

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS**

No. 10-565V

Filed: October 27, 2015

For Publication

MEGAN L. GODFREY,

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HPV Vaccine; Gardasil; Juvenile

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Ankylosing Spondylitis; JAS;

Petitioner,

*

Causation-in-Fact; Expert;

v.

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Qualifications; Remand in light of

*

intervening Federal Circuit Decision;

SECRETARY OF HEALTH

*

Effect of Prior Fact-finding in

AND HUMAN SERVICES,

*

Transferred Case

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Respondent.

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Milton Clay Ragsdale, IV, Ragsdale LLC, Birmingham, AL, for petitioner.

Jennifer Reynaud, U.S. Department of Justice, Washington, DC, for respondent.

DECISION ON REMAND DENYING ENTITLEMENT¹

Corcoran, Special Master:

Ms. Megan Godfrey filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² [the “Vaccine Act” or “Program”], on August 20, 2010, alleging, among other things, that the human papillomavirus [“HPV”] vaccine she received on August 22, 2007 was the cause of her subsequent development of juvenile ankylosing spondylitis [“JAS”]. After hearing testimony and considering the record as a whole, however, former Chief Special Master Vowell³ issued a decision denying entitlement on June 11, 2014 (ECF No. 72). *Godfrey*

¹ Because this decision contains a reasoned explanation for my action in this case, it will be posted on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002) (current version at 44 U.S.C. § 3501 (2014)). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-10 through 34 (2012)). Hereinafter, for ease of citation, all references to Vaccine Act sections will be to the pertinent subparagraph of 42 U.S.C. § 300aa (but will omit that statutory prefix).

³ Chief Special Master Vowell retired in September 2015.

v. Sec’y of Health & Human Servs., No. 10-565V, 2014 WL 3058353 (Fed. Cl. Spec. Mstr. June 11, 2014) [hereinafter, “Entitlement Decision”].

Ms. Godfrey subsequently filed a motion for review, which was granted in part by Judge Firestone of the U.S. Court of Federal Claims on July 29, 2015 (*Godfrey v. Sec’y of Health & Human Servs.*, 2015 WL 4972882 (Fed. Cl. Aug. 19, 2015) [hereinafter, the “Remand Decision”]⁴), in order to permit reconsideration in light of the Federal Circuit’s intervening decision in *Koehn v. Sec’y of Health & Human Servs.*, 773 F.3d 1239 (Fed. Cir. 2014) – and, in particular, whether its discussion of a causation theory that has some arguable application to the present action warrants a different outcome than the Entitlement Decision. The matter has now been transferred to me. For the reasons set forth in more detail below, I find that *Koehn* does not compel a different result from that reached in the existing Entitlement Decision, and therefore Ms. Godfrey remains unentitled to compensation.

I. Relevant Factual and Procedural History.

A. Summary of Medical History

Ms. Godfrey’s medical history is recounted in some detail in the Decision, which I incorporate by reference here. See Entitlement Decision at *4-*6. The essential facts are these. Ms. Godfrey was born in August of 1989 into a family with a notable medical history of Crohn’s disease and rheumatoid arthritis. *Id.* at *4; see also Pet. Exs. 7, p. 182; 8, p. 9. Save for routine childhood illnesses, however, she was generally healthy. Entitlement Decision at *4. During high school, she was a student athlete and participated in her school’s cheerleading team. *Id.*

On August 22, 2007, just after she turned 18, Ms. Godfrey received a single dose of the HPV [“Gardasil”] vaccine from her pediatrician. Entitlement Decision at *4. Nearly four months later, on December 19, 2007, she returned to her doctor complaining of sharp, intermittent pain in her left hip that had been ongoing for the previous three months. *Id.* at *5. An x-ray of her hip indicated no problems and she did not report any recent injury. Pet. Ex. 3 at 1. The next week, however, an MRI revealed “[b]ilateral femoral benign fibrous dysplasia, greater on the left side than the right, and left-sided sacroiliitis, which the radiologist thought might have been inflammatory.” Entitlement Decision at *5; Pet. Ex. 8 at 86.

Over the next several weeks, Ms. Godfrey underwent many tests, including a bone scan indicating “increased activity at the left [sacroiliac] joint,” similar to what could be seen “in osteomyelitis or in an inflammatory sacroiliitis.” Pet. Ex. 11, p. 11. In January of

⁴ Judge Firestone’s decision was initially issued under seal in July in an attempt to give the parties the opportunity to request redaction. It was subsequently published in August (ECF No. 95) after Petitioner failed to establish grounds for redaction.

2008, Ms. Godfrey tested positive for HLA-B27, a genetic marker that left her predisposed to conditions such as JAS. Entitlement Decision at *5; Pet. Ex. 11, p. 7.

During a visit to a pediatric rheumatologist in April 2008, Ms. Godfrey was diagnosed with HLA-B27 spondyloarthropathy. Pet. Ex. 7 at 180-84. Her physician, Dr. Randy Cron, noted her familial history of Crohn's disease and arthritis. *Id.* Several years later, in August 2012, Petitioner visited another rheumatologist (Pet. Ex. 88 at 10-14), who proposed that she had ankylosing spondylitis/axial spondyloarthropathy, and therefore continued her course of Infliximab injections. *Id.* at 9. Initially prescribed the injections by Dr. Cron in April of 2008, Petitioner has acknowledged that the "treatment has been successful in terminating [her] symptoms" of JAS. Pet. Post-Hearing Brief (ECF No. 69) at 2. Significantly, none of Ms. Godfrey's treaters ever concluded that the single Gardasil dose she had received was connected in any way with her subsequent JAS.

B. JAS and Associated Risk Factors

JAS is the pediatric form of ankylosing spondylitis ["AS"], and is in essence the same disease. Entitlement Decision at *11. The "juvenile" modifier is applied to those who exhibit the symptoms of AS before the age of 16. Although the experts who testified at the hearing in this matter agreed that Ms. Godfrey was over 16 when she first began displaying symptoms, they were satisfied with the JAS diagnosis.

There are several risk factors associated with JAS. Researchers have estimated that "genetic risk factors contribute to 80-90% of the susceptibility to [AS]." Entitlement Decision at *12; see *also* Dougados, Pet. Ex. 54⁵ at 2128; see *also* Lin, Pet. Ex. 56, at 578. The primary genetic risk factor is possession of the HLA-B27 genetic marker, which has been described as having a "direct and dominant effect." Entitlement Decision at *12; see *also* Dougados, Pet. Ex. 54, at 2129; see *also* Lin, Pet. Ex. 56, at 579. HLA-B27 is present in 80-90 percent of patients with AS. Entitlement Decision at *12; see *also* Dougados, Pet. Ex. 54, at 2129. In patients with JAS, it is even more prevalent. Thus, in a study of 47 patients with JAS, over 97 percent tested positive for HLA-B27. Lin, Pet. Ex. 56, at 577.⁶ A negative genetic test result, however, "does not preclude the presence of spondyloarthritis." Entitlement Decision at *12; see *also* Dougados, Pet. Ex. 54, at 2128. Moreover, "only a small proportion of people in the general population who harbour HLA-B27 (5-6% in white people) develop [AS], and HLA-B27 explains only 20-40% of the genetic susceptibility to [AS]—suggesting the contribution of additional genes." Dougados, pet. Ex. 54, at 2129.

⁵ In referencing medical literature in this decision, I adhere to the former Chief Special Master's practice from the Entitlement Decision of specifying articles by the name of the primary author, cross-referenced with the relevant exhibit number.

⁶ See *also* NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) at Pt. XV, Ch. 150, Lab. Findings, <https://expertconsult.inkling.com/read/nelson-pediatrics-kliegman-behrman-19th/chapter-150/chapter150-reader-4> (noting that "HLA-B27 is present in > 90% of children with JAS.").

In addition to genetic factors, specific types of infection (gastrointestinal or genitourinary infection), and physical trauma are JAS risk factors. Lin, Pet. Ex. 56, at 578; Tr. at 195-97 (Dr. Zweiman). JAS is closely linked to gut inflammation, in association with Crohn's disease. Entitlement Decision at *12; see *also* Burgos-Vargas, Pet. Ex. 61, at iii34. The incidence of non-specific inflammatory bowel disease in patients with JAS is about 80 percent. Entitlement Decision at *12; see *also* Burgos-Vargas, Pet. Ex. 61, at iii 35. Intense physical training has also been observed in JAS patients before symptom onset. Lin, Pet. Ex. 56, at 578.

C. *Procedural History*

1. Entitlement Hearing and Decision - As stated above, Ms. Godfrey contended in this case that the HPV vaccination she received on August 22, 2007, substantially contributed to her development of JAS. An entitlement hearing in the matter was held on December 10, 2012, at which time Dr. Michael McCabe (Ph.D.), Dr. Carlos Rosé (M.D.), and Dr. Burton Zweiman (M.D.) testified as expert witnesses.

At hearing, Dr. McCabe (Petitioner's expert) opined that the single dose of Gardasil vaccination Ms. Godfrey received triggered (and thus substantially contributed to) the manifestation of her JAS, through the release of proinflammatory cytokines.⁷ Entitlement Decision at *13; see *also* Tr. at 16; Pet. Ex. 52 at 7. According to Petitioner's theory, the increase of pro-inflammatory cytokines incited by the Gardasil vaccine "worked as an environmental trigger causing the onset of JAS in a genetically predisposed individual." Pet. Brief at 6. In effect, Ms. Godfrey was "climbing a hill" toward JAS given her susceptibility, but Gardasil pushed her to the top. Entitlement Decision at *14, *citing* Tr. at 56. Dr. McCabe thus opined that the HPV vaccine was the "but for" factor triggering her JAS.

In offering the above opinion, Dr. McCabe relied on several pieces of medical literature discussing the effect of components of the HPV vaccine on cytokine levels in the blood that have special relevance herein (given, as discussed below, the Federal Circuit's discussion in *Koehn* of some of these studies). See *generally* Pinto I, Ex. 73 and Marks, Pet. Ex. 87. Both involved the *in vitro* testing of blood samples taken from individuals who had been vaccinated with a version of the HPV vaccine containing virus-like particles ("VLPs").⁸ In the study discussed in Pinto I, cytokine levels were measurably higher when the vaccinated blood samples were stimulated with additional HPV VLPs. Pinto I, Pt. Ex. 73 at 3556-59. The study examined in the Marks article was actually intended to evaluate the effects of hormones contained in combined oral contraceptives on inflammatory response of women immunized with the HPV vaccine, but (as an incident

⁷ As defined in the Entitlement Decision, proinflammatory cytokines are "proteins released by one cell population . . . on contact with a specific antigen" that can stimulate inflammation. Entitlement Decision at *9 n.19.

⁸ As defined in the Entitlement Decision (and taken from the Pinto I article), VLPs are noninfectious viral capsids that help activate the innate and adaptive immune system, increasing a vaccine's potency.

to its purpose) observed the same increase in cytokines. Marks, Pet. Ex. 87 at 610. Because the study evaluated in the Marks article involved the stimulation by HPV VLPs of unvaccinated blood, Dr. McCabe directly invoked the Marks article as the best evidence of which he was aware that a single dose of Gardasil would be sufficient to administer the level of proinflammatory cytokine response to result in a spondyloarthropathy such as JAS. Tr. at 52-53.

Respondent, by contrast, asserted there was no evidence to support a link between Ms. Godfrey's Gardasil vaccination and her subsequent JAS diagnosis. Dr. Rosé opined that there were no studies linking JAS or similar conditions to Gardasil; that Petitioner had a strong genetic predisposition toward the development of JAS as evidenced by her HLA-B27 marker and a family history of Crohn's disease (and that those factors were far more likely to have caused the JAS given the known and studied relationship between them and the disease); that Petitioner's participation in cheerleading could cause micro-trauma sufficient to trigger her JAS; and (most significantly for present purposes) that Dr. McCabe's reliance on cytokines in JAS's etiology was incorrect, as cytokines do not cause JAS, but at best play a role in its symptomology that can be treated and alleviated, but without effect in treating the underlying disease. Entitlement Decision at *16-*18. Dr. Zweiman similarly rejected Dr. McCabe's causation theory, finding it unsupported in medical literature and proposing that other factors more fully explained the cause of her JAS. *Id.* at *18. He also expressed additional views on the role of cytokine production in resulting in JAS, opining that Dr. McCabe's theory would require a prolonged increase in cytokine production to have the effect proposed by Dr. McCabe. *Id.* But in fact, the relevant studies (such as the Pinto study) supported the conclusion that Gardasil did not in fact produce sustained increases in cytokine levels of the kind necessary for the reaction Dr. McCabe proposed. *Id.* at *20. Respondent's experts for their part did not contest the general concept that HPV VLPs would be effective in stimulating the production of pro-inflammatory cytokines. See, e.g., Tr. at 212.

In her Entitlement Decision, the former Chief Special Master determined that Petitioner had not met her burden on any of the prongs set forth by the Federal Circuit for establishing causation in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) – but in particular with respect to the first, “can cause” prong. Entitlement Decision at *21-*23. She found Petitioner's theory to be unreliable because (among other things) there was no evidence in the record suggesting that pro-inflammatory cytokines actually play a role in the pathogenesis of JAS, although they are known to play a role in symptomatology. *Id.* at *21-*22. Moreover, Ms. Godfrey had not demonstrated (by citation to reliable medical studies or general literature) that a transient increase in cytokine levels of the sort that would occur following the receipt of the HPV vaccination would be sufficient to even cause the symptoms of JAS. *Id.* at *21. She also disputed Dr. McCabe's suggestion that Ms. Godfrey's genetic susceptibility to developing JAS also made her sensitive to increases in pro-inflammatory cytokines, noting that the position lacked evidentiary support. *Id.* at *14 and *21. There was also a general lack of evidence that Ms. Godfrey had even had an increase in cytokines after the first Gardasil dosage. *Id.* at *15-*16 and *21.

By contrast, the former Chief Special Master found far more persuasive the concept that other factors were more likely to cause JAS (and likely did so under the facts of this case). Thus, her Entitlement Decision observes the uncontested fact that Ms. Godfrey had a number of identified “substantial risk factors for developing JAS”: (a) her HLA-B27 gene, (b) family history of Crohn’s disease, and (c) participation in an activity known to cause micro-trauma in ankles and hips. The Chief Special Master found the evidence presented in the testimony of Drs. Rosé and Zweiman to be more persuasive than that offered by Dr. McCabe, concluding on that basis that “[g]enetics alone is a sufficient ‘but for’ cause for Ms. Godfrey’s condition.” *Id.* at *23.

Following her discussion of Petitioner’s failure to satisfy the first *Althen* prong, the Chief Special Master noted that the other two *Althen* prongs were similarly unsatisfied. There was little in Petitioner’s medical history to suggest an actual link between her Gardasil vaccination and her JAS, such as treater opinions or test results confirming that Dr. McCabe’s theory had occurred as posited. And the Petitioner had not demonstrated a medically acceptable temporal relationship between the onset of her symptoms and her receipt of one dose of the Gardasil vaccine. *Id.* at *23.⁹

2. Motion for Review and Remand – After issuance of the Entitlement Decision, Petitioner filed a timely motion for review in July 2014 (ECF No. 74). The matter was assigned to Judge Firestone. In the course of briefing the motion, Petitioner moved to stay the review petition given the pendency of the *Koehn* case, which Petitioner argued could impact the outcome of this case, because of the similarity of causation theories offered in both cases. The motion to stay was granted, and then (after the issuance of the *Koehn* decision) the parties briefed their respective positions. Oral arguments were held before Judge Firestone on July 14, 2015.

On July 29, 2015, Judge Firestone of the Court of Federal Claims issued an Opinion partially remanding this case to the Office of Special Masters. In her Remand Decision, Judge Firestone determined that the Federal Circuit’s decision in *Koehn* raised issues that were best addressed by a special master in a reevaluation of the entitlement decision in this case. Remand Decision at *6-*7. Specifically, she noted that the Federal Circuit had suggested (albeit in *dicta*) in *Koehn* that Dr. McCabe’s theory of causation as offered in that case (which, as discussed below, involved the autoinflammatory injury of systemic juvenile idiopathic arthritis [“SJIA”], and also relied on the concept of the HPV

⁹ In so determining, the former Chief Special Master relied on the testimony of Dr. Rosé, who explained that determining the actual onset of her JAS would be impossible given the facts. Entitlement Decision at *23. The parties did not dispute that Ms. Godfrey’s first complained-of symptom was pain in her left hip beginning about four weeks after her receipt of the HPV vaccine. *Id.* at *6. Yet imaging studies (performed after Ms. Godfrey sought treatment in December of 2007) showed that JAS was present at that time in both hips. *Id.* at *23. Dr. Rosé testified that an individual could have JAS and not experience symptoms, meaning that the onset of Ms. Godfrey’s JAS could not be assumed to be the day she first experienced symptoms (but could well have been much earlier). *Id.* This (along with Dr. McCabe’s failure to substantiate his assertion that the timeframe for the immunological response to the HPV dose was consistent with the onset of Ms. Godfrey’s first symptoms) was the basis for the former Chief Special Master’s *Althen* three determination.

vaccine purportedly stimulating cytokine production) may have been legally probable, and thus sufficient to meet the requirement of *Althen*'s first prong. *Id.* at *7. Therefore, in light of Petitioner's argument that Dr. McCabe's causation theory was virtually identical to the theory he also offered in this case and also highly apposite to Petitioner's case, it was advisable to have the former Chief Special Master reconsider on remand her decision to take into account *Koehn*'s holding. *Id.* At the same time, however, Judge Firestone also remarked that the two cases presented differences in terms of relevant disease, dosage, and the onset of petitioners' symptoms, the significance of which were to be addressed on remand.

On remand, the former Chief Special Master ordered the parties to brief in simultaneous submissions the issues raised in Judge Firestone's Opinion. Both parties filed their briefs on August 24, 2015. ECF Nos. 98 ["Pet. Brief"] and 97 ["Resp. Brief"]. Ms. Godfrey argued that because her causation theory was identical to that offered in *Koehn*, the Federal Circuit's "findings regarding Koehn's *Althen* theory" (i.e., that it was "legally probable") meant that she had satisfied her burden of proof. Pet. Brief at 2. Indeed, Petitioner maintained that she had presented stronger evidence of a temporal relationship between her single vaccination and JAS than the *Koehn* petitioner's multiple vaccinations and SJIA. Pet. Brief at 15. Petitioner also reargued points addressed in the original Decision but not directly impacted by *Koehn*; thus, she denied that there were other events that could have served as a trigger for the onset of her JAS, such as her high school cheerleading, which ceased several months prior to the administration of the single HPV vaccine dose, and maintained (in somewhat conclusory fashion) that other medical literature offered at the hearing stood for propositions that the former Chief Special Master contested she had established.¹⁰ Pet. Brief at 16-17.

Respondent's brief argued that Petitioner's reliance on *Koehn* was misplaced because that opinion was neither relevant nor applicable to the issue of causation presented herein. Resp. Brief at 1. In particular, Respondent noted that Petitioner had "overstated the significance of the *dicta* contained in the *Koehn* decision." *Id.* at 2, n.4. In addition, Respondent argued that Dr. McCabe had not presented entirely identical causation theories in both *Koehn* and *Godfrey*; his opinion in *Koehn* did not address "the HLA-B27 gene or any known mechanical or biological stressors." *Id.* at 5, n.5. Further, the *Koehn* petitioner's evidence was more compelling, as Dr. McCabe was able to offer as support for his theory several articles discussing vaccines as a possible trigger for the *Koehn* petitioner's disease, but failed to offer any similar support in this case suggesting

¹⁰ Thus, Petitioner posits in several places in her post-remand brief that the Dougados article (Pet. Ex. 54 at 2132-33 "explains how this increase in cytokines results in pathogenesis of JAS." Pet. Brief at 7; see also *id.* at 13. This is explicitly contrary to the former Chief Special Master's Entitlement Decision about the *lack* of evidence connecting cytokines to JAS pathogenesis, however – and the Entitlement Decision accurately observed that the Dougados article in fact supported Dr. Rosé's theory, because it stands for the proposition that treatment of proinflammatory cytokine inhibitors "alleviates symptoms, but does not affect the progression of [JAS]." Entitlement Decision at *21. My own review of the Dougados article is consistent with that of the former Chief Special Master, and I therefore find unpersuasive Petitioner's conclusory assertions that the article provides the very link in Dr. McCabe's theory that the former Chief Special Master found missing.

a connection between vaccines and any form of spondyloarthropathy. *Id.* at 6. By contrast, Respondent asserted that her two witnesses in the instant case thoroughly discredited Dr. McCabe's theory of causation. *Id.* at 6-8. Thus, because the facts and evidence were distinguishable from what was presented in *Koehn*, the case was not relevant "for purposes of assessing the reliability of petitioner's theory of causation." *Id.* at 8.

II. The Federal Circuit's Decision in *Koehn*.

Because the purpose of the present remand is to evaluate whether the Federal Circuit's analysis in *Koehn* should alter the entitlement decision herein, discussion of the facts of the *Koehn* case, as well as its holding, is warranted.

In *Koehn*, vaccine/petitioner Vanessa Koehn had been diagnosed with SJIA after receiving two doses of the Gardasil vaccine. *Koehn*, 773 F.3d 1239 at 1241. A pediatric rheumatologist later observed that the petitioner's family history was notable for SJIA. *Id.* Approximately two months after she received the second Gardasil injection, petitioner developed a rash which was subsequently resolved after she was prescribed Benadryl and prednisone.¹¹ *Id.* One week later, she was hospitalized with a high fever and severe joint pain. *Id.* While in the hospital, she saw a rheumatologist who prescribed her more prednisone. When she was discharged a few days later, her presumptive diagnosis was juvenile idiopathic arthritis. *Id.* Several days after her receipt of the third Gardasil dose, petitioner developed a fever, rash, and joint pain. *Id.*

The *Koehn* petitioner thus proceeded upon the theory that her SJIA was caused by receipt of the HPV vaccine. To establish that theory, she relied upon the expert opinion of Dr. McCabe (the expert in the present case as well). Dr. McCabe testified therein that the petitioner "had a predisposition for SJIA, and that Gardasil was an environmental trigger because the vaccine caused a strong response in the same cytokines which are dysregulated in SJIA." *Koehn*, 773 F.3d at 1242. There are thus relevant factual parallels between the theories advanced in *Koehn* and the present case.

One of the articles that Dr. McCabe cited in support of his theory had particular significance to the Federal Circuit's comments that prompted the present remand because it was also offered in this case - Pinto I (Pet. Ex. 73). *Koehn*, 773 F.3d at 1242.¹² This study was offered therein to support the concept that Gardasil could trigger SJIA environmentally through the cytokine response, by providing evidence (at least from an

¹¹ Prednisone is "a synthetic glucocorticoid derived from cortisone, administered orally as an anti-inflammatory and immunosuppressant in a wide variety of disorders." *Dorland's Illustrated Medical Dictionary* (32d ed. 2012) at 1509. It is sometimes prescribed for patients with SJIA. *Koehn*, 773 F.3d at 1241.

¹² The Federal Circuit's decision does not cite the Pinto I article explicitly, but it is cited in the special master's underlying decision, and it is the same article as Pinto I herein. See *Koehn v. Sec'y of Health & Human Servs.*, 2013 WL 3214877, at *4 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd*, 113 Fed. Cl. 757, *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

in vitro study) that the HPV vaccine did in fact result in an increase in proinflammatory cytokines, consistent with “those dysregulated in SJIA.” *Id.*

Dr. Rosé, who was also retained as an expert by Respondent in the instant case, similarly offered an opinion in *Koehn* for Respondent. He opined that the *Koehn* petitioner’s SJIA was not caused by her Gardasil vaccinations, but more likely developed by chance. *Koehn* at 1242. In so opining, he proposed that the study upon which Dr. McCabe relied so heavily was unhelpful to petitioner’s case; the vaccinated blood samples that were not stimulated by VLPs had consistent levels of cytokines, whereas patients with SJIA generally have up-regulated cytokine levels, thus diminishing rather than strengthening the relationship between the HPV vaccine and the claimed injury, despite the study’s other findings. *Id.*

After conducting a hearing, the *Koehn* special master determined that the petitioners had failed to offer a persuasive, reliable medical theory causally connecting the vaccination and the injury, and thus had not satisfied the first *Althen* prong. In so ruling, the special master found significant the fact that “the relevant scientific community, pediatric rheumatologists, did not accept Dr. McCabe’s theory, primarily basing that conclusion on Dr. Rosé’s testimony that he, as head of pediatric rheumatology at his hospital, did not recall ever hearing of such a theory.” *Koehn*, 773 F.3d at 1243. But the *Koehn* special master also found that the petitioners had not met their burden for the second or third prongs of *Althen*, because they established neither a logical sequence of cause and effect between the receipt of the vaccination and her subsequent SJIA diagnosis, nor a proximate temporal relationship between the vaccination and her SJIA. *Id.*

Petitioners sought review of the entitlement denial, and after the Court of Federal Claims affirmed, *C.K. v. Sec’y of Health & Human Servs.*, 113 Fed. Cl. 757 (2013), they appealed to the Federal Circuit. The appeal was not successful, however. The Federal Circuit determined that the special master’s decision presented “sufficient grounds to deny *Koehn*’s petition because *Koehn* failed to meet her burden under the third *Althen* prong.” *Koehn*, 773 F.3d at 1243.

Nevertheless, the Federal Circuit was critical of the special master’s application of the first and second *Althen* prongs in *Koehn* - and it is this criticism, and the attendant brief discussion of some of the proof and testimony offered in support of the first prong, that lies at the heart of *Koehn*’s facial relevance to the present case. For the most part, the Federal Circuit was not specific in identifying what errors had been committed in analysis of the petitioners’ causation theory; the *Koehn* decision only takes issue with the special master’s determination to give Dr. McCabe’s opinion less weight because Dr. Rosé individually denied hearing others in the “relevant scientific community” mention or embrace it, before moving on to the second *Althen* prong. *Koehn*, 773 F.3d at 1243-44.

But in a footnote, the Federal Circuit went on to suggest in *dicta* its supposition that “[h]ad the Special Master properly evaluated the evidence, we believe [he] would

have likely found that Koehn met her burden under the first *Althen* prong.” *Koehn*, 773 F.3d at 1244 n.1. The sole provided basis for this suggestion was its analysis of the weight that it proposed should have been given to the Pinto I study. The Federal Circuit took to task the argument of Respondent’s expert (embraced by the special master) that the study addressed in Pinto I was problematic in part because it relied on additional stimulation of blood samples that already had been vaccinated; the only way to measure cytokine levels was via an *in vitro* experiment, the Federal Circuit reasoned, and the only way to simulate the effect of an antigen on such samples (in order to replicate what would occur *in vivo*) was to stimulate the samples in the manner performed by the study. To require petitioners to have conducted a study that might more precisely measure the *in vivo* effects of the vaccine was, in the Federal Circuit’s view, to impose a higher burden of proof than that applicable to Vaccine Program claimants. *Id.*

In effect, then, the Federal Circuit suggested in this footnote that the Pinto I study was far more probative evidence supporting causation with respect to HPV and SJIA than the *Koehn* special master had allowed – but that even a finding that the *Koehn* petitioners had satisfied the first *Althen* prong would still not have been sufficient for them to prevail.

III. Legal Standards

A. Legal Standards for Off-Table Claims

Ms. Godfrey alleges an off-Table injury in this case, and in any event there is no specified Table injury for the HPV vaccine at this time. Under such circumstances, eligibility for compensation is established by demonstrating (by a preponderance of the evidence¹³) that she received, in the United States, a vaccine set forth on the Vaccine Injury Table and sustained an illness, disability, injury, or condition caused by the vaccine (or experienced a significant aggravation of a preexisting condition), and that the condition has persisted for more than six months. Section 13(a)(1)(A).

Here, Ms. Godfrey’s causation showing was a central disputed issue. To establish legal causation in an off-Table case, petitioners must establish by preponderant evidence: (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 proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1278; see also *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); *Caves v. Sec’y of Health & Human Servs.*, 100 Fed. Cl. 119, 132 (2011), *aff’d per curiam*, 463 Fed. Appx. 932, 2012 WL 858402 (Fed. Cir. 2012)

¹³ The applicable level of proof in Vaccine Act cases is the “traditional tort standard of ‘preponderant evidence.’” *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (citing *de Bazan*, 539 F.3d at 1351; *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *Althen*, 418 F.3d at 1278)). The preponderance standard “requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence.” *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring) (internal quotation and citation omitted).

(specifying that each *Althen* factor must be established by preponderant evidence); *Lalonde v. Sec’y of Health & Human Servs.*, 746 F.3d 1334, 1337-38 (Fed. Cir. 2014).

Failure to establish any one *Althen* prong constitutes a failure to establish entitlement to compensation. A special master must evaluate a case in its entirety, balancing all evidence offered. While scientific or medical fact evidence, whether set forth in a record or proposed by an expert, can be persuasive, special masters are not bound by any “diagnosis, conclusion, judgment, test result, report, or summary” contained in the record. Section 13(b)(1).

It is important in Vaccine Act cases for special masters to take care not to elevate the burden of proof imposed by law on a claimant. Petitioners are not required to establish identification and proof of specific biological mechanisms, as “the purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” *Althen*, 418 F.3d at 1280. The petitioner similarly need not show that the vaccination was the sole cause, or even the predominant cause, of the injury or condition; showing that the vaccination was a “substantial factor” in causing the condition and was a “but for” cause are sufficient for recovery. *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); see also *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (petitioner must establish that a vaccination was a substantial factor and that harm would not have occurred in the absence of vaccination). Petitioners also cannot be required to offer into evidence “epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” *Capizzano*, 440 F.3d at 1325. Ultimately, causation is determined on a case by case basis, with “no hard and fast *per se* scientific or medical rules.” *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280; but see *Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof fails to meet that burden).

Congress contemplated that special masters would weigh and evaluate opposing expert opinions in determining whether petitioners have met their burden of proof. It is now clearly established that special masters may use the framework established by *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), to evaluate such expert testimony on causation. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) and *Moberly*, 592 F.3d at 1324; *Terran*, 195 F.3d at 1316 (concluding it was reasonable for the special master to use *Daubert* to evaluate the reliability of an expert’s testimony); *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (noting that special masters are to consider all relevant and reliable evidence filed in a case and may use *Daubert* factors in their evaluation of expert testimony); *Davis v. Sec’y of Health & Human Servs.*, 94 Fed. Cl. 53, 67 (2010) (describing the *Daubert* factors as an “acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted . . . by special masters in vaccine

cases”); see also *Ryman v. Sec’y of Health & Human Servs.*, 65 Fed. Cl. 35, 40-41 (2005) (special masters perform gatekeeping function when determining “whether a particular petitioner’s expert medical testimony supporting biological probability may be admitted or credited or otherwise relied upon” and as a “trier-of-fact [a special master] may properly consider the credibility and applicability of medical theories”).

B. *Review of Fact Findings from Transferred Cases*

In ruling upon the present remand, I am called upon to apply Federal Circuit precedent to a case I did not originally hear, and in which the former Chief Special Master made specific findings of fact. Generally, special masters may change or revisit any ruling until judgment enters, even if the case has been transferred. See *McGowan v. Sec’y of Health & Human Servs.*, 31 Fed. Cl. 734, 737-38 (1994).¹⁴ In most cases, however, a judicial officer such as a special master departs from previously decided issues only in the event of “new evidence, supervening law, or a clearly erroneous decision.” *Id.* at 737; see also *Sullivan v. Sec’y of Health & Human Servs.*, No. 10-398V, 2015 WL 1404957, at *20, n.36 (Fed. Cl. Spec. Mstr. Feb. 13, 2015). In fact, it is appropriate to give some deference to prior factual determinations of the judicial officer formerly responsible for a matter, assuming circumstances do not demand otherwise. See, e.g., *Pacific Gas & Elec. Co. v. United States*, 114 Fed. Cl. 146, 149 (2013) (when a successor judge is transferred a case in which a prior order has been rendered, the successor judge “should not overrule the earlier judge’s order or judgment merely because the later judge might have decided matters differently,” but should exercise his discretion in determining if circumstances warrant reopening the previously-determined issue) (quoting *United States v. O’Keefe*, 128 F.3d 885, 891 (5th Cir. 1997)).

Here, although I am not compelled to defer to the former Chief Special Master’s findings of fact, in the exercise of my discretion I do so, because I find that they are reasonable, comprehensive, and the result of a proceeding in which both sides had ample opportunity to present evidence. I base this determination on a careful review not only of her Entitlement Decision, but of the case file as well. I also note that the remand was prompted not by any change in facts or new evidence, but rather by an intervening decision from a higher court that should reasonably be taken into account. To do so, I need not rehear or second guess the former Chief Special Master’s factual determinations.

IV. *Analysis*

I begin by observing the similarities, and then differences, between the facts of this case forming the basis of the former Chief Special Master’s decision and the *Koehn* case, and then comparing the expert theories offered in each. My analysis is based not only

¹⁴ This flows naturally from the fact that in Vaccine Act cases, decisions issued by special masters and judges of the Court of Federal Claims constitute persuasive, not binding, authority. *Hanlon v. Sec’y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). Only decisions issued by the Federal Circuit are binding.

upon review of the relevant published decisions, but my own review of the record herein (including the expert report offered by Dr. McCabe). It also takes into account the undeniable fact that, although I am bound to follow the conclusions of law as set forth in the decisions of the Federal Circuit, the *Koehn* court **did not** find that the petitioners therein established the first *Althen* prong (despite its non-binding suggestions that the *Koehn* special master should have so determined). See *Koehn*, 773 F.3d at 1243-44; see also Remand Decision at *7 (recognizing that “the circuit’s criticisms of the special master’s decision in *Koehn* with regard to causation are *dicta*”).

A. *Factual Similarities and Differences between Koehn and Godfrey Cases.*

The baseline similarities between the two cases is facially apparent - both involve the HPV vaccine, and both involve autoinflammatory diseases. In addition, the petitioners in both cases relied on the same expert, as did the Respondent. However, the factual differences are significant, beginning with the amount of vaccine received as well as timing of onset of symptoms. Ms. Godfrey received only one dose of the HPV vaccine, while Ms. Koehn received two. Compare Entitlement Decision at 6 with *Koehn*, 773 F.3d at 1241. Ms. Godfrey’s symptoms of hip pain began a month after the first dose, although she sought treatment only four months later (Entitlement Decision at *5), suggesting the severity of her pain was not immediately significant enough to require medical intervention; by contrast, Ms. Koehn’s first claimed symptoms were a rash (followed soon thereafter by joint pain and a high fever) that manifested two months after the second HPV vaccine dose. *Koehn*, 773 F.3d at 1241.

Underscoring such differences is the fact that the two cases involve distinct illnesses (even if both are autoinflammatory). The petitioner in *Koehn* was diagnosed with SJIA, whereas here Ms. Godfrey has been diagnosed with JAS - indisputably a condition brought on at least in part by an identified genetic predisposition (possession of the HLA-B27 marker) for which Ms. Godfrey tested positive. Entitlement Decision at 5 and 12. SJIA, however, lacks such an identified biomarker and/or the same one, and so its etiology is less traceable to such a source (and certainly *Koehn* does not say otherwise). The scope of the diseases is different as well, with SJIA affecting Ms. Koehn’s entire body, while Ms. Godfrey’s JAS was specific to her hips. *Id.* As a result, the two petitioners suffered different symptoms, as noted above.

B. *Factual Similarities and Differences Between Causation Theories.*

While the factual differences between the two cases alone would seem to be enough to dismiss *Koehn*’s application to the present case, comparison of the theories offered in each reveals far more significant differences that help illuminate why finding that Ms. Godfrey’s *Althen* one showing herein was deficient despite the suggestion in *Koehn* that there it was adequate.

Admittedly, there are facial similarities between the theories Dr. McCabe advanced in *Koehn* and the present action – for in each, he relied heavily on an increased level of cytokines as the instigating factor for the claimed illness. Thus,

- Here, Petitioner described Dr. McCabe’s theory as: “[1.] mechanical and biological stressors increase certain types of cytokines; [2.] these events are considered plausible triggers in HLA-B27 individuals of the pathogenesis of JAS; [3.] Gardasil provokes cytokines similar in quality to the known triggers, ergo, Gardasil is also a plausible trigger.” Pet. Motion for Review (ECF No. 74), filed July 11, 2014, at 17; whereas,
- In *Koehn*, Dr. McCabe’s theory was that petitioner “had a predisposition for SJIA, and that Gardasil was an environmental trigger because the vaccine caused a strong response in the same cytokines which are dysregulated in SJIA.” *Koehn*, 773 F.3d at 1242.

But the theories were not identical, despite their parallels, given differences in their articulation and the evidence supporting them. The identified biologic underpinnings for JAS are one such notable distinct element. Whereas in this case, Dr. McCabe admitted that the HLA-B27 gene was a primary causative factor underlying the development of JAS (albeit, in his view, exacerbated after vaccine-induced cytokine production), he offered no similar explanation in *Koehn* – thus increasing the likelihood in that case that a vaccine could more probably be a “but for” causative factor. Similarly, in *Koehn*, Dr. McCabe was able to cite some scientific studies linking vaccines to SJIA (*Koehn*, 2013 WL 3214877, at *8-9), but offered no similar evidence in this case linking Gardasil to JAS or any spondylopathy for that matter. Entitlement Decision at *16. Although medical and/or scientific publications are not in every case required to establish a causation theory’s viability from a legal standpoint, a theory is unquestionably rendered more reliable to the extent it has been tested and analyzed. See *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Daubert*, 509 U.S. at 593-94); see also *Andreu*, 569 F.3d at 1379.

Particularly relevant to the lack of persuasive evidence supporting the theory offered in this case is the Pinto I article that was mentioned in *Koehn* and also relied upon in this case. The Federal Circuit’s decision strongly suggests that in its view (despite the special master’s misgivings therein about the reliability of Dr. McCabe’s theory), the Pinto I study provided legally sufficient support for the opinion that an upregulation in cytokines would be caused by the HPV vaccine. The desire for a better experiment or study to support the theory “would have compelled *Koehn* to present more than what is scientifically possible or legally necessary.” *Koehn*, 773 F.3d at 1244 n.1.

In this case, by contrast, there are many more reasons to find Dr. McCabe’s theory wanting beyond the nature of the science supporting it. Indeed, Respondent’s experts appear to have not contested its basic premise about the relationship between cytokine levels and the components of the HPV vaccine. But (as reflected in the Entitlement

Decision), numerous other “links” in the chain of Dr. McCabe’s theory were lacking, such as: (a) an inability to offer proof that showed cytokine levels were related to the development of JAS, as opposed to symptoms associated with it, (b) a related lack of evidence that Gardasil’s effect in increasing proinflammatory cytokines would be more than transient, and (c) a lack of proof that Ms. Godfrey herself actually experienced an inflammatory incident or increase in the relevant cytokines. Entitlement Decision at *21-*22. In fact, Dr. McCabe pointed to Marks rather than Pinto I as the “best evidence” he could muster in support of elements of his theory, thereby diminishing the role Pinto I played in his overall theory. It is thus evident to me from the record in this case that not only was Pinto I not as significant to Ms. Godfrey’s causation theory, but that it can be given less weight herein without diminishing the validity of its science (which seems to have been the nub of the Federal Circuit’s criticism in *Koehn*).¹⁵

Thus, the core component for both theories – the concept that cytokine production activated by the HPV vaccine was itself the disease trigger – was shown, through evidence and testimony elicited at this case’s hearing, to be deficient *in this particular context*. In *Koehn*, it was established on the record that individuals suffering from SJIA experience some symptoms attributable to “dysfunctional production of proteins called cytokines.” *Koehn*, 773 F.3d at 1240. Here, Dr. McCabe similarly testified that JAS’s manifestation was dependent on a “sustained elevation” of cytokines (*Godfrey*, 2014 WL 3058353, at *14, *citing* Tr. at 57), yet he could not offer any reliable evidence sufficient to make it legally probable that Gardasil would cause such an elevation (*Id.*, *citing* Tr. at 75-77). At best (as was elicited in this proceeding), the vaccine might result in a *transient* increase in cytokines, no different than what would be experienced after an infection or more mundane occurrences (such as exercise). *Godfrey*, 2014 WL 3058353 at *21. But Dr. McCabe did not offer sufficient persuasive proof that such an increase would be sustained enough (and over the time that lapsed between Ms. Godfrey’s vaccination and development of hip pain symptoms) after a single Gardasil dose to result in JAS. *Godfrey*, 2014 WL 3058353, at *14, *18, and *21-22. Indeed, there have been no studies demonstrating an association between Gardasil and arthritic conditions or JAS, while Respondent in this case offered reliable epidemiologic evidence¹⁶ that refutes such an

¹⁵ Other special masters have reached similar conclusions about the scope of findings in the Pinto I study, and the extent to which it supports the conclusion that excessive cytokine production attributable to the HPV vaccine (or at least to certain of its components) is pathologic. *See, e.g., McGuire v. Sec’y of Health & Human Servs.*, No. 10-609V, 2015 WL 6150598, at *13 (Fed. Cl. Spec. Mstr. Sept. 18, 2015) (rejecting theory that HPV vaccine caused chronic headaches).

¹⁶ Unquestionably, a petitioner need not offer epidemiologic proof to establish a reasonable and scientifically-reliable theory under *Althen* prong one. *Capizzano*, 440 F.3d at 1325. However, I may properly weigh such evidence, when offered by the Respondent, against Petitioner’s proof in evaluating whether she has carried her overall burden as to this first *Althen* prong. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (“[a]lthough *Althen* and *Capizzano* make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury”).

association. *Id.* at *19 (remarking that if Gardasil could trigger JAS in HLA-B27 positive people, “one would expect that the incidence of JAS among the over one million HLA-B27 positive individuals who received the vaccine would be notable,” but it is not).

Thus, even if Dr. McCabe’s theory as applied to a related but distinct disease might have been sufficient in that context to satisfy the first *Althen* prong, it was reasonably determined in this case, based on the proof presented, to be insufficient when applied to a different disease, and one with a firmly identified genetic risk factor that the Petitioner was found to possess. No evidence in this record supports the conclusion that pro-inflammatory cytokines play any role in the pathogenesis of JAS (though they can play a role in the symptoms displayed).¹⁷

Equally relevant to the present analysis is the rebuttal evidence and testimony offered by Respondent. In *Koehn*, the Federal Circuit expressed concern that the special master had perhaps too readily rejected Dr. McCabe’s causation theory, based in part on Dr. Rosé’s *ipse dixit* statements that the theory did not enjoy general acceptance in the scientific community. *Koehn*, 773 F.3d at 1243-44. Here, by contrast, there is ample evidence rebutting the legal sufficiency of the theory. Thus, Respondent’s experts, Drs. Rosé and Zweiman, proposed their alternative theory (based on their reading of the record) that Ms. Godfrey’s JAS developed spontaneously, largely the result of her strong genetic predisposition to the disease (a factor that all parties acknowledged underlies JAS). Entitlement Decision at *21.¹⁸ According to Dr. Rosé, this gave her a one-in-five chance of developing JAS; a condition found in about seven of every 100,000 individuals. *Id.* at *22. She also had a known trigger in her history (her cheerleading activity) that rendered her susceptible to chronic micro-trauma in hips and ankles. *Id.* Respondent also offered epidemiologic evidence suggesting Gardasil is not associated with JAS that the former Chief Special Master observed amounted to unrebutted “circumstantial evidence” against causation. *Id.* at *17.

Respondent thus offered persuasive evidence based on objective record facts to support her assertion that Petitioner’s genetic makeup was itself sufficient to be the actual “but-for” cause of her JAS. While this evidence itself may not have been enough to prove

¹⁷ Although this constitutes, in my review of the matter, the most substantive basis for finding that Dr. McCabe’s theory did not satisfy the first *Althen* prong, the trial transcript and record (as highlighted in the former Chief Special Master’s Entitlement Decision) identifies many other deficiencies with the theory as applied to the facts in this case. For example, Dr. McCabe was inconsistent and confusing in explaining his views about how cytokine production in response to the HPV vaccine impacted Ms. Godfrey’s JAS. Entitlement Decision at *14. He also could not deny that there was no epidemiologic evidence favoring his theory (*Id.* at *16); at best, he attempted to distinguish such evidence when offered by the Respondent as insufficiently powered (given the sample size of studied individuals) to disprove his theory.

¹⁸ Although the trial transcript evidences some discussion about the fact that most people with HLA-B27 do not develop JAS or similar diseases, the very high percentage of those who do develop JAS as children (one study indicated that in children with JAS, 97 percent carry the HLA-B27 marker (Lin, Pet. Ex. 56, at 577)), coupled with Ms. Godfrey’s inherited HLA-B27 marker and a first degree relative with Crohn’s disease, are all strong indications of her high genetic predisposition to developing JAS.

preponderantly the most likely cause of her JAS, Respondent can (in asserting that a petitioner has not met her prima facie burden) offer evidence in Vaccine Act proceedings that merely undermines Petitioner's own proposed causation theories or evidence, without having to meet the preponderant evidence standard of a "factor unrelated" as the more likely cause. *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[o]ur decisions support the commonsense proposition that evidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question"); *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 198 (2013) ("[r]egardless of whether the burden ever shifts to the respondent, the special master may consider the evidence presented by the respondent" when determining if petitioner's initial burden has been met), *aff'd*, 736 F.3d 1334 (Fed. Cir. 2014). In any event, the record indicates that such evidence was not effectively rebutted by Petitioner.

I thus find insufficient evidence in the record that a genetic susceptibility to JAS also encompasses a susceptibility to increases in pro-inflammatory cytokines, or that a vaccine such as Gardasil could cause a sufficient cytokine level increase to trigger the disease processes proposed by Petitioner. Rather, the evidence and expert testimony illustrated only that Gardasil produces at best a transient increase in cytokine levels no different than other kinds of mundane activities, such as sun exposure. Entitlement Decision at *18, *citing* Tr. at 116-17, 158-59, and 161-62. This was the theory offered in this case, and the record supports the conclusion that the theory was appropriately found wanting, despite the suggestion from *Koehn* (in a case involving a different disease, different factual circumstances, and different proof) that a similar theory might have been legally preponderant.

This is not the first time that a petitioner has invoked *Koehn* as controlling in a case alleging injury based on administration of the HPV vaccine – nor the first time such an argument has been rejected based on inherent factual differences between the cases and the resulting nature of the precise theories alleged therein. See, e.g., *McGuire v. Sec'y of Health & Human Servs.*, No. 10-609V, 2015 WL 6150598, at *13 (Fed. Cl. Spec. Mstr. Sept. 18, 2015) (rejecting application of *Koehn* causation theory to argument that HPV vaccine caused chronic headaches). And there is nothing legally troubling about such an outcome, given the context: the Vaccine Program. As the Federal Circuit has acknowledged, factually similar Vaccine Act cases often yield different results as reflected at the level of a special master's decision. *Moberly v. Secretary of Health & Human Servs.*, 592 F.3d 1315 (Fed. Cir. 2010).¹⁹ Even cases involving the same vaccinations or similar

¹⁹ In *Moberly*, the Federal Circuit rejected the petitioners' contention that they were entitled to compensation because their case was similar to *Andreu*, where compensation had been awarded. In both *Andreu* and *Moberly*, the children in question suffered seizures after receiving DPT vaccinations. However, petitioners in *Andreu* presented testimony by treating physicians supporting their causation theory, and the government's witness did not dispute the plausibility of that theory. In contrast, the *Moberly* petitioners were unable to present testimony of a treating physician supporting their causation theory, and, further, their own witness called into question the plausibility of their causation theory. *Moberly*, 592 F.3d at 1325. There were

injuries may turn out differently, as no two cases are truly identical. This is to be expected, as different records can lead to different outcomes despite facial similarities between cases. *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1366 (Fed. Cir. 2000) (“a special master’s task is to make a factual determination of causation based on the evidence in a particular case. A study of many individual cases may be useful evidence as to causation, but it does not compel the finder of fact to find causation in a particular case”).

C. *Bases for Denying Entitlement Independent of Petitioner’s Theory.*

Even if I were to assume for sake of argument that (adopting the viewpoint of *Koehn’s dicta*) Ms. Godfrey established the first of the three *Althen* prongs via Dr. McCabe’s theory, there is still ample, persuasive, and/or unrebutted evidence supporting the conclusion that the Petitioner in this case failed to establish by preponderant evidence an entitlement to a damages award.

Thus, it was undisputed that none of Ms. Godfrey’s treaters linked the single dose of Gardasil she received to her subsequent illness (other than noting the temporal relationship between the two – a fact well understood to be insufficient to establish causation). *Godfrey*, 2014 WL 3058353 at *23, *citing Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Respondent’s experts also noted that (in addition to the genetic risk factor that Ms. Godfrey had) Petitioner’s familial history of Crohn’s disease increased her risk of developing JAS fourfold, given the demonstrated relationship between gut inflammation (itself associated with Crohn’s disease) and JAS. Entitlement Decision at *17, *citing* Tr. at 144; *see also* Burgos–Vargas, Pet. Ex. 61, at iii 34.

Furthermore, the factual record does not contain the kind of evidence (such as test results) that would lend credence to Dr. McCabe’s theory by showing it “working” in real time. Thus, there was no testing performed to measure Ms. Godfrey’s cytokine levels after her single HPV vaccine, and no evidence that she experienced an inflammatory incident in the time period Dr. McCabe suggested the immune response should have occurred. Entitlement Decision at *15-*16. And it was unrebutted that Petitioner’s physical activity as a cheerleader had the potential to injure her sacroiliac joints (Tr. at 162-63), since strenuous physical activity is a known environmental risk factor for JAS. Entitlement Decision at *17, *citing* Tr. at 109-11, 113-15, and 162-63.²⁰ All of the above factors are

therefore key differences between the *Moberly* and *Andreu* petitioners as well as the cases’ respective records, and thus the results in the earlier case did not compel a similar result in the later one. *Id.*

²⁰ The Opinion remanding this matter mentions in a footnote that the former Chief Special Master made a fact finding as to a “more likely alternative environmental trigger” for Petitioner’s JAS. Remand Decision at *7 n.10. I could not identify discussion of such a finding in the Entitlement Decision or the trial transcript. But the record strongly supports the general conclusion (unrebutted by Petitioner, as discussed above) that it was “more likely than not” that Ms. Godfrey’s genetic susceptibility to JAS was the basis for the disease’s pathogenesis, and that any increase in proinflammatory cytokine production was insufficient to trigger the disease.

sufficient to conclude that Petitioner did not meet the second *Althen* “did cause” prong under the circumstances presented by this case.

Regarding the third prong (which focuses on the timing of the injury after vaccination and inquires if the period is medically acceptable), Dr. McCabe opined that the four-week interval between Ms. Godfrey’s first symptoms and her single HPV vaccine dose was medically acceptable. Entitlement Decision at *14, *citing* Tr. at 79. But in so doing, he highlights a particularly inconvenient equivalence between the theory espoused herein and in *Koehn*. Thus, Dr. McCabe argued in this case that “the expected interval between vaccination and the onset of the autoinflammatory trigger is predicted by the time period that measurable changes in the immune response are known to be elicited.” Tr. at 75-76. Because onset was within one month of the single HPV dose, under Dr. McCabe’s theory one month was also the “medically acceptable” period.

Dr. McCabe made the same argument in *Koehn* to defend a longer, ***seven-month interval*** between first symptom and onset of SJIA, but failed to explain therein why the period of time it took for the immune response to occur aligned precisely with the onset of symptoms in that case, instead simply assuming the periods were the same. The Federal Circuit explicitly rejected his reasoning as a “proposition . . . without any evidentiary support,” leading it to uphold the special master’s denial of entitlement in spite of its other criticisms. *Koehn*, 773 F.3d at 1244.

If Petitioner is to hold out *Koehn* as exemplifying the conclusion I should adopt when taking into account Dr. McCabe’s theory in this case, then she must also ask me to consider the entirety of that decision. She cannot selectively invoke the portions that benefit her argument while ignoring the rest of the opinion – especially the aspect of it that is the very basis for its holding. See *McGuire*, 2015 WL 6150598, at *21 n.25 (“[i]f [petitioner’s] reliance on *Koehn* to establish prong one were correct, then it would seem to follow that [petitioner] would also be bound by *Koehn* on prong three”).

V. Conclusion.

Despite the facial similarities between the theories advanced by Dr. McCabe in this case and *Koehn*, I do not find that the Federal Circuit’s *dicta* in that intervening decision compels a finding favorable to the Petitioner, given the many relevant factual distinctions between the two matters. The record from this case, as discussed in detail in the former Chief Special Master’s decision, simply did not support the theory proposed by Petitioner – nor in this case did the theory itself prove to be sufficiently reliable. As a result, I do not find that the suggestion from *Koehn* that the same theory should have been deemed reliable when applied to a related disease compels the same outcome herein.

Accordingly, Petitioner still fails to meet the burden of persuasion on any of the *Althen* prongs by preponderant and reliable evidence. The petition for compensation is therefore DENIED. The clerk is directed to enter judgment accordingly, and is instructed

to transmit this Remand Decision to the presiding judge in accord with Vaccine Rule 28.1(a).

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Special Master