



compensation, on behalf of her son, N.H., under the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. § 300aa-10 *et seq.* (the “Vaccine Act” or “Act”).<sup>2</sup> Petitioner alleges that the Human Papillomavirus vaccine (“HPV” or “Gardasil”) that she received on June 1, 2009, while pregnant, caused her son, N.H., to be born with a tracheoesophageal fistula, an imperforate anus, and a tethered spinal cord (a condition collectively known as “VACTERL association.”). Petition at ¶¶ 2, 3, 8. ECF No. 1. Petitioner subsequently filed medical records in support of her claim, which were designated as Petitioner’s Exhibits one through seventeen.

On December 28, 2011, Respondent filed a Motion to Dismiss. Following briefing by the parties, on April 23, 2012, Chief Special Master Campbell-Smith denied the motion to dismiss, and ordered Petitioner to file a medical expert report in support of her claim on or before June 18, 2012. Order at 11, ECF No. 17. The case was reassigned from Chief Special Master Campbell-Smith to the undersigned on March 4, 2013. Order Reassigning Case, March 4, 2013.

Following the denial of the Motion to Dismiss, Petitioner requested and was granted six extensions of time to file her expert report. Motions for Extension of Time, ECF Nos. 18, 21, 22, 23, 24, 26; Orders granting Motion for Extension of Time, June 18, 2012, August 17, 2012, October 16, 2012, December 17, 2012, February 15, 2013, May 22, 2013. When Petitioner moved for the sixth 60-day extension of time on April 15, 2013, she stated, as she had previously, that she was “consulting with a perineonatologist and a pediatric colorectal physician regarding rendering an expert opinion(s).” Motion, ECF No. 26. The motion was granted. However, Petitioner was told that if she was unable to file an expert report by June 14, 2013, a status conference would be scheduled to discuss the course of further proceedings in this case. Order, May 22, 2013.

Petitioner was unable to file an expert report by June 14, 2013, and a status conference was held on July 10, 2013. Minute Entry, July 10, 2013. At the status conference, Petitioner’s counsel admitted that she had not yet retained an expert. She asserted that this case was more challenging than most Vaccine Act cases, because it involved an in utero injury and a “novel birth defect not previously attributed to a vaccine.” *See* Order, July 16, 2013, ECF No. 30. Petitioner’s counsel also represented that Petitioner had obtained information from Gardasil’s manufacturer, Merck & Co., Inc.

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<sup>2</sup> The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. § 300aa-10-§ 300aa-34 (2006) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

(“Merck”),<sup>3</sup> and that she believed a subpoena was necessary to obtain additional information from Merck.

On July 11, 2013, Petitioner filed a motion to issue a subpoena to Merck for “[a]ny and all information regarding pregnancy registry, reports, research, clinical trials and post-marketing surveillance etc. [for the Gardasil vaccine].” Petitioner’s Motion for Subpoena, ECF No. 27. Respondent advised the Court that Respondent intended to respond to the motion. Informal Communication, July 11, 2013. By Order dated July 11, 2013, the Court requested that Respondent indicate whether she would oppose “a subpoena limited to Merck’s information regarding pregnancy registry and reports and post-marketing surveillance of women who were vaccinated with Gardasil while pregnant along with the children born from those pregnancies.” Order, July 11, 2013, ECF No. 28.

Following the Court’s Order, Petitioner filed an Amended Motion for Subpoena to Merck, making the following four requests for information:

1. Any and all information regarding surveillance studies, clinical trials, pre-licensure studies, post-marketing studies and all research data developed relating to pregnancy outcomes for infants born to mothers who were exposed to and received Gardasil during pregnancy;
2. All prospective and retrospective reports involving exposures during pregnancy, including all reports contained in the safety database maintained by Merck’s pregnancy registry since establishment;
3. Any papers, reports or studies relating to a possible biological mechanism by which inadvertently [sic] exposure to Gardasil vaccination during pregnancy could cause a birth defect, abnormality, chromosomal abnormalities &/or any other adverse event;
4. Any and all files related to the pregnancy registry, including case notes of enrolled and non-enrolled participants (please redacted any patient identifying information).

Motion for Subpoena, ECF No. 29.

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<sup>3</sup> This information proved to be Merck’s Sixth Annual Report on Exposure During Pregnancy from the Merck Pregnancy Registry for Quadrivalent Human Papillomavirus Recombinant Vaccine, filed as Pet’r’s Ex. 2.

## LEGAL STANDARD

The Vaccine Act provides that “there shall be no discovery in a proceeding on a petition other than the discovery required by the special master.” 42 U.S.C. §300aa-12(d)(3)(B); see also Vaccine Rule 7(a)<sup>4</sup> (“There is no discovery as a matter of right.”). A special master should limit discovery to circumstances where she finds that discovery is “reasonable and necessary” to resolution of the factual issues in dispute. See 42 U.S.C. §300aa-12(d)(3)(B); see also *Mostovoy v. Sec’y of Dep’t of Health & Human Servs.*, No. 02-10V, 2013 WL 3368236 at \*10-11 (Fed. Cl. Spec. Mstr. Jun. 12, 2013). “The standard applied to determine whether requested material is ‘necessary’ in vaccine proceedings is whether, based on ‘the overall context of the factual issues to be decided, the special master *could not make a fair and well-informed* ruling on those factual issues without the requested material.” *Mostovoy*, 2013 WL 3368236, at \*11 (citing *In re Claims for Vaccine Injuries Resulting In Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder* (“2007 OAP Ruling”)<sup>5</sup>, 2007 WL 1983780, at \*7 (Fed. Cl. Spec. Mstr. May 25, 2007) (emphasis in original)). See also *King v. Sec’y of Dep’t of Health & Human Servs.*, No. 03-584V, 2008 WL 1994968, \*3 (Fed. Cl. Spec. Mstr. Feb. 7, 2008). In making this determination, a Special Master should evaluate what other information is available and compel discovery only where the available evidence is insufficient to reach a fair and well-informed decision. *Deloatch v. Sec’y of Dep’t of Health & Human Servs.*, No. 09-171V, 2010 WL 5558349, at \*4 (Fed. Cl. Spec. Mstr. Apr. 27, 2010, reissued Jul. 28, 2010); *In re Claims for Vaccine Injuries Resulting In Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder* (“2004 OAP Ruling”), 2004 WL 1660351, at \*8. However, an interpretation of the rules to allow discovery only if rendering a decision would be absolutely impossible without it is too restrictive. See 2007 OAP Ruling, 2007 WL 1983780, at \*7.

If a special master determines that the requested material is “necessary,” she must then evaluate whether requiring production is “reasonable” under the circumstances. *Mostovoy*, 2013 WL 3368236, at \*11. A reasonableness determination is made by balancing the burden imposed on the producing party against the importance of the materials to the special master’s consideration of the factual issues in the case. *Id.*; 2007 OAP Ruling, 2007 WL 1983780, at \*7.

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<sup>4</sup> The “Vaccine Rules” are set forth in Appendix B of the Rules of the United States Court of Federal Claims, as amended through August 30, 2013.

<sup>5</sup> This was an early proceeding in what eventually came to be known as the Omnibus Autism Proceeding (“OAP”).

## DISCUSSION

Categories 1, 2, and 4 of the subpoena are requests for epidemiological information. Despite Petitioner's assertions to the contrary, the Annual Report, (Petitioner's Exhibit 2, a copy of which was provided to Petitioner upon request) contains significant epidemiological information concerning reported birth defects and other side effects from administration of the Gardasil vaccination during pregnancy. That information includes not only summary information, such as the gross number of birth defects reported, it also includes a chart of the most serious birth defects (including, apparently, those experienced by Petitioner), with information about when during the pregnancy the vaccine was administered, the outcome of the pregnancy, and other information available to Merck about the health of the mother and of the fetus/infant. Petitioner argues in her motion that Merck possesses case reports and other materials "that would assist the Special Master as the trier of fact in this matter." Petitioner's Response to Respondent's Opposition to Petitioner's Motion for Subpoena at 3, August 1, 2013, ECF No. 33. Petitioner does not explain in any way how additional epidemiological information would assist either her expert in formulating a theory or the special master in understanding the biological mechanism or other scientific questions relevant to determining causation in this case. Request numbers 1, 2, and 4 of Petitioner's Amended Motion for Subpoena are therefore **DENIED**.

The crux of this subpoena is clearly request number 3, for "[a]ny papers, reports or studies relating to a possible biological mechanism by which inadvertently [sic] exposure to Gardasil vaccination during pregnancy could cause a birth defect, abnormality, chromosomal abnormalities &/or any other adverse event." Motion for Subpoena, ECF No. 29. There are a number of problems with this request. First, it appears to be fishing for information that may not even exist. In the Sixth Annual Report, Merck reports that there is no greater incidence of birth defects, either in gross number or by particular defect, in the *in utero* vaccine population versus the background population. Pet'r's Ex. 2 at 21. Thus, theoretically, Merck is not looking and has not looked for such a biological mechanism because it has concluded that there is no mechanism to look for.

A far more significant problem with this request, however, is the burden shifting it has the potential to create. The Court agrees that one of the primary purposes of the Vaccine Act is to benefit persons injured by vaccines by establishing "a no-fault compensation program 'designed to work faster and with greater ease than the civil tort system.'" *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011) (quoting *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995)). Another significant purpose of the Act, however, was to "stabilize the vaccine market," *Sebelius v. Cloer*, 133 S. Ct. 1886, 1890 (2013) and to insure that manufacturers would continue both to produce existing vaccines and to conduct the research necessary to produce new vaccines such as the vaccine at issue in this case. H.R. Comm. On Energy and Commerce, National Childhood Vaccine Injury

Act of 1986, H.R. Rep. No. 99-908, 99<sup>th</sup> Cong., 2d Sess. 4, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6348. To accomplish this purpose, vaccine manufacturers were removed as parties from Vaccine Act cases—they do not participate in Vaccine Act proceedings, nor are they bound by any orders that issue from those proceedings. To grant the subpoena requested by Petitioner in this case would be to eviscerate this portion of the Act: any petitioner who cannot develop a cogent theory of causation could simply shift the burden onto the manufacturer by requesting from it “any papers, reports or studies relating to a possible biological mechanism,” or other documents by which a vaccine could allegedly be linked to an injury. That is clearly not the limited discovery envisioned by the Act or Vaccine Rules.

In addition, as Respondent notes, manufacturers will not provide this kind of information without dispute. Manufacturers cannot intervene in Vaccine Act cases, Vaccine Rule 15, but they can be afforded an opportunity to be heard, *see, e.g., Mostovoy*, 2013 WL 3368236 at \*3, and they can file motions to quash. In either event the Court, the parties, and the manufacturers would become embroiled in the very expensive and time-consuming litigation the Act was intended to eliminate. While the undersigned agrees with Petitioner that special masters do have the authority to issue subpoenas to manufacturers under the appropriate circumstances, those circumstances do not exist in a case in which no theory of causation has been advanced and no argument except a conclusory one has been put forth that establishes that the evidence sought is reasonable and necessary to the special master’s inquiry. *See, e.g., 2004 OAP Ruling*, 2004 WL 1660351, at \*11 (“The [Petitioner’s Steering Committee] has not even articulated a general theory as to how the MMR vaccine might cause or contribute to autism, so that I might consider how the requested documents might potentially yield evidence relevant to that theory.”). Petitioner’s subpoena request category 3 is therefore **DENIED**.

### **ORDER**

As discussed above, Petitioner’s Amended Motion for Subpoena is **DENIED IN ITS ENTIRETY**. Petitioner can no longer delay obtaining an expert and moving forward with this case. Petitioner shall file an expert report, or show cause why his petition should not be dismissed for failure to prosecute it, **no later than 63 days from the date of this Order, by no later than Wednesday, November 6, 2013**.

**IT IS SO ORDERED.**

s/ Lisa Hamilton-Fieldman  
Lisa Hamilton-Fieldman  
Special Master