In the United States Court of Federal Claims

No. 10-565V (Filed: August 19, 2015)* *Opinion originally issued under seal on July 29, 2015

MEGANIL CODEREY)
MEGAN L. GODFREY,)
Petitioner,	 Vaccine Petition; Intervening Federal Circuit Decision; Koehn v. Sec'y of
V.) <u>Health and Human Servs.</u> , 773 F.3d) 1239 (Fed. Cir. 2014); Remand to
SECRETARY OF HEALTH AND HUMAN SERVICES,) Special Master
Respondent.)))

Clay Ragsdale, Birmingham, AL, for petitioner.

Jennifer Reynaud, United States Department of Justice, Civil Division, Washington, DC, with whom were *Benjamin C. Mizer*, Acting Assistant Attorney General, *Rupa Bhattacharyya*, Director, Torts Branch, *Vincent J. Matanoski*, Assistant Director, and *Catherine E. Reeves*, Assistant Director.

OPINION

Pending before the court is Megan L. Godfrey's ("Ms. Godfrey" or "petioner")

petition for review of the June 11, 2014 decision of Chief Special Master Vowell ("chief

special master") denying Ms. Godfrey's claim for compensation under the National

Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 to -34, as amended

("Vaccine Act"). Godfrey v. Sec'y of Health and Human Services, No. 10-565, 2014

WL 3058353 (Fed. Cl. June 11, 2014) ("Decision").

Petitioner alleges that the single dose of the Gardasil human papillomavirus ("HPV") vaccine she received on August 22, 2007, "substantially contributed" to her development of juvenile ankylosing spondylitis ("JAS").¹ An entitlement hearing was held on December 10, 2012. The chief special master, applying the test set forth in Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005), determined that petitioner had not met her burden of proof to show causation-in-fact. Specifically, the chief special master found that the medical theory presented by petitioner—which posited that the HPV vaccine could have "triggered" petitioner's JAS in a manner similar to other environmental triggers—was not a sufficiently plausible theory to show that the vaccine could actually "cause" petitioner's JAS as required under the <u>Althen</u> standard. The chief special master also found that the dose of HPV vaccine given could not have caused or triggered petitioner's JAS symptoms. The chief special master further determined that petitioner had failed to establish a temporal relationship between receipt of the vaccination and her JAS diagnosis, in that it was not clear when the petitioner contracted JAS due to the staggered onset of symptoms.

Petitioner seeks reversal of the chief special master's decision, arguing that the chief special master erred in rejecting petitioner's expert's opinion that the HPV vaccine can trigger or cause JAS and that a single dose of the vaccine could have triggered petitioner's JAS. Petitioner argues that she presented a viable, legally-probable medical

¹ JAS is the juvenile form of ankylosing spondylitis, and typically causes peripheral arthritis and peripheral enthesopathies. Dec. at 11 (citing Pet.'s Ex. 52 at 2, Pet.'s Ex. 57 at 2, 4). JAS commonly affects the pelvis, heels, knee joints, and hip joints. <u>Id.</u> (citing Pet.'s Ex. 56 at 575).

causation theory and established a proper temporal reaction, both of which petitioner argues the chief special master improperly disregarded. In support of her petition, Ms. Godfrey relies extensively on the recent decision of the Federal Circuit in <u>Koehn v. Sec'y</u> <u>of Health and Human Servs.</u>, 773 F.3d 1239 (Fed. Cir. 2014). <u>Koehn</u> also involved a claim of injury from the HPV vaccine and discusses the testimony of the two principal experts that appeared in this case. Petitioner argues that the <u>Koehn</u> decision dictates reversal of the chief special master's decision rejecting a finding of causation in this case due to the Federal Circuit's criticism of the analysis in that case. Respondent argues that <u>Koehn</u> does not undermine the chief special master's decision because the relevant discussion is dicta and this case is factually distinct because, unlike <u>Koehn</u>, it involves a disease with a strong genetic component. Therefore, the government argues that the decision of the chief special master should be affirmed.

For the reasons set forth below, the court finds that <u>Koehn</u> raises issues that are best addressed by the chief special master in the first instance. Specifically, there are several statements in the <u>Koehn</u> decision which suggest that the chief special master's grounds for rejecting petitioner's causation theory should be re-examined. Accordingly, the court **GRANTS IN PART** petitioner's motion and **REMANDS** the case for further consideration regarding whether the <u>Koehn</u> decision warrants a different outcome.

I. BACKGROUND

A. Procedural History

On August 10, 2010, Ms. Godfrey filed a petition under the Vaccine Act. Additionally, petitioner filed her medical records, medical literature, and an expert report

from David Axelrod, M.D. ("Dr. Axelrod"), a clinical immunologist. On September 26, 2011, the government filed an expert report from Carlos D. Rose, M.D. ("Dr. Rose"), a pediatric rheumatologist. On October 26, 2011, the government filed medical literature, an expert report from Burt Zweiman, M.D. ("Dr. Zweiman"), an immunologist, and a Vaccine Rule 4(c) report recommending against awarding compensation.

A Vaccine Rule 5 status conference was held on November 5, 2011, at which the chief special master noted deficiencies in Dr. Axelrod's report. Thereafter, on April 24, 2012, petitioner filed an expert report from Michael J. McCabe, Jr., Ph.D. ("Dr. McCabe"), a toxicologist/immunologist. On June 18, 2012, the Secretary filed a responsive expert report from Dr. Zweiman addressing Dr. McCabe's report.

An entitlement hearing was held on December 10, 2012.² At the hearing, petitioner presented testimony from Dr. McCabe, while the government presented testimony from Drs. Rose and Zweiman. On June 11, 2014, the chief special master issued a decision denying compensation. The chief special master determined that respondent's experts were entitled to greater weight based on both their qualifications and their testimony that petitioner's causation theory was not supported by the medical and scientific literature. On July 11, 2014, petitioner timely filed a petition for review in this court. The petition was stayed pending the appeal in Koehn. Supplemental briefs were

² Petitioner initially indicated that she wished to file an expert report from Anthony Turkiewicz, M.D., her treating rheumatologist. The chief special master denied a postponement of the hearing, but granted leave to file an affidavit. On January 18, 2013, petitioner gave notice that no affidavit would be filed.

filed following the resolution of that appeal. Oral argument on the petition for review was held on July 14, 2015.

B. Facts

Ms. Godfrey was born on August 1, 1989. Dec. at 6. Her medical records indicate that she was generally healthy through age 18. <u>Id.</u> Her family medical history included Crohn's disease (father) and rheumatoid arthritis (paternal grandparents and paternal aunts and uncles). <u>Id.</u> at 6; Pet.'s Exs. 7 at 182, 8 at 9. She participated in athletics during high school, including as a member of the school's cheerleading team. Dec. at 6 & n.12.

On August 22, 2007, petitioner received HPV and meningococcal conjugate vaccines. <u>Id.</u> at 6; Pet.'s Ex. 2 at 1. Four months later, on December 19, 2007, petitioner presented to her pediatrician, Mark Woods, M.D., complaining of sharp intermittent left hip pain that had been ongoing for three months. Dec. at 6; Pet.'s Ex. 3 at 1. She reported no injury and an X-ray of her hip was negative. Pet.'s Ex. 3 at 1. She received an MRI on December 28, 2007, which revealed "[b]ilateral femoral benign fibrous dysplasia, greater on the left side than the right, and left-sided sacroiliitis, which the radiologist thought could be inflammatory." Dec. at 7; Pet.'s Ex. 8 at 86.

Petitioner was also treated by Steve Lovelady, M.D., an orthopedist, on December 28. Pet.'s Ex. 11 at 12-14. He found tenderness at the left sacroiliac joint and admitted her to DCH Regional Medical Center for further evaluation to rule out osteomyelitis. <u>Id.</u> He also noted that petitioner's father suffered from inflammatory bowel disease and anemia. <u>Id.</u>

A bone scan performed on January 8, 2008 showed "increased activity at the left [sacroiliac] joint." <u>Id.</u> at 11. It was read as indicative of hyperemia and active bone turnover, "which could be seen in osteomyelitis or in an inflammatory sacroiliitis." <u>Id.</u> On January 14, 2008, petitioner tested positive for the HLA-B27 protein, a genetic marker showing susceptibility to conditions such as JAS. <u>Id.</u> at 7. Petitioner received a steroid injection in the left sacroiliac joint in January 2008, which relieved the left hip pain, but she developed tenderness in her right sacroiliac joint by March 2008. Pet.'s Ex. 9 at 89-90, 122.

On April 15, 2008, petitioner was evaluated by Randy Cron, M.D., a pediatric rheumatologist. Pet.'s Ex. 7 at 180-84. He again noted petitioner's familial history of Crohn's disease and arthritis, as well as her own history of sacroiliac joint pain and the positive test for HLA-B27. <u>Id.</u> He diagnosed her with HLA-B27 spondyloarthropathy. <u>Id.</u> After this visit, petitioner continued her treatment, including receiving injections of Infliximab.³ <u>Id.</u> at 73-77, 94-98, 132-35, 149-52, 157-61; Pet.'s Ex. 9 at 12-13.

On August 22, 2012, petitioner had an initial visit with Anthony Turkiewicz, M.D., a rheumatologist. Pet.'s Ex. 88 at 10-14. His impression was that the petitioner was suffering from ankylosing spondylitis/axial spondyloarthropathy, and he continued petitioner's prescription of Infliximab injections. <u>Id.</u> at 9. Ms. Godfrey states that she

³ Injections of Infliximab inhibit tumor necrosis factor- α and other pro-inflammatory cytokines. Dec. at 8 n.15 (citing Physician's Desk Reference 1145 (58th ed. 2004)).

believes that "[t]his treatment has been successful in terminating [her] symptoms." Pet.'s Post-Hearing Br. 2.

C. The Chief Special Master's Decision

At the entitlement hearing, Dr. McCabe, who has a Ph.D. in microbiology and immunology but is not a medical doctor, testified that petitioner's HPV vaccination triggered the manifestation of her JAS.⁴ His theory was that the vaccination triggered the release of pro-inflammatory cytokines and that pro-inflammatory cytokines can trigger the onset of JAS. Dr. McCabe explained that JAS is a disease with an auto-inflammatory etiology, which means the disease is "driven by dysregulation of the innate immune system." Pet.'s Ex. 52 at 3. While Dr. McCabe acknowledged that petitioner had a genetic susceptibility for JAS and that infections, stress, and trauma are all known environmental triggers associated with the onset of JAS, he opined that the HPV vaccine is also a trigger because it provokes a strong antibody response that in turn causes the production of pro-inflammatory cytokines. Dr. McCabe explained that pro-inflammatory cytokines have been implicated in the etiology of autoimmune disorders like JAS and testified that the HPV vaccine was likely to have acted as an environmental trigger for petitioner. He further testified that he believed that a single dose of the HPV vaccine would be sufficient to stimulate enough pro-inflammatory cytokines to cause the onset of JAS. Dr. McCabe acknowledged that there was no direct evidence demonstrating that

⁴ Dr. McCabe has been a professor at the University of Rochester since 2000. Dec. 9. He also reviews and testifies in cases involving environmental and occupational exposures for Robson Forensic. <u>Id.</u>

petitioner had an inflammatory response to the vaccine, but testified that he would "expect that her antibody titers in response to the HPV were increasing." Tr. 39, 74-75.

The respondent addressed Dr. McCabe's contentions with evidence from Dr. Rose⁵ and Dr. Zwieman.⁶ Dr. Rose did not dispute that pro-inflammatory cytokines can cause symptoms of JAS, but disputed that pro-inflammatory cytokines can cause the onset of the disease itself. Put another way, Dr. Rose opined that there is no evidence that pro-inflammatory cytokines play a role in the pathogenesis of JAS, which Dr. Rose testified is caused by genetics and other stressors, and instead is more likely to be involved in the symptomology of the disease. Dr. Zweiman testified that, given the transient increase in cytokine levels produced by the vaccine, the evidence would not support a finding that petitioner's single dose would be sufficient to trigger JAS symptoms.

Based on this evidence and taking into account the professional backgrounds of the experts,⁷ the chief special master found that petitioner's JAS was attributable to her "genetic background, coupled with a family history and the presence of a known 'trigger'

⁵ Dr. Rose is a board-certified pediatric rheumatologist and works at the Alfred I. duPont Institute and at the Thomas Jefferson University's Jefferson Medical College. Dec. 10.

⁶ Dr. Zweiman was board certified in internal medicine, allergy and clinical immunology, and laboratory immunology and between 1963 and his death taught at the University of Pennsylvania School of Medicine. Dec. 11.

⁷ The chief special master noted that she found Dr. Rose's testimony more reliable and persuasive. She explained that Dr. McCabe was "out of his depth in presenting a theory of the cause of a medical condition, with little, if any, support in the medical and scientific literature" whereas Dr. Rose, who diagnoses and treats JAS, was more "familiar with the etiologic factors that are accepted as causal in the scientific and medical communities." Dec. at 30.

for development of JAS," which the chief special master identified as petitioner's cheerleading. Dec. 29.

Finally, the chief special master found that petitioner had also failed to satisfy the other two <u>Althen</u> prongs. She noted that petitioner's medical records merely recorded that she had the HPV vaccine a month before she complained of her JAS symptoms without linking the events. She further noted that she agreed with Dr. Rose that it was not possible to determine the precise onset of petitioner's JAS because petitioner had initially complained of hip pain in only one hip while imaging studies showed that the disease was present in both hips, suggesting that the disease may have existed for a period of time without petitioner experiencing symptoms. Dec. 31.

D. The Koehn Decision

<u>Koehn</u> involved a claim by a 13-year-old female who developed an autoinflammatory disease known as systematic juvenile idiopathic arthritis ("SJIA") following receipt of two of three HPV vaccine doses. 773 F.3d at 1240. As in this case, the petitioner in <u>Koehn</u> relied on the testimony of Dr. McCabe to support her claim that the vaccine triggered her disease by producing cytokines. <u>Id.</u> at 1242. Also as in this case, the respondent relied on the testimony of Dr. Rose to rebut Dr. McCabe's theory.⁸ <u>Id.</u> At trial, the special master determined that the petitioner had not met her burden under any of the Althen prongs, and specifically found against Dr. McCabe's theory

⁸ Dr. Zweiman was not called as an expert in the case.

because it had not been peer-reviewed or published and Dr. Rose had not heard of it. <u>Id.</u> at 1242-43.

In its decision, the Federal Circuit affirmed the special master, finding that petitioner had not met Althen prong three, but stated that the special master "committed several errors in the assessment of the first and second Althen prongs." Id. at 1243. Regarding prong one, the circuit criticized the special master for basing his conclusions about the acceptance of Dr. McCabe's theory by the scientific community on whether Dr. Rose had heard of the theory and for finding Dr. Rose more reliable because he treats patients. Id. at 1243-44. Regarding Dr. McCabe's experience with patients, the circuit stated that "[w]e see no reasonable basis for why this distinction has any meaningful effect on the cause and effect inquiry." <u>Id.</u> at 1244. Regarding Dr. McCabe's theory itself, the circuit stated that "[h]ad the Special Master properly evaluated the evidence, we believe the Special Master would have likely found that Koehn met her [causation] burden." Id. at 1244 n.1. While the special master in that case found the Pinto article relied on by the petitioner to be unconvincing due to Dr. Rose's testimony that the measurements performed in that study required a stimulus and therefore did not mirror what might happen in the body, the circuit found that "[e]specially given the low incidence rate of SJIA, requiring a measurement without a stimulus would have compelled Koehn to present more than what is scientifically possible or legally necessary." Id. As a result, the circuit indicated that it believed that Dr. McCabe had presented a "viable, 'legally probable' medical theory." Id. (quoting Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010)).

Ultimately, the circuit agreed that Ms. Koehn had not met her burden of establishing that the onset of symptoms had occurred within a timeframe that was medically acceptable to infer "causation-in-fact." <u>Id.</u> at 1244-45. In the opinion, the circuit explained that Dr. McCabe had failed to explain how the timing of the SJIA onset "aligns with the timing of a sufficient immune response in patients receiving the vaccine," in that Dr. McCabe agreed that the immune system produces cytokines quickly and the petitioner's symptoms did not appear for seven months. <u>Id.</u> Thus, the circuit affirmed the special master's decision on the ground that "Koehn did not sufficiently establish why onset of SJIA can occur within seven months after receiving the first dose of Gardasil, especially when cytokine release is generally a more immediate response." <u>Id.</u> at 1245.

II. STANDARD OF REVIEW

This court has jurisdiction to review the decisions of a special master in a Vaccine Act case upon a motion from the petitioner. 42 U.S.C. § 300aa-12(e)(2). The court uses three distinct standards of review in Vaccine Act cases: findings of fact are reviewed under the arbitrary and capricious standard, questions of law under the not in accordance with law standard, and discretionary rulings under the abuse of discretion standard. <u>Masias v. Sec'y of Health & Human Servs.</u>, 634 F.3d 1283, 1287-88 (Fed. Cir. 2011); <u>Munn v. Sec'y of Health & Human Servs.</u>, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992); <u>see</u> 42 U.S.C § 300aa-12(e)(2)(B). In this connection, the court does not "reweigh the factual evidence," "assess whether the special master correctly evaluated the evidence," or "examine the probative value of the evidence or the credibility of the witnesses." <u>Lampe</u>

<u>v. Sec'y of Health & Human Servs.</u>, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal quotation marks omitted) (quoting <u>Munn</u>, 970 F.2d at 871). If the special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision," then "reversible error is extremely difficult to demonstrate." <u>Id.</u> at 1360 (internal quotation marks omitted) (quoting <u>Hines ex rel.</u> <u>Sevier v. Sec'y of Health & Human Servs.</u>, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

III. DISCUSSION

A. Vaccine Act Standards

Under the Vaccine Program, there are two types of claims: claims based on injuries listed in the Vaccine Injury Table ("Table") and claims based on injuries not listed in the Table, known as off-Table claims. If the petitioner presents a Table claim, the petitioner is granted a presumption of causation if he or she shows that he or she received a vaccine listed in the Table, that he or she suffered an injury listed in the Table, and that the injury occurred within the prescribed time period. <u>See Andreu v. Sec'y of Health & Human Servs.</u>, 569 F.3d 1367, 1374 (Fed. Cir. 2009) (describing Table cases). In an off-Table case, like the present case, a petitioner who received a vaccine listed in the Table on the table does not receive a presumption of causation, and instead must prove causation by a preponderance of the evidence. <u>See</u> Moberly, 592 F.3d at 1321 (describing off-Table cases).

In order to prove causation in an off-Table case, the petitioner must show that the injury "was caused by a vaccine" listed in the Table. 42 U.S.C. § 300aa-

11(c)(1)(C)(ii)(I). The Federal Circuit explained the evidentiary burden placed on petitioners to show causation-in-fact in <u>Althen</u>, stating that a petitioner must

show by preponderant evidence that the vaccination brought about her injury by providing: (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.

418 F.3d at 1278. This showing of causation requires "a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain." <u>Broekelschen v.</u>
<u>Sec'y of Health & Human Servs.</u>, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)).⁹

Once the petitioner satisfies this burden under <u>Althen</u>, he or she is "entitled to recover unless [the respondent] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." <u>Walther v. Sec'y of Health & Human Servs.</u>, 485 F.3d 1146, 1151-52 (Fed. Cir. 2007) (quoting <u>Whitecotton v. Sec'y</u> <u>of Health & Human Servs.</u>, 17 F.3d 376 (Fed. Cir. 1994), <u>rev'd on other grounds sub</u> <u>nom. Shalala v. Whitecotton</u>, 514 U.S. 268 (1995)) (citing <u>Knudsen</u>, 35 F.3d at 547). The evidence presented to establish an unrelated cause of injury may also be considered

⁹ This determination is notably different from a medical diagnosis: "the function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury." <u>Andreu</u>, 569 F.3d at 1382 (quoting <u>Knudsen</u>, 35 F.3d at 549).

in determining whether the petitioner has met the burden of establishing a prima facie case in the first instance. <u>Stone v. Sec'y of Health & Human Servs.</u>, 676 F.3d 1373, 1379-80 (Fed. Cir. 2012).

B. The Chief Special Master's Conclusions Regarding Causation-In-Fact Should Be Re-Evaluated in Light of <u>Koehn</u>

The primary dispute between the parties in this case concerns the first <u>Althen</u> prong. Specifically, petitioner argues that she met her burden of demonstrating a legally probable and biologically-plausible mechanism causally connecting her receipt of a single dose of the HPV vaccine with the onset of her JAS. The government, as noted above, argues that petitioner failed to establish such a connection by a preponderance of the evidence as required by <u>Althen</u>.

According to petitioner, the expert testimony that she presented established a legally probable theory that the HPV vaccine can be an environmental trigger that can cause the onset of JAS in genetically-predisposed individuals, in the same manner as other known environmental triggers such as bacterial infections or traumatic stress injuries. Petitioner notes that the parties' experts agreed on the genetic components of JAS, the identified environmental triggers, the existence of other unidentified environmental triggers, the mechanisms by which environmental triggers initiate the disease process, and the similarity of the immune response elicited by the HPV vaccine to the immune response to known environmental triggers. In addition, petitioner argues that Dr. McCabe's opinion was supported by scientific studies showing that the HPV vaccine triggers a response that is associated with the onset of diseases like JAS. In such

circumstances, petitioner argues that the chief special master's failure to find a causal connection between receipt of the HPV vaccine and the onset of JAS was arbitrary and capricious. Regarding the second <u>Althen</u> prong, petitioner further argues that Dr. McCabe was able to demonstrate through existing studies that a single dose of the HPV vaccine would be sufficient to trigger a response capable of causing JAS symptoms. Petitioner argues that she presented sufficient evidence to support the third <u>Althen</u> prong in that her symptoms began within one month of her receiving the HPV vaccine and thus her vaccination and the onset of symptoms were temporally-related. Finally, petitioner argues that the discussion in <u>Koehn</u> regarding Dr. McCabe's testimony in that case demonstrates that the chief special master's rejection of his testimony in favor of Dr. Rose's testimony was erroneous. According to petitioner, the Federal Circuit's approving statements and analysis in <u>Koehn</u> mean that Dr. McCabe's theory should be accepted in this case.

In response, the government argues that the chief special master's decision is rationally supported by the evidence presented and that nothing in the <u>Koehn</u> decision warrants a reversal of the decision. According to the government, petitioner presented a theory that the HPV vaccine might be a trigger for JAS symptoms but failed to present evidence to support a finding that the HPV vaccine actually "causes" JAS as required by the <u>Althen</u> test. The government relied on the testimony of its expert to draw a distinction, which the chief special master accepted, between the vaccine triggering the onset of symptoms in a patient with existing-but-dormant JAS and the vaccine actually causing JAS itself. The government further argues that its experts demonstrated that

there is no reliable evidence in the medical literature for petitioner's theory that a single dose of the HPV vaccine could trigger the onset of JAS or its symptoms. The government contends that the chief special master properly agreed with its expert that the study that Dr. McCabe relied upon was based on in-vitro responses and thus did not establish what an in-vivo response would be. Thus, the government argued that the chief special master was correct in finding that the government's experts effectively rebutted petitioner's causation theory. In addition, as noted above, the government argues that the chief special master's rejection of petitioner's temporal evidence is supported by the evidence presented.

Based on the circuit's intervening decision in <u>Koehn</u>, the court finds that this matter should be remanded to the chief special master to evaluate in the first instance whether, as the circuit suggested in <u>Koehn</u>, Dr. McCabe has identified a legally probable theory of causation with regard to the HPV vaccine to satisfy the first prong of <u>Althen</u> in cases involving auto-inflammatory diseases. <u>See Graves v. Sec'y of Health and Human</u> <u>Servs.</u>, 101 Fed. Cl. 310, 314 & n.2 (2011) (remanding for damages determination where an intervening Federal Circuit decision "potentially expands the scope of recovery" (citing <u>Zatuchni v. Sec'y of Health & Human Servs.</u>, 516 F.3d 1312 (Fed. Cir. 2008))). While the court recognizes that the circuit's criticisms of the special master's decision in <u>Koehn</u> with regard to causation are dicta, the court notes that there are sufficient similarities regarding the auto-inflammatory illnesses at issue in both cases to warrant a review. In this connection, the court also recognizes that there are also differences between the diseases at issue in both cases and in the dosages and the timing of

petitioner's reactions. The significance of these similarities and differences are matters that are best left for the chief special master to determine in the first instance, rather than this court.¹⁰

IV. CONCLUSION

Accordingly, for the reasons set forth above, petitioner's motion for review is **GRANTED-IN-PART** and the case is **REMANDED** for further proceedings in accordance with this opinion. The chief special master shall perform the re-evaluation within **90 days**, in accordance with Vaccine Rule 28(b).

IT IS SO ORDERED.

s/Nancy B. Firestone NANCY B. FIRESTONE Judge

¹⁰ The court also notes that the chief special master made a finding of a more likely alternative environmental trigger as the cause of petitioner's JAS. This conclusion was not discussed at length and may warrant further explanation in her new review.