for [p]etitioner to meet her burden of proof." *H. v. Sec'y of Health & Hum. Servs.*, No. 17-1739V (Fed. Cl. June 27, 2022).
Hoddick, Jeffrey	3:22-cv-00394	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).
Horton, Tristen	3:22-cv-00441	Petition withdrawn by petitioner prior to entitlement hearing. Petitioner stated at the time of withdrawal that "given the course of [HPV vaccine] cases like

		Petitioner's in the Vaccine Program, [he] also does not anticipate prevailing on the merits in the Program on this case." *Horton v. Sec'y of Health & Hum. Servs.*, No. 19-262V (Fed. Cl. Nov. 18, 2021). The special master also noted that, given the petitioner's withdrawal, additional review of the record was not necessary and that "the information in the record . . . does not show entitlement to an award by a preponderance of the evidence based on causation in fact." *Id.*
Humphries, Cooper	3:22-cv-00395	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).
Ivey, Madison	3:22-cv-00437	Petition withdrawn by petitioner prior to entitlement hearing. *Ivey v. Sec'y of Health & Hum. Servs.*, No. 20-1956V (Fed. Cl. Oct. 26, 2021).
Landers, Elizabeth OBO I.L.	3:22-cv-00385	Petition withdrawn by petitioner prior to entitlement hearing. *Landers v. Sec'y of Health & Hum. Servs.*, No. 21-1499V (Fed. Cl. Feb. 22, 2022).
Landers, Krista	3:22-cv-00360	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).
Levy, Jacob	3:22-cv-00423	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).

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Lipscomb, Madelyn	3:22-cv-00396	Petition withdrawn by petitioner prior to entitlement hearing. *Lipscomb v. Sec'y of Health & Hum. Servs.*, No. 21-784V (Fed. Cl. Oct. 19, 2021).
Lukas, Sarah	3:22-cv-00425	Petition withdrawn by petitioner prior to entitlement hearing. *Lukas v. Sec'y of Health & Hum. Servs.*, No. 21-1627V (Fed. Cl. Apr. 27, 2022).
Malloy, Madelyn	3:22-cv-00407	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).
McElerney, Corrine	3:22-cv-00382	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).
Merino, Adriana	3:22-cv-00378	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).
Muller, Ashley	3:22-cv-00390	Petition dismissed on petitioner's motion 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).
Neves, Isabella	3:22-cv-00446	Petition withdrawn by petitioner prior to entitlement hearing. *Neves v. Sec'y of Health & Hum. Servs.*, No. 20-1678V (Fed. Cl. Sept. 13, 2021).
O'Brien, Krista	3:22-cv-00440	Petition withdrawn by petitioner prior to entitlement hearing. *O'Brien v. Sec'y of Health & Hum. Servs.*, No. 21-1680V (Fed. Cl. May 11, 2022).

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Pennell, Amy J., guardian of minor, M.L.P.	3:22-cv-00426	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).
Prudden, Christina	3:22-cv-00429	Petition withdrawn by petitioner prior to entitlement hearing. *Prudden v. Sec'y of Health & Hum. Servs.*, No. 21-1818V (Fed. Cl. June 3, 2022).
Raymer, Jessica	3:22-cv-00359	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).
Reddicks, Arianna	3:22-cv-00438	Petition withdrawn by petitioner prior to entitlement hearing. *Reddicks v. Sec'y of Health & Hum. Servs.*, No. 21-1099V (Fed. Cl. Jan. 12, 2022).
Rizvi, Aina	3:22-cv-00433	Petition withdrawn by petitioner prior to entitlement hearing. *Rizvi v. Sec'y of Health & Hum. Servs.*, No. 21-1744V (Fed. Cl. May 17, 2022).
Roeder, Megan Marie	3:22-cv-00431	Petition withdrawn by petitioner prior to entitlement hearing. *Roeder v. Sec'y of Health & Hum. Servs.*, No. 19-1897V (Fed. Cl. Apr. 25, 2022).
Rolf, Cheryl OBO M.R.	3:22-cv-00434	Petition withdrawn by petitioner prior to entitlement hearing. *Rolf v. Sec'y of Health & Hum. Servs.*, No. 21-2010V (Fed. Cl. July 5, 2022).
Sarni, Audrey	3:22-cv-00432	Petition withdrawn by petitioner prior to entitlement hearing. *Sarni v. Sec'y of Health & Hum. Servs.*, No. 19-1403V (Fed. Cl. May 21, 2021).
Silver, Ruby	3:22-cv-00384	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).
Soileau, Nalon	3:22-cv-00399	Petition withdrawn by petitioner prior to entitlement hearing. *Canning v. Sec'y of Health & Hum. Servs.*, No. 21-1016V (Fed. Cl. Nov. 22, 2021).

Appendix B –Vaccine Court Summary

Sullivan, Emma	3:22-cv-00400	Petition dismissed on petitioner's motion and 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).
Thomas, Mark OBO Z.T.	3:22-cv-00392	Petition withdrawn by petitioner prior to entitlement hearing. *Thomas v. Sec'y of Health & Hum. Servs.*, No. 20-886V (Fed. Cl. Apr. 12, 2021).
Vela, Allen OBO J.V.	3:22-cv-00379	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".
Wagner, Tanja & Scott OBO S.W.	3:22-cv-00362	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).

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Walker, Sahara	3:22-cv-00388	Petition dismissed on petitioner's motion and "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).
Wingerter, Ken & Shaun OBO H.W.	3:22-cv-00402	Petition withdrawn by petitioner prior to entitlement hearing. *Wingerter v. Sec'y of Health & Hum. Servs.*, No. 20-1408V (Fed. Cl. July 8, 2021).

Appendix C

Appendix C – Status of Related Federal and State Gardasil Litigation

Federal Gardasil Cases Transferred to MDL					
Case Caption	**Case No. (W.D.N.C.)**	**Case No. (Original)**	**Original District**	**Pending Motions (Prior to 9/12/2022 Order)**	**Status**
Atjian v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00404	2:22-CV-01739	C.D. Cal.	Merck's motion to dismiss filed on 7/6/2022	Complaint filed on 4/18/2022
Balasco v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00386	1:20-CV-00364	D.R.I.	N/A	Complaint filed on 8/19/2020 Answer filed on 5/6/2021 Merck's and Plaintiff's written discovery served
Bergin v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00117	3:22-CV-00117	W.D.N.C.	Merck's motion to dismiss amended complaint filed on 7/15/2022	First amended complaint filed on 7/1/2022
Butler v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00406	3:22-CV-10006	D. Mass.	Merck's fully briefed motion to dismiss complaint filed on 4/28/2022	Complaint filed on 1/3/2022
Canitz v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00435	2:22-CV-01134	D. Ariz.	N/A	Complaint filed on 7/6/2022 (unserved as of 9/19/2022)
Colbath v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00398	3:21-CV-00120	S.D. Cal.	N/A	Complaint filed on 1/21/2021 Order denying in part Merck's motion to dismiss entered on 3/29/2022 Answer filed on 5/3/2022

Appendix C – Status of Related Federal and State Gardasil Litigation

Federal Gardasil Cases Transferred to MDL					
Case Caption	**Case No. (W.D.N.C.)**	**Case No. (Original)**	**Original District**	**Pending Motions (Prior to 9/12/2022 Order)**	**Status**
Counts v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00443	4:22-CV-00613	N.D. Tex.	N/A	Complaint filed on 7/18/2022 (unserved as of 9/19/2022)
Dalton v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00387	2:21-CV-12324	E.D. Mich.	Merck's fully briefed motion to dismiss complaint filed on 1/19/2022	Complaint filed on 10/1/2021
Derr v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00381	1:22-CV-00212	M.D.N.C.	Merck's motion to dismiss amended complaint filed on 7/15/2022 Hearing held on 4/11/2022 and taken under advisement. Merck's supplemental brief filed 5/3/2022. Plaintiff's response filed on 5/24/2022	First amended complaint filed on 7/1/2022
Eshelman v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00424	5:22-CV-00523	W.D. Okla.	N/A	Complaint filed on 6/23/2022
Fetters v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00403	8:22-CV-00422	C.D. Cal.	Merck's motion to dismiss filed on 7/6/2022. Plaintiff's opposition filed on 8/8/2022	Complaint filed on 4/18/2022

Appendix C – Status of Related Federal and State Gardasil Litigation

Federal Gardasil Cases Transferred to MDL					
Case Caption	**Case No. (W.D.N.C.)**	**Case No. (Original)**	**Original District**	**Pending Motions (Prior to 9/12/2022 Order)**	**Status**
Flores v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00397	3:21-CV-00166	D. Nev.	Merck's motion to dismiss amended complaint filed on 4/29/2022	First amended complaint filed on 4/16/2022 Merck's written discovery served
Gramza v. Merck & Co., Inc., and Merck Sharp & Dohme LLC	3:22-CV-00377	2:20-CV-01425	D. Ariz.	N/A	Complaint filed on 7/17/2020 Answer filed on 9/25/2020 Merck's and Plaintiff's written discovery served Fact depositions of Plaintiff, Plaintiff's mother, and treating physician taken
Graves v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00445	3:22-CV-01432	N.D. Tex.	N/A	Complaint filed on 7/1/2022 (unserved as of 9/19/2022)
Hartle v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00427	4:22-CV-00195	S.D. Iowa	N/A	Complaint filed on 6/17/2022
Hendrix v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00401	1:22-CV-01171	N.D. Ga.	Merck's motion to dismiss amended complaint filed on 7/29/2022	First amended complaint filed on 7/15/2022

Appendix C – Status of Related Federal and State Gardasil Litigation

Federal Gardasil Cases Transferred to MDL					
Case Caption	**Case No. (W.D.N.C.)**	**Case No. (Original)**	**Original District**	**Pending Motions (Prior to 9/12/2022 Order)**	**Status**
Herlth v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:21-CV-00444	3:21-CV-00438	D. Conn.	Merck's fully briefed motion to dismiss second amended complaint filed on 5/16/2022	Court granted Merck's motion to dismiss first amended complaint on 3/15/2022 with leave to amend. Second amended complaint filed on 4/14/2022 Merck's written discovery served
Hilton v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	5:22-CV-00030	5:22-CV-00030	W.D.N.C.	Merck's motion to dismiss amended complaint filed on 7/15/2022	First amended complaint filed on 7/1/2022
Hoddick v. Merck & Co., Inc., et al.	3:22-CV-00394	1:22-CV-00144	D. Haw.	Merck's motion to dismiss filed on 7/6/2022	Complaint filed on 4/18/2022
Horton v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00441	1:22-cv-00177	N.D. Fla.	N/A	Complaint filed on 7/28/2022

Appendix C – Status of Related Federal and State Gardasil Litigation

Federal Gardasil Cases Transferred to MDL					
Case Caption	**Case No. (W.D.N.C.)**	**Case No. (Original)**	**Original District**	**Pending Motions (Prior to 9/12/2022 Order)**	**Status**
Humphries v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00395	4:21-cv-04154	C.D. Ill.	N/A	Complaint filed on 9/14/2021 Answer filed on 11/24/2021 Merck's written discovery served Fact depositions of Plaintiff, Plaintiff's mother taken
Ivey v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00437	1:22-CV-00741	W.D. Tex.	N/A	Complaint filed on 7/25/2022 (unserved as of 9/19/2022)
Landers, E. v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00385	1:22-CV-00144	S.D.W. Va.	Merck's motion to dismiss filed on 8/1/2022	Complaint filed on 4/18/2022
Landers, K. v. Merck & Co., Inc., and Merck Sharp & Dohme LLC	3:22-CV-00360	1:22-CV-01696	N.D. Ill.	N/A	Complaint filed on 4/18/2022 Answer filed on 7/8/2022
Levy v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00423	8:22-CV-00431	C.D. Cal.	Merck's motion to dismiss filed on 7/6/2022	Complaint filed on 4/18/2022
Lipscomb v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00396	1:22-CV-00116	N.D. Ind.	N/A	Complaint filed on 4/18/2022 Answer filed on 7/6/2022

Appendix C – Status of Related Federal and State Gardasil Litigation

Federal Gardasil Cases Transferred to MDL					
Case Caption	**Case No. (W.D.N.C.)**	**Case No. (Original)**	**Original District**	**Pending Motions (Prior to 9/12/2022 Order)**	**Status**
Lukas v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00425	1:22-CV-01306	N.D. Ohio	N/A	Complaint filed on 7/23/2022
Malloy v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00407	6:21-cv-00506	E.D. Tex.	Merck's motion to dismiss filed on 4/21/2022	Complaint filed on 12/29/2021
McElerney v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00382	8:21-CV-01814	M.D. Fla.	N/A	Second amended complaint filed on 12/14/2021 Answer to second amended complaint filed on 12/28/2021 Merck's written discovery served
Merino v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00378	2:22-CV-00398	D. Ariz.	N/A	Complaint filed on 3/15/2022 (unserved as of 9/19/2022)
Muller v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00390	3:21-CV-01335	N.D. Fla.	N/A	Complaint filed on 10/08/2021 Answer filed on 1/25/2022 Merck's written discovery served
Neves v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00446	3:22-CV-05062	D.N.J.	N/A	Complaint filed on 6/27/2022

Appendix C – Status of Related Federal and State Gardasil Litigation

Federal Gardasil Cases Transferred to MDL					
Case Caption	**Case No. (W.D.N.C.)**	**Case No. (Original)**	**Original District**	**Pending Motions (Prior to 9/12/2022 Order)**	**Status**
O'Brien v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00440	4:22-CV-02436	S.D. Tex.	N/A	Complaint filed on 7/22/2022 (unserved as of 9/19/2022)
Pennell v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00426	5:22-CV-00619	N.D. Ohio	N/A	First amended complaint filed on 8/2/2022
Prudden v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00429	5:22-cv-06074	W.D. Mo.	Merck's motion to dismiss filed on 8/4/2022	Complaint filed on 6/16/2022
Raymer v. Merck & Co., Inc., and Merck Sharp & Dohme LLC	3:22-CV-00359	1:22-CV-01643	N.D. Ill.	N/A	Complaint filed on 4/18/2022 Answer filed on 7/8/2022 Merck's and Plaintiff's written discovery served
Reddicks v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00438	6:22-CV-00881	D. Or.	N/A	Complaint filed on 6/16/2022
Rizvi v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00433	3:22-CV-04471	D.N.J.	N/A	Complaint filed on 6/8/2022 Answer filed on 7/28/2022
Roeder v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00431	2:22-cv-04284	C.D. Cal.	N/A	Complaint filed on 6/22/2022 (unserved as of 9/19/2022)

Appendix C – Status of Related Federal and State Gardasil Litigation

Federal Gardasil Cases Transferred to MDL					
Case Caption	**Case No. (W.D.N.C.)**	**Case No. (Original)**	**Original District**	**Pending Motions (Prior to 9/12/2022 Order)**	**Status**
Rolf v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00434	2:22-cv-01188	D. Ariz.	N/A	Complaint filed on 7/15/2022 (unserved as of 9/19/2022)
Sarni v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00432	2:22-cv-01139	D. Ariz.	N/A	Complaint filed on 7/7/2022 (unserved as of 9/19/2022)
Silver v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00384	8:21-cv-02903	M.D. Fla.	N/A	Complaint filed on 12/14/2021 Answer filed on 1/11/2022
Soileau v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00399	3:22-cv-00210	M.D. La.	N/A	First amended complaint filed on 8/5/2022
Sullivan v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00400	3:22-cv-00116	D.N.J.	Plaintiff's fully briefed motion to remand filed 2/9/2022 Case was tagged for JPML by plaintiff on 4/25/2022; no order entered on remand motion	Complaint filed on 12/1/2021 Answer filed on 1/18/2022
Thomas v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00392	9:22-CV-80445	S.D. Fla.	N/A	Complaint filed on 4/18/2022 Answer filed on 7/5/2022
Vela v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00379	2:22-CV-00420	D. Ariz.	N/A	Complaint filed on 3/18/2022 (unserved as of 9/19/2022)

Appendix C – Status of Related Federal and State Gardasil Litigation

Federal Gardasil Cases Transferred to MDL					
Case Caption	**Case No. (W.D.N.C.)**	**Case No. (Original)**	**Original District**	**Pending Motions (Prior to 9/12/2022 Order)**	**Status**
Wagner v. Merck & Co., Inc., and Merck Sharp & Dohme LLC	3:22-CV-00362	1:22-CV-01717	N.D. Ill.	N/A	Complaint filed on 4/18/2022 Answer filed on 6/27/2022
Walker v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00388	3:20-CV-01048	W.D. Wis.	N/A	Complaint filed on 11/18/2020 Amended answer filed on 4/1/2021 Merck's and Plaintiff's written discovery served Fact depositions of Plaintiff, Plaintiff's mother, and vaccinating physician taken
Wingerter v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-00402	1:22-CV-01178	N.D. Ga.	Merck's motion to dismiss amended complaint filed on 7/22/2022	First amended complaint filed on 7/8/2022

Appendix C – Status of Related Federal and State Gardasil Litigation

Gardasil State Court Cases Related to MDL						
Case Caption	**Case No.**	**State Court and Assigned Judge**	**Other Defendants**	**Plaintiffs' Counsel**	**Pending Motions**	**Status (summary of discovery)**
Brunker v. Merck & Co., Inc., et al.	56-2022-00563045-CU-PL-VTA	Cal. Super. Ct. – Ventura Cty. Dept. 20 – Judge Matthew P. Guasco Judge Guasco's judicial secretary, Denise Arreola, may be reached at (805) 289-8705.	Southern California Permanente Medical Group; Tina Kosakyan, M.D.	Baum Hedlund Aristei & Goldman, P.C.	Merck's fully briefed demurrer to complaint filed on 5/23/2022 Hearing on demurrer and motion to strike held on 8/8/2022 (currently under submission)	Complaint filed on 2/8/2022 No trial date set
Carrillo v. Merck & Co., Inc., et al.	30-2021-01182274-CU-PL-CJC	Cal. Super. Ct. – Orange Cty.; Dept. W02 - Judge Nathan Scott 657-622-5902	Memorialcare Medical Group; Gina Posner, M.D.; Julie Fallon, M.D.	Baum Hedlund Aristei & Goldman, P.C.; Robert F. Kennedy, Jr.	Merck's demurrer to third amended complaint filed on 6/30/2022 Plaintiff's opposition to Merck's demurrer filed on 9/16/2022 Merck's reply due on 9/22/2022, and hearing on demurrer set for 10/14/2022	Third amended complaint filed on 5/31/2022 Merck's and Plaintiff's written discovery served Trial set for 7/7/2023

Appendix C – Status of Related Federal and State Gardasil Litigation

Gardasil State Court Cases Related to MDL						
Case Caption	**Case No.**	**State Court and Assigned Judge**	**Other Defendants**	**Plaintiffs' Counsel**	**Pending Motions**	**Status (summary of discovery)**
Otto v. Merck & Co., Inc., et al.	30-2020-01160496-CU-PL-WJC	Cal. Super. Ct. – Orange Cty.; Dept. W02 - Judge Nathan Scott 657-622-5902	Kaiser Foundation Hospitals; Southern California Permanente Medical Group; Nigel L. Kent, M.D.; Timothy Allyn Munzing, M.D.; Hemesh Mahesh Patel, D.O. [Note: Merck understands that Plaintiff dismissed these non-diverse defendants approx. the week of September 12.]	Baum Hedlund Aristei & Goldman, P.C.; Robert F. Kennedy, Jr.	Plaintiff's motion to compel Merck's further responses to discovery requests filed on 7/29/2022 Hearing on motion to compel set for 11/4/2022	Complaint filed on 9/16/2020 Answer filed on 3/10/2021 Merck's and Plaintiff's written discovery served Trial set for 8/4/2023
Rizi v. Merck & Co., Inc., et al.	22STCV11784	Cal. Super. Ct. – L.A. Cty. Dept. 78 – Judge Robert S. Draper 213-830-0878	Columbia Pediatrics Medical Group, Inc.; Eddie Quan, M.D.	Baum Hedlund Aristei & Goldman, P.C.	Merck's demurrer and motion to strike filed on 9/16/2022	Complaint filed on 4/6/2022 No trial date set

Appendix C – Status of Related Federal and State Gardasil Litigation

Gardasil State Court Cases Related to MDL						
Case Caption	**Case No.**	**State Court and Assigned Judge**	**Other Defendants**	**Plaintiffs' Counsel**	**Pending Motions**	**Status (summary of discovery)**
Robi v. Merck & Co., Inc., et al.	BC628589	Cal. Super. Ct. – L.A. Cty. Dept. 9 – Judge Yvette M. Palazuelos 213-310-7009	Kaiser Foundation Hospitals; Southern California Permanente Medical Group; Judith Garza, M.D.; Claire Valencia Fuller, M.D.; Robin B. Scanlon, M.D.	Baum Hedlund Aristei & Goldman, P.C.; Ajalat & Ajalat, LLP	Merck's motion to retain confidentiality designations for discovery documents anticipated to be filed on or by 9/26/2022	Complaint filed on 7/27/2016 Answer filed on 10/3/2016 Merck's and Plaintiff's written discovery served Partial fact depositions of Plaintiff and Plaintiff's mother taken; fact deposition of Plaintiff's father taken Trial set for 5/1/2023
Shain v. Merck & Co., Inc., et al.	21STCV35340	Cal. Super. Ct. – L.A. Cty. Dept. O – Judge H. Jay Ford III 310-255-1866	Providence Health System – Southern CA; Providence Saint John's Medical Foundation dba Saint John's Physician Partners; Alisa A. Bromberg, M.D.	Baum Hedlund Aristei & Goldman, P.C.; Robert F. Kennedy, Jr.	N/A	Complaint filed on 9/24/2021 Merck's and Plaintiff's written discovery served Trial set for 9/25/2023

Appendix C – Status of Related Federal and State Gardasil Litigation

Gardasil State Court Cases Related to MDL						
Case Caption	**Case No.**	**State Court and Assigned Judge**	**Other Defendants**	**Plaintiffs' Counsel**	**Pending Motions**	**Status (summary of discovery)**
Trevisan v. Merck & Co., Inc., et al.	22STCV24209	Cal. Super. Ct. – L.A. Cty. Dept. 50 – Judge Teresa A. Beaudet 213-633-0650	Providence Health System - Southern California; Providence Medical Institute; Providence Medical Associates, Inc.; Tristy Shaw, M.D.	Baum Hedlund Aristei & Goldman, P.C.; Robert F. Kennedy, Jr.	N/A	Complaint filed on 7/27/2022 (unserved as of 9/19/2022) No trial date set

Appendix C – Status of Related Federal and State Gardasil Litigation

Related Federal Gardasil Cases Not Yet Transferred to MDL					
Case Caption	**Case No.**	**District**	**Plaintiffs' Counsel**	**Pending Motions**	**Status**
Brayboy v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-05131	D.N.J.	Sadaka Associates, LLC	Opposition to CTO-6 (not yet briefed); motion due 9/22/2022, response due 10/13/2022, and reply due 10/20/2022	Complaint filed in N.J. Super Ct., Hudson Cty. on 8/16/2022 (unserved as of 9/19/2022) Merck removed case to D.N.J. on 8/19/2022 Merck filed a Notice of Potential Tag-Along on 8/29/2022 Notice of Opposition to CTO-6 filed on 9/7/2022
Nunez v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-05128	D.N.J.	Sadaka Associates, LLC	Opposition to CTO-6 (not yet briefed); motion due 9/22/2022, response due 10/13/2022, and reply due 10/20/2022	Complaint filed in N.J. Super Ct., Hudson Cnty. on 8/16/2022 (unserved as of 9/19/2022) Merck removed case to D.N.J. on 8/19/2022 Merck filed a Notice of Potential Tag-Along on 8/29/2022 Notice of Opposition to CTO-6 filed 9/7/2022

Appendix C – Status of Related Federal and State Gardasil Litigation

Related Federal Gardasil Cases Not Yet Transferred to MDL					
Case Caption	**Case No.**	**District**	**Plaintiffs' Counsel**	**Pending Motions**	**Status**
Nyboer v. Merck & Co., Inc., and Merck Sharp & Dohme Corp.	3:22-CV-05499	D.N.J.	Feldman & Pinto LLC; Baum Hedlund Aristei & Goldman, P.C.	N/A	Complaint filed in N.J. Super Ct., Hunterdon Cty. on 9/6/2022 (unserved as of 9/19/2022) Merck removed case to D.N.J. on 9/12/2022 Merck filed a Notice of Potential Tag-Along on 9/15/2022

Appendix D

Appendix D – Summary of Merck Document Productions to Date

Merck Employee Custodial Files[1] Collected and Produced

Custodian (Employment Status at the Time of Collection)	Title (at the Time of Collection)
Maria Allende (former)	Associate Director, Biologics, Clinical Research
Michael Armstrong (former)	Principal Scientist, Research
Walter Bagdon (former)	Senior Investigator
Eliav Barr (current)	Clinical Research
Oliver Bautista (current)	Senior Biometrician, Vaccine Biostatistics and Research Decisions Sciences ("BARDS")
Patrick Brill-Edwards (former)	Regulatory Affairs
Janine Bryan (former)	Senior Research Biochemist
Ulrike Kirsten Buchwald (current)	Principal Scientist, Clinical Research, Global Clinical Development ("GCD")-Vaccines Adult
Barry Buckland (former)	Principal Scientist, Clinical Research, GCD-Vaccines Adult
Michael Caulfield (former)	Senior Director, Research
Adrian Dana (former)	Pharmacovigilance
Rita Das (current)	Clinical Research
Jon Edelman (former)	Executive Director, Clinical Studies
Maria Celina Edmonds (current)	Director, Labeling
Xiaoyin Fan (former)	Senior Biometrician, Vaccines BARDS
Alison Fisher (former)	Director, Regulatory Affairs

[1] Merck has produced both "custodial" and "non-custodial" documents. Custodial documents refer to emails and other documents specific to current or former Merck employees. Non-custodial documents refer to materials from centralized files—e.g., structured databases and other sources not specific to employees.

Appendix D – Summary of Merck Document Productions to Date

Custodian (Employment Status at the Time of Collection)	Title (at the Time of Collection)
Elizabeth Garner (former)	Clinical Research, Infectious Diseases Vaccines; Associate Director, Clinical Research, Clinical and Quantitative Sciences
Christine Gause (current)	Senior Biometrician, Vaccines BARDS
Julie Gerberding (current)	Executive Vice President
Katherine Giacoletti (former)	Senior Biometrician, Vaccines BARDS
Dalya Guris (current)	Director, Clinical Research, Infectious Diseases Vaccines; Director, Clinical Research, Clinical and Quantitative Sciences
Rick Haupt (current)	Clinical Research
Bernard Heiles (current)	Pharmacovigilance
Kathryn Hofmann (former)	Senior Director, Alliance Management
Louise Houson (current)	Senior Vice President, Market Access
Kathrin Jansen (former)	Senior Research Biochemist
Lynn Khosrowshahi (former)	Statistician, Vaccines BARDS
Lee-Lian Kim (former)	Biometrician, Vaccines BARDS
Victoria Kindt (former)	Executive Director, Toxicology
Huiling Li (former)	Biometrician, Vaccines BARDS
Kai-Li Liaw (current)	Director, Epidemiology
Fabio Lievano (former)	Pharmacovigilance
Alain Luxembourg (current)	Clinical Research
Brooke Marshall (former)	Biometrician, Vaccine BARDS
Tom Monticello (former)	Executive Director, Toxicology
Nemisha Patel (former)	Senior Specialist, Quality Assurance

Appendix D – Summary of Merck Document Productions to Date

Custodian (Employment Status at the Time of Collection)	Title (at the Time of Collection)
Darryl Patrick (former)	Vice President, Safety Assessment
Jay Pearson (former)	Assistant Vice President, Epidemiology
David Radley (former)	Associate Director, Scientific Staff, Vaccine BARDS
Radha Railkar (current)	Senior Biometrician, Vaccines BARDS
Al Saah (current)	Clinical Research
Carlos Sattler (former)	Director, Biologics, Clinical Research
David Schechter (current)	Assistant Vice President, Regional Marketing
Joseph Sullivan (former)	Executive Director, Marketing
Gretchen Tamms (current)	Principal Scientist, Clinical Operations
Veronica Urdaneta (current)	Pharmacovigilance
Matthew Van Zweiten (former)	Executive Director, Pathology
Christine Velicer (current)	Epidemiology
Carmen Villar (current)	Vice President, Social Business Innovation
Jayanthi Wolf (current)	Executive Director, Regulatory Liaison
Jimmy Yu (former)	Biometrician, Vaccines BARDS

Appendix D – Summary of Merck Document Productions to Date

Non-Custodial Documents Produced[2]	Description
Gardasil and Gardasil 9 Regulatory files,[3] including Investigational New Drug Applications ("IND"), Biologics License Applications ("BLA"), patient-level clinical trial data ("SAS data") and correspondence files	Merck produced the entirety of the Gardasil and Gardasil 9 regulatory files (minus the Chemistry Manufacturing and Controls ("CMC") section as noted in footnote 1). The regulatory files include the following: - IND Application, which is submitted to the FDA for approval to conduct experimental trials on an unapproved drug. - BLA, which contains information to support initial licensure and any amendments thereto, including data derived from Merck's non-clinical laboratory and clinical studies for Gardasil and Gardasil 9. - Correspondence between Merck and the FDA as maintained in the FDA regulatory file for Gardasil and Gardasil 9.
Gardasil and Gardasil 9 15-Day Reports	Merck produced Gardasil and Gardasil 9 15-day reports which are reports of adverse experiences, received globally, that are both serious and unexpected and are required to be reported to the FDA within 15 calendar days of Merck's receipt.
Gardasil and Gardasil 9 Clinical Study Reports ("CSRs")	Merck produced Gardasil and Gardasil 9 CSRs which are often voluminous, providing details about the trial's investigational plan, the efficacy evaluations, the safety evaluations, documentation of the study findings, and extensive appendices (e.g., protocol amendments, patient information, consent forms, investigator information, individual patient data).
Non-Clinical Study Reports	Merck produced Gardasil and Gardasil 9 non-clinical (animal studies) toxicology and immunogenicity study reports, as well as reports of non-clinical studies conducted specifically on the aluminum adjuvant. The laboratory studies (in vivo or in vitro experiments) test certain components of a product in laboratory conditions to assess safety.

[2] Merck has made certain case-specific productions in individual cases and is willing to meet and confer with Plaintiffs' counsel to discuss making similar case-specific productions in other cases now part of this MDL through the Defendants' Fact Sheet process.

[3] Merck has objected to the production of the complete Gardasil CMC because, among other reasons, it is irrelevant in light of the Vaccine Act's express preemption of design defect claims and because it contains proprietary, trade secret information.

Appendix D – Summary of Merck Document Productions to Date

Non-Custodial Documents Produced[2]	Description
Gardasil and Gardasil 9 Periodic Safety Update Reports ("PSURs")	Merck produced Gardasil and Gardasil 9 PSURs, which are pharmacovigilance filings that Merck is required to submit on a regular basis to certain regulatory agencies. The PSURs provide agencies with updated comprehensive and critical safety profiles for Gardasil and Gardasil 9. The PSURs contain Merck's aggregated and comprehensive review of safety-related data and information from various sources including clinical and non-clinical studies, spontaneous reports, usage and utilization information, observational studies, and scientific literature.
Gardasil and Gardasil 9 Package Inserts	Merck produced final Gardasil and Gardasil 9 package inserts (i.e., labeling). The package inserts contain the FDA-approved prescribing information and provide key information to healthcare providers on the safety, efficacy, and use of the vaccines.
Gardasil and Gardasil 9 Publication Plans	Merck produced Gardasil and Gardasil 9-related publication plans which are internal strategic plans that describe Merck's efforts to evaluate publication concepts, develop scientific publications, and track publication activity related to Gardasil and Gardasil 9.
Gardasil and Gardasil 9 Physician Information Request ("PIR") responses	Merck produced template responses to Gardasil and Gardasil 9 PIRs which are requests to Merck from a healthcare provider ("HCP") for medical, scientific, or other information about Gardasil or Gardasil 9. Merck responds to the HCP requests by providing answers to the specific information requests.
Gardasil and Gardasil 9 Promotional/Marketing Materials	Merck produced Gardasil and Gardasil 9 marketing and promotional materials, which include direct-to-consumer advertisements, branded packaging, information packets, reminder cards, etc.
Extract of Gardasil and Gardasil 9 Postural Orthostatic Tachycardia Syndrome ("POTS")-related adverse events from Merck's Global Safety database ("MARRS") in *Robi*	Merck produced an extract of data from MARRS for Gardasil and Gardasil 9 adverse events hitting on the Medical Dictionary for Regulatory Activities ("MedDRA") terms listed below and exported the data for production. MedDRA terms are clinically validated medical terminology used by regulatory authorities and the pharmaceutical industry throughout the regulatory process: - Postural orthostatic tachycardia syndrome

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Non-Custodial Documents Produced[2]	Description
	- (((Palpitations; Tremor; Heart rate increased; Tachycardia; Tachyarrhythmia)) AND ((Dizziness; Dizziness exertional; Dizziness postural; Exercise tolerance decreased; Muscular weakness; Fatigue)) AND ((Syncope; Presyncope; Loss of consciousness)) AND ((Orthostatic intolerance; Orthostatic heart rate response increased)) AND ((Paraesthesia; Sensory disturbance; Vision blurred)) AND ((Hyperhidrosis)) AND ((Memory impairment; Disturbance in attention; Confusional state; Cognitive disorder)) AND ((Autonomic nervous system imbalance; Urinary retention; Constipation; Diarrhea))) - (((Palpitations; Tremor; Heart rate increased; Tachycardia; Tachyarrhythmia)) AND ((Dizziness; Dizziness exertional; Dizziness postural; Exercise tolerance decreased; Muscular weakness; Fatigue)) AND ((Orthostatic intolerance; Orthostatic heart rate response increased)) AND ((Hyperhidrosis))) - (((Palpitations; Tremor; Heart rate increased; Tachycardia; Tachyarrhythmia)) AND ((Dizziness; Dizziness exertional; Dizziness postural; Exercise tolerance decreased; Muscular weakness; Fatigue)) AND ((Orthostatic intolerance; Orthostatic heart rate response increased)) AND ((Paraesthesia; Sensory disturbance; Vision blurred))) - (((Syncope; Presyncope; Loss of consciousness)) AND ((Paraesthesia; Sensory disturbance; Vision blurred)) AND ((Hyperhidrosis))) - (((Syncope; Presyncope; Loss of consciousness)) AND ((Orthostatic intolerance; Orthostatic heart rate response increased)) AND ((Paraesthesia; Sensory disturbance; Vision blurred)) AND ((Hyperhidrosis))) - (((Syncope; Presyncope; Loss of consciousness)) AND ((Orthostatic intolerance; Orthostatic heart rate response increased)) AND ((Paraesthesia; Sensory disturbance; Vision blurred)) AND ((Autonomic nervous system imbalance; Urinary retention; Constipation; Diarrhea)))
Extract of Gardasil and Gardasil 9 Peripheral neuropathy-related adverse events from MARRS in *Robi*	Merck produced a MARRS extract for Gardasil and Gardasil 9 adverse events resulting from a Peripheral Neuropathy standardized MedDRA query.

Appendix D – Summary of Merck Document Productions to Date

Non-Custodial Documents Produced[2]	Description
Extract of Gardasil and Gardasil 9 Immune Thrombocytopenia-related ("ITP") adverse events from MARRS in *Gramza*	Merck produced a MARRS extract for Gardasil and Gardasil 9 adverse events hitting on the MedDRA terms listed below, which relate to ITP: - Idiopathic thrombocytopenic purpura - Thrombocytopenia - Thrombocytopenic purpura - Platelet count decreased
Gardasil and Gardasil 9 Vaccine Adverse Event Reporting System ("VAERS") and Counsel for International Organizations of Medical Sciences ("CIOMS") forms for the POTS and ITP-related adverse events extracted from MARRS for production to Plaintiffs	The VAERS is a national early warning system designed to detect possible safety issues for U.S. licensed vaccines. VAERS is co-managed by the CDC and FDA, and Merck is obligated to report certain Gardasil and Gardasil 9 adverse events to VAERS using the VAERS form. CIOMS forms are like the VAERS forms and provide a standardized format for reporting suspected adverse event reactions. After running the MedDRA terms relating to POTS and ITP across its Global Safety database and exporting the adverse events for production to Plaintiffs, Merck then also produced VAERS and CIOMS forms for each of the POTS and ITP-related adverse events and produced the VAERS and CIOMS forms.
LEAD/LAST committee meeting minutes	Merck produced meeting minutes of the Gardasil and Gardasil 9 LEAD and LAST committees, which are Merck's product-specific teams responsible for analyzing, reviewing, and approving proposed changes to the Gardasil and Gardasil 9 product labels. The LEAD/LAST committees meet on a routine basis as needed to review potential or actual changes to the labels.
Risk Management Safety Team ("RMST") committee materials	Merck produced the Gardasil and Gardasil 9 meeting materials for the RMST committee, which is a product-specific, cross functional team responsible for the overall safety profile and the overall risk management strategy for Gardasil and Gardasil 9 throughout the product lifecycle. RMST's activities include: - evaluating potential safety issues and signals - establishing and communicating the overall safety, strategy and safety profile of a product; and - developing and recommending the core risk management strategy of risks.