In the United States Court of Federal Claims

No. 15-124V
(Filed: February 19, 2021)[1]

CHRISTINE DeLOZIER, parent and next friend of L.T., a minor, **Petitioner,** **v.** **SECRETARY OF HEALTH AND HUMAN SERVICES,** **Respondent.**	**National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq.; Causation-in-fact; Burden of Proof; Chronic Condition; Recurrence; Remand.**

Richard Gage, Richard Gage, P.C., 1815 Pebrican Avenue, P.O. Box 1223, Cheyenne, WY 82003, for Petitioner.

Jeffrey B. Clark, C. Salvatore D'Alessio, Catharine E. Reeves, Alexis B. Babcock, Julia M. Collison, United States Department of Justice, Civil Division, Torts Branch, P.O. Box 146, Benjamin Franklin Station, Washington, D.C. 20044, for Respondent.

OPINION AND REMAND ORDER

WILLIAMS, Senior Judge.

In the underlying action, Petitioner, on behalf of her minor daughter L.T., claimed that L.T. developed alopecia areata ("AA") as a result of receiving a hepatitis B vaccine ("HBV vaccine") and sought compensation under the National Vaccine Injury Compensation Program. The Chief Special Master ruled that Petitioner established that the HBV vaccine caused the onset of a single AA occurrence, but that Petitioner did not prove that the HBV vaccine could cause subsequent or future outbreaks of AA. The Chief Special Master awarded Petitioner $50,000 for pain and suffering limited to the first occurrence of AA.

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[1] Pursuant to Vaccine Rule 18 of the Rules of the United States Court of Federal Claims, the Court issued its Opinion under seal to provide the parties an opportunity to submit redactions. The parties did not propose any redactions. Accordingly, the Court publishes this Opinion.

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Petitioner timely filed a motion for review requesting that this Court remand the case to the Chief Special Master for a new damages calculation that takes into account L.T.'s recurrences of AA. This Court grants the motion. After finding that the HBV vaccine caused the onset of L.T.'s AA, a chronically recurring autoimmune condition, the Chief Special Master applied a heightened burden of proof in requiring Petitioner to again demonstrate causation for each subsequent outbreak of AA. As such, this Court remands this matter for a reassessment of damages that takes into account L.T.'s recurring episodes of AA.

Background[2]

Relevant Medical History

On November 6, 2012, L.T. received a third dose of an HBV vaccine. ECF No. 68 at 3. At the time of the vaccination, L.T. was three years old and had a history of eczema and asthma, as well as a family history of autoimmune disease. Id. at 2, 9 n.8, 11. L.T. had previously received her first and second HBV doses without any reported reaction. Id. at 2. Within a few days of her third HBV dose, L.T. began experiencing hair loss, complained of joint pain in her hip and wrists, developed a rash, and appeared to walk with a limp. Id. at 3. Later that month, Dr. Elaine Gilmore, a dermatologist, diagnosed L.T. with AA, noting "widespread . . . alopecic patches on the scalp" and prescribing a topical steroid for treatment. Id. (quoting Ex. 4 at 9).

L.T.'s hair loss continued to worsen and did not show evidence of improvement until more than six months after the onset of her symptoms, when a June 2013 visit with a dermatologist revealed that new hairs had appeared in L.T.'s bald patches. Id. at 3-4. L.T. continued to "gradually recover[] some of her hair," though her hair did not return to baseline. See Entitlement Hr'g Tr. 17-18. In a 2017 letter, L.T.'s treating dermatologist reported that L.T. "has areas of the scalp and eyebrows in which hair has not regrown, despite best efforts." ECF No. 37, Ex. 13. L.T.'s mother testified that L.T. "has a permanently receded hairline all the way around her scalp." Entitlement Hr'g Tr. 18.

In years following L.T.'s 2012 onset of AA, she experienced recurrences of AA resulting in additional patches of hair loss -- in August 2015, and April, November, and December 2016. ECF No. 68 at 5-6.

Overview of Alopecia Areata

As the Chief Special Master found, AA is an autoimmune disease characterized by hair loss, typically appearing in patches on the scalp. ECF No. 68 at 19 (citing Stanca A. Birlea et al., Chapter 66: Non-bulbous Skin Diseases: Alopecia Areata, Vitiligo, Psoriasis, and Urticaria, in The Autoimmune Diseases 971-74 (N. Rose & I. Mackay eds., 2014) ("Autoimmune Diseases"). "AA is associated with a number of other diseases and conditions, such as vitiligo, atopic dermatitis (eczema), hyper and hypothyroidism, and, less commonly, other autoimmune diseases like connective tissue disease," and "unquestionably has a genetic aspect" that determines susceptibility. Id. (citing Autoimmune Diseases at 972-73; Norris Report at 1; Tollefson Report at 2-3).

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[2] This background is derived from the record before the Chief Special Master and this Court.

"AA occurs when 'a mononuclear cell inflammatory infiltrate attacks the hair follicle (HF) bulb.'" Id. (quoting Autoimmune Diseases at 971). "Thereafter, T cell cytokines and cytotoxic T cells produce cytotoxic damage," which disrupts the functioning of the hair follicle and results in "thin, fragile hairs that easily detach or break off." Id. (citing Autoimmune Diseases at 971-72). Although it is not well understood what causes the onset of AA, "[p]otential triggers include emotional stress, metabolic or endocrine disorders, infections, drugs, and vaccines." Id. (quoting Autoimmune Diseases at 972). As the Chief Special Master determined, "[o]nce AA is triggered, its clinical course is variable and not monophasic in progression." Id. at 20. "[S]ome patients will experience 'recurring loss and regrowth,' while others may experience only one episode of AA and some will experience 'everything in between.'" Id. (quoting Entitlement Hr'g Tr. 51-52).

Petitioner's Expert

Dr. David Norris, M.D., board certified in Dermatology, Dermatologic Immunology and Diagnostic and Laboratory Immunology, testified for Petitioner. ECF No. 68 at 7. Dr. Norris is the chairman of the Department of Dermatology at the University of Colorado School of Medicine, and he has conducted and published research relating to AA, dermatology, and immunodermatology. Id.; Entitlement Hr'g Tr. 34-35. The Chief Special Master found Dr. Norris to be a "qualified and persuasive expert witness." ECF No. 68 at 21.

Dr. Norris described AA as a clinical hair loss disease that "at its root is an immunologic disease controlled by genes." Entitlement Hr'g Tr. 42. Specifically, AA is a polygenic disease -- "meaning that [it] may be determined not by one gene but by 30 genes or 40 genes," and "that disease is expressed when you have the gene, or 30 genes, and then you get some kind of an environmental trigger that makes the person have an autoimmune response against the target." Id. "In the case of [AA], it's the hair follicle that's the target." Id.

Dr. Norris explained the waxing and waning nature of AA, stating:

> There's no one pattern that you can say, well, this is typical of [AA]. So these patients often develop hair loss and then get regrowth, and at a later time, they'll also have more hair loss and regrowth. And that may progress to the loss of all of the hair on the head and no regrowth. Or, the most common patient that you see is someone who comes in and . . . they've had one or two or three patches of hair loss, it regrows, and that's the end of it. And we see everything in between.

Id. at 51-52.

Dr. Norris proposed a theory of how the HBV vaccine could cause AA, opining that because it is an autoimmune disease, "the onset of AA may follow infections, periods of stress, and immunostimulation, including vaccination." ECF No. 40, Ex. 16 (Norris Report) at 2 (citing Yaron Zafrir et al., Vaccines, Infections, and Alopecia Areata, in Vaccines & Autoimmunity (Yehuda Shoenfeld et al. eds., 2015) ("Zafrir"). Dr. Norris explained: "The way that the immune response works in autoimmune diseases, it's dependent on a broad immunologic genetic network, [and] really makes it quite ideal for the idea of a trigger being necessary to make the disease appear, even if the genetic susceptibility is there." Entitlement Hr'g Tr. 57. Dr. Norris further explained that the trigger can destroy a person's "immune privilege":

> [Immune privilege] is a unique characteristic of some organs in the body that . . . are protected from the induction of autoimmunity in that target so that you don't end up destroying important parts of the body, like the eyes or sometimes reproductive organs. Hair is also believed to be a structure that is protected by immune privilege and that in [AA] this immune privilege is destroyed by changing . . . the immune makeup of the hair follicle so that it is more susceptible to the induction of autoimmunity that attacks that hair follicle.

Id. at 44-45 (citing Zafrir). In further support of the proposition that the HBV vaccine could cause AA, Dr. Norris cited a study, R. Wise et al., Hair Loss After Routine Immunizations, 278 JAMA 1176 (1997) ("Wise"), which concluded that "immunizations warrant consideration among potential causes of hair loss." See id. at 49-51, 57; ECF No. 68 at 8.

In Dr. Norris' opinion, when AA patients "get a really strong immune response, and especially early in their life if they get a very extensive hair loss, like we see in L.T., then she's more likely to have an immune response that after that trigger, will continue through her life." Entitlement Hr'g Tr. 175. He elaborated:

> When we see a patient who has early onset and also has extensive hair loss, even total hair loss of the scalp, and if they have atopy, which is another health factor . . . then those patients may go on for their whole lives to have [AA] significantly. They may along the way also be stimulated, so that . . . they have a little kerosene thrown on [the fire that's already burning] if they get infection, or if they take certain kinds of medications, or if they have stress.
>
> But it's that initial presentation of disease that determines that they've got the population of specifically activated T cells that will carry them through with that disease for a long time.

Id. at 175-76.

Dr. Norris further explained that when AA is in a period of waxing, or increasing, it is not a new disease process, but rather is "the same immunologic process, attacking the same targets and making the same destruction of hair follicles." Id. at 176. In Dr. Norris' opinion, although patients may have a "smoldering specific immune response that can be reactivated by some other trigger, . . . it's not a new disease and it's not a new target that it's going after. It's the same target, the same disease as before, only reactivated."[3] Id. at 177.

Respondent's Expert

Dr. Megha Tollefson, M.D., board certified in general pediatrics, dermatology, and pediatric dermatology, served as Respondent's expert in the field of pediatric dermatology. Entitlement Hr'g Tr. 146-47, 149. Presently, Dr. Tollefson is a pediatric dermatologist at the Mayo

[3] The Chief Special Master disagreed with this aspect of Dr. Norris' opinion, stating "[a]t best, Dr. Norris attempted to outline how a vaccine could theoretically create a 'smoldering immune response,' consistent with the condition's relapsing nature, and thus even separate subsequent triggers would be linked to the initial event, but such assertions were (unlike most of his testimony) conclusory and unpersuasive." ECF No. 68 at 23.

Clinic in Rochester, Minnesota. Id. at 146; ECF No. 43, Ex. A at 1. As part of her clinical practice, Dr. Tollefson treats pediatric patients with AA, and she has published approximately 70 articles relating to pediatric dermatology. Entitlement Hr'g Tr. at 147-48.

Dr. Tollefson agreed with Petitioner's expert, Dr. Norris, that AA is an autoimmune disease, and she acknowledged its chronic nature, noting that L.T. "has [AA] that is at high risk for remaining a chronic disease." ECF No. 43, Ex. A (Tollefson Expert Report) at 4; Entitlement Hr'g Tr. 150. Dr. Tollefson agreed with Petitioner's expert, Dr. Norris, that "most, if not all, patients with [AA] likely have a genetic predisposition, but then there is also a trigger or a variety of triggers that are necessary or part of the process to develop [AA]." Entitlement Hr'g Tr. 151. Dr. Tollefson opined that "[i]n pediatric dermatology, the two main triggers are infections, and that's probably number one, two, and three, but also stress." Id.

Dr. Tollefson disagreed that the HBV vaccine received by L.T. in November 2012 was a "substantial contributing factor in her developing [AA]." Id. at 150. Although she acknowledged that "a temporal association has been reported in . . . medical literature," Dr. Tollefson emphasized that L.T. did not have a reaction to the first two HBV vaccines she received, opining that if a person is "going to have an autoimmune response to all three exposures, then [the vaccine] would be more likely to be the trigger." Id. at 159, 162-64.

When asked what triggered L.T.'s AA, Dr. Tollefson responded:

> Well, you know the thing about children is that their bodies and immune systems are constantly being exposed to viruses. That might be a subclinical infection. You might not actually see the [symptoms] -- like a fever or cold symptoms at the time, but everybody, and especially children, are much more -- they're a lot more exposed. And so in pediatrics in general, we believe that an actual symptoms infection doesn't mean that your body's not fighting something off. And so that potentially could be also considered as a possible trigger.

Id. at 166. Dr. Tollefson opined that when considering "numerically the number of doses of vaccines that are given, the number of children that develop [AA] as well as the number of viruses children continually are exposed to, I think it's much more likely for a viral infection to be the trigger" of a child's AA. Id. at 169. However, Dr. Tollefson acknowledged that there is no record of L.T. having an infection at the time she received the vaccination. Id. at 165-66.

Based on L.T.'s family history of autoimmune disease, Dr. Tollefson opined that L.T. had an increased risk of autoimmune disease and development of AA. ECF No. 43, Ex. A at 3-4. Dr. Tollefson also noted the presence of other risk factors in L.T., such as a history of eczema and respiratory problems, which indicate that L.T. has "a genetic make-up at risk for atopic disorders such as eczema, asthma, and allergies, none of which are caused by any vaccine" -- but the presence of such disorders "actually increases the risk for [AA]." Id. at 4 (citing Nazila Barahmani et al., History of Atopy or Autoimmunity Increases Risk of Alopecia Areata, 61 J. Am. Acad. Dermatol. (2009)).

When asked by the Chief Special Master about the "breaking [of] immune privilege" that Dr. Norris discussed, Dr. Tollefson indicated that she was familiar with the concept of immune privilege but had not studied it in detail. Entitlement Hr'g Tr. 167-68. The Chief Special Master

then asked whether "the genetic basis for someone developing alopecia areata [would] be a better indication of why they get it or more central than the thing that triggers it manifests it?" Id. at 168. Dr. Tollefson responded:

> I believe so. I mean, I think from seeing children with [AA], I think that there is a genetic basis that a certain percentage of these kids that have that genetic basis will develop [AA], but whatever trigger . . . that leads to that is not necessarily consistent, even in the same person, as Dr. Norris also said.

Id.

> Additionally, the Chief Special Master initiated the following exchange:
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> CHIEF SPECIAL MASTER: [W]ith respect to triggers, let's pose a hypothetical. So let's talk about a trigger you'd agree on, so an infectious trigger. And let's say you had a case where an individual was -- it was understood and agreed by treaters that that was the trigger of their [AA]. If they subsequently down the road, a year or two later, had recurrences, could they be triggered by different things?
>
> DR. TOLLEFSON: Yes.
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> CHIEF SPECIAL MASTER: And those recurrences would not pertain to the initial manifestation of the condition?
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> DR. TOLLEFSON: Not necessarily. I mean, I think similar to what is seen in L.T., you know, recurrent infectious triggers are probably what we know most commonly, but it's not necessarily the same exact virus every time. You know, there are multiple viruses kids get, so it could be that, it could be stress. You know, a lot of times what we'll see in the pediatric population is that initially the triggers are viruses and infections. Later on in life, when they became teenagers, that's more stress.
>
> CHIEF SPECIAL MASTER: So what would bring it -- cause the recurrence of symptoms would again be the underlying genetic susceptibility to the condition.
>
> DR. TOLLEFSON: Right.

Id. at 171-72. However, as Dr. Tollefson acknowledged, "most, if not all, patients with [AA] likely have a genetic predisposition, but then there is also a trigger or a variety of triggers that are necessary or part of the process to develop [AA]." Id. at 151.

The Chief Special Master's Entitlement Ruling

In his December 10, 2019 Entitlement Ruling, the Chief Special Master determined that Petitioner established that "the HBV vaccine could trigger AA, and did so in L.T.'s case in November 2012." ECF No. 68 at 24. With regard to the first Althen[4] prong, the Chief Special Master concluded that "there is just enough evidence to support Petitioner's contention under the

[4] Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

'can cause' prong that AA could be triggered by the vaccination - and the HBV vaccination in particular." Id. at 20. He explained:

> It was largely agreed-upon by the experts in this case that AA is likely an autoimmune process, thereby 'opening the door' to a determination that something impacting the immune response could be implicated as causal. In addition, Petitioner offered some reasonable items of literature, like Wise, supporting the association between the HBV vaccine and hair loss generally, if not AA specifically.

Id.

With regard to the second Althen prong -- "did cause" -- the Chief Special Master concluded that "the HBV vaccine in this case likely triggered L.T.'s AA onset in November 2012." Id. at 21. With regard to the third Althen prong -- "a proximate temporal relationship" -- the Chief Special Master concluded that "the timeframe in which L.T.'s AA began—two to four days post-vaccination—was established to be a medically acceptable temporal relationship for an autoimmune response." Id. at 22. Accordingly, he ruled that "the record in this case establishes that, at least with respect to the first occasion of L.T.'s AA, Petitioner carried her preponderant burden." Id.

However, regarding L.T.'s subsequent recurrences of AA, the Chief Special Master ruled:

> I do not find that [Petitioner] persuasively established that any subsequent recurrences (the first of which appears to have happened around the time of her August 2015 return visit to Dr. Gilmore, reporting new-onset AA symptoms) can also be attributed to that same initial vaccine event. The thinness of Petitioner's overall evidentiary showing may have been just enough to be preponderant in determining causation with respect to the first occurrence of AA, but that same slim showing shifts against Petitioner when the larger picture (including what the experts agreed about AA) is taken into account.

Id.

In making this determination, the Chief Special Master separately required Petitioner to establish vaccine-related causation for each subsequent recurrence of AA, and found that Petitioner was unable to meet the first Althen prong -- that the vaccine could cause L.T.'s AA recurrences in August 2015 and later. Id. at 22-23. He noted that "[b]oth experts agreed that AA is known to have a significant genetic component that serves as a baseline 'requirement' for AA to manifest" and that "L.T. was just such a person." Id. The Chief Special Master concluded that the evidence did not support the assertion that "the same initial trigger -- here, the November 2012 vaccination -- could reliably be deemed responsible for all future AA recurrences." Id. at 23. "At bottom, nothing that is known about AA (at least as reflected in the filings in this case) suggests that the first instance of AA in a person (likely to occur in childhood) is the linchpin explanation for all subsequent recurrences." Id.

The Chief Special Master distinguished this case from others where a "trigger effect" has been found, such as encephalopathy which causes both injury to the brain and significant ensuing

impacts, or a seizure triggered by a vaccination which "will set up conditions for . . . more harmful seizures in the future." Id. He reasoned:

> The "trigger" effect of the vaccine in this case, by contrast, is different – more isolated and discrete in scope. Both sides' experts agreed that AA has a significant genetic underpinning, and thus a person who likely possesses that predisposition (a conclusion that can be made about L.T. based on preponderant evidence) is more susceptible to experiencing AA on a lifelong basis. While it may have been established in this case that the HBV vaccine could trigger one instance of AA, it has not been similarly shown that any trigger (vaccine or not) would so alter a person's immune response that all AA recurrences would invariably be associated with the first, made worse due to the first, etc. None of the medical literature filed in this case stands for this proposition, and in fact (in stressing the importance of the genetic susceptibility to AA) actually undermines it.
>
> It is more likely that an individual's subsequent recurrences are attributable to the genetic susceptibility underlying AA. See McClellan, 2019 WL 4072130, at *35-36 (finding that petitioner "did not establish that a vaccine could, under the circumstances, trigger a non-febrile seizure sufficient to significantly worsen a preexisting seizure disorder with an unmistakable genetic origin"); Sharpe v. Sec'y of Health & Human Servs., No. 14-65V, 2018 WL 7625360 (Fed. Cl. Spec. Mstr. Nov. 5, 2018) (finding that neither the record supported "[p]etitioner's contention that the vaccines [] received could, or did, injure [their daughter] as alleged," nor did petitioners establish a significant aggravation claim given their daughter's existing "DYNC [gene] mutation"), aff'd, 142 Fed. Cl. 630 (2019), appeal docketed, No. 19-1951 (Fed. Cir. May 31, 2019). And Dr. Norris did not otherwise credibly establish with reliable evidence that AA can be thought of as a "smoldering" condition, in which the instigating trigger for an outbreak is a spark that is never extinguished.

Id. at 24 (alterations in original).

The Chief Special Master denied compensation for "any new, discrete AA recurrences that L.T. experienced post-vaccination, beginning no later than August 2015," because these recurrences "have not preponderantly been shown to be attributable to the earlier HBV vaccine." Id.

The Chief Special Master's Damages Decision

The Chief Special Master awarded Petitioner $50,000 for pain and suffering associated with L.T.'s first AA episode and explained:

> My December 2019 Ruling was favorable to Petitioner—but only with respect to the initial occurrence of AA in November 2012 that appears to have thereafter required approximately two years to treat before resolving. Petitioner had only preponderantly established that the HBV vaccine could cause (and in L.T.'s case, had caused) a single episode of AA—not initiated a chronic process that would likely recur. The evidence and expert testimony (which acknowledged that AA was

> believed to have a genetic origin) did not support the conclusion that a one-time triggering of AA, due to vaccine or otherwise, meant that the same initial trigger was also responsible in part for all subsequent occurrences. As a result, the HBV vaccine L.T. received in 2012 could not be blamed for any subsequent occurrences L.T. experienced (or may yet experience).

ECF No. 75 at 2 (internal citations omitted).

In calculating damages for pain and suffering, the Chief Special Master ruled:

> L.T. suffered from the less severe, AA-subtype of alopecia, and her symptoms persisted for approximately two years. Although she required minimal treatment of a non-invasive nature, she still suffered from the stigma and embarrassment of hair loss, at an age where she would likely comprehend the experience. I thus find that an award of $50,000 is fair, in light of the circumstances of this case and best comparables available. This sum fairly captures the temporally-limited severity of L.T.'s suffering, and generously compensates her for the experience of her AA, which thankfully happened when she was quite young (thus limiting somewhat the trauma that a teenager (subject to peer pressure) or older adult might experience.

Id. at 7.

The Chief Special Master added:

> Although I did not find that any of L.T.'s subsequent AA occurrences were vaccine-caused—and thus [did] not include any costs associated with them in my award—I invited Petitioner to substantiate future costs associated with her one-time AA occurrence. But Petitioner has offered no evidence to this effect, nor did she attempt to substantiate these future treatment costs, despite repeated opportunities to do so.

Id. at 8 n.10 (internal citations omitted).

When Petitioner requested a life care planner to substantiate future treatment needs, the Chief Special Master denied the request, stating:

> [A]larmingly, certain representations contained in the [Joint Status Report filed by Petitioner (ECF No. 69)] suggest that the Petitioner is seeking to relitigate issues already decided by my Ruling (or worse, is not even aware of how I ruled in the first place). Thus, Petitioner attempts to justify the lack of progress on damages by noting that she requires the assistance of a life care planner to "assess treatment options and costs for her chronic hair loss" attributable to her first AA, adding that "L.T.'s hair never grew back fully from her initial episode of [AA]." These rationales directly contradict the existing fact findings in this case. In effect, Petitioner wants time to obtain a life care planner who will substantiate treatment needs associated with ongoing hair loss—even though my Ruling (by its very terms) largely precludes such damages as inconsistent with the nature of the injury supported by the preponderant record.

ECF No. 70 at 2 (internal citations omitted).

Discussion

Jurisdiction and Standard of Review

This Court has jurisdiction under the Vaccine Act to review the decision of a special master to:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision, (B) set aside any of the findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2)(A)-(C); Doe 93 v. Sec'y of Health & Human Servs., 98 Fed. Cl. 553, 564-65 (2011).

"Findings of fact of the special master are reviewed under the arbitrary and capricious standard, conclusions of law are reviewed under the not in accordance with law standard, and discretionary rulings are reviewed under the abuse of discretion standard." Broekelschen v. Sec'y of Health & Human Servs., 89 Fed. Cl. 336, 343 (2009), aff'd, 618 F.3d 1339 (Fed. Cir. 2010) (internal citations and quotation marks omitted).

An abuse of discretion occurs when a special master's decision is: "(1) … clearly unreasonable, arbitrary, or fanciful; (2) … based on an erroneous conclusion of the law; (3) … clearly erroneous; or (4) the record contains no evidence on which the … [special master] rationally could have based his decision." Murphy v. Sec'y of Health & Human Servs., 30 Fed. Cl. 60, 61 (1993) (quoting Hendler v. United States, 952 F.2d 1364, 1380 (Fed. Cir. 1991)) (alteration in original).

The Court's role is not to "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." Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal citation and quotation marks omitted). However, the Court has "a duty to ensure that the special master has properly applied Vaccine Act evidentiary standards, 'considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for [his] decision.'" Paluck v. Sec'y of Health & Human Servs., 786 F.3d 1373, 1380 (Fed. Cir. 2015) (quoting Hines ex rel. Sevier v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)) (alteration in original). Conclusions of law are reviewed de novo by this Court. See 42 U.S.C. § 300aa–12(e)(2)(B); Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278-79, 1281 (Fed. Cir. 2005).

Burden of Proof under the Vaccine Act

In the seminal case of Althen v. Secretary of Health & Human Services, the Federal Circuit articulated the petitioner's burden to demonstrate causation-in-fact as follows:

> [Petitioner's] burden is to 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 1274, 1278 (Fed. Cir. 2005).

Petitioner must prove causation-in-fact "by a preponderance of the evidence." 42 U.S.C. § 300aa–13(a)(1)(A). The Federal Circuit "has interpreted the preponderance of the evidence standard referred to in the Vaccine Act as one of proof by a simple preponderance, of more probable than not causation." Althen, 418 F.3d at 1279 (internal citation and quotation marks omitted). Petitioner's claim must be "substantiated by medical records or medical opinion." Id.

The Federal Circuit "adopt[ed] the Restatement rule for purposes of determining vaccine injury, that an action is the 'legal cause' of harm if that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action." Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999) (citing Restatement (Second) of Torts § 431)).

To effectuate Congress's intent and advance the objectives of the Vaccine Act, causation is determined on a case-by-case basis, as follows:

> Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is "logical" and legally probable, not medically or scientifically certain. Thus, for example, causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms.

Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994) (internal citations omitted).

The Vaccine Act permits proof of causation through "the use of circumstantial evidence envisioned by the preponderance standard." Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006) (internal citation and quotation marks omitted). As the Federal Circuit has consistently reiterated, under the Vaccine Act, "close calls regarding causation are resolved in favor of injured claimants." Althen, 418 F.3d at 1280; Capizzano, 440 F.3d at 1324-26; Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1378 (Fed. Cir. 2009).

If the petitioner proves by a preponderance of the evidence that the vaccine caused petitioner's injury under the Althen test, the burden then shifts to the Government to prove, by a preponderance of the evidence, that a factor unrelated to the vaccination actually caused the injury. de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008); 42 U.S.C. § 300aa–13(a)(1)(B). If the Government fails to meet this burden, the petitioner is entitled to compensation. de Bazan, 539 F.3d at 1352. "So long as the petitioner has satisfied all three prongs

of the Althen test, she bears no burden to rule out possible alternative causes." Id. (footnote and citation omitted).

After Finding the HBV Vaccine Caused L.T.'s AA, the Chief Special Master Erroneously Required Petitioner to Separately Prove that the Vaccine Caused Each Recurrence of Her AA

The Chief Special Master found that the HBV vaccine could cause and did cause L.T.'s autoimmune disease, a condition that "waxes and wanes" and entails recurring episodes. In his entitlement ruling, the Chief Special Master found "that the HBV vaccine in this case likely triggered L.T.'s AA onset in November 2012." ECF No. 68 at 21. Rather than compensate Petitioner for subsequent and future recurrences of this condition, the Chief Special Master stopped at the first episode and required Petitioner to prove that each recurrence of her AA was also caused by that vaccine. Specifically, the Chief Special Master ruled that L.T. could not "recover damages associated with any new, discrete AA recurrences that [she] experienced post-vaccination, beginning no later than August 2015," because these recurrences "have not preponderantly been shown to be attributable to the earlier HBV vaccine." ECF No. 68 at 24.

The requirement that petitioners separately prove each ensuing episode of an autoimmune condition found to be caused by a vaccine imposes a heightened burden of proof inconsistent with the Vaccine Act and precedent. In articulating this onerous causation standard in the instant case, the Chief Special Master acknowledged the chronic aspect of AA: the Chief Special Master stated that "[o]nce AA is triggered, its clinical course is variable and not monophasic in progression." ECF No. 68 at 20. He continued: "some [AA] patients experience recurring loss and regrowth, other patients experience only one episode, and some will experience 'everything in between.'" Id. (quoting Entitlement Hr'g Tr. at 51-52).[5]

The parties' experts both acknowledged, and the medical literature of record substantiates, that AA is a chronic disease. As Respondent's expert, Dr. Tollefson, opined in her expert report: "[L.T.] has [AA] that is at high risk for remaining a chronic disease." ECF No. 43, Ex. A at 4 (emphasis added). Literature cited by Dr. Tollefson in her expert report states: "[a]ny mode of treatment may need to be used for long periods because of the chronic nature of [AA]." ECF No. 54, Ex. J (Yong-Kwang Tay, Pediatric Dermatology, ch.11 (4th ed. 2010)) at 6 (emphasis added). Literature cited in Dr. Norris' expert report provides: "AA is a chronic disease, typically presenting as patches of hair loss involving the scalp that can progress to alopecia totalis (loss of all scalp hair) or alopecia universalis (loss of all body hair)." ECF No. 42, Ex. 20 (Lucy Y. Liu et al., Health-related Quality of Life (HRQoL) Among Patients with Alopecia Areata (AA): A Systemic Review, 75 J. Am. Acad. Dermatol. 806 (2016)) at 1 (emphasis added); ECF No. 40, Ex. 16 at 3.

Another publication cited in Dr. Norris' expert report states:

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[5] This Court recognizes that the Chief Special Master did not accept Dr. Norris' opinion that AA is "a 'smoldering' condition, in which the instigating trigger for an outbreak is a spark that is never extinguished." ECF No. 68 at 24. But the Chief Special Master described AA as a condition that, once triggered, is "inherently subject to recurrence," and both experts characterized the condition as chronic. Id. at 23.

> Alopecia areata (AA) is an autoimmune disease characterized by one or more well demarcated oval and round noncicatricial patches of hair loss. The disease usually involves the scalp but may affect any hair-bearing parts of the body, including the eyebrows, beard, and body hair. It may include the entire scalp (alopecia totalis, AT) or the entire body (alopecia universalis, AU). Furthermore, due to its chronic relapsing nature and its profound effect on physical appearance, patients may experience a devastating loss of quality of life and self-esteem.

ECF No. 55, Ex. 27 (Zafrir) at 1 (emphasis added); ECF No. 40, Ex. 16 at 3.

Further, the Chief Special Master acknowledged that L.T. is not among the AA patients fortunate enough to only experience one episode. ECF No. 68 at 22. He recognized that a person who is genetically predisposed to AA, "(a conclusion that can be made about L.T. based on preponderant evidence) is more susceptible to experiencing AA on a lifelong basis." Id. at 24. In 2015 and in 2016, while the record in this case was being developed, L.T. experienced two recurrences of AA.[6]

To this Court's knowledge, no other Vaccine Act case holds that a petitioner must demonstrate causation for each recurring outbreak of a chronic condition triggered by a vaccine and that each recurrence must be separately analyzed under Althen. On the contrary, in other Vaccine Program cases, special masters have only required petitioners to prove causation for the onset of waxing and waning conditions in awarding compensation. See Bryan v. Sec'y of Health & Human Services, No. 14-898V, 2020 WL 7089841, at *1, 28, 30 (Fed. Cl. Spec. Mstr. Oct. 9, 2020) (granting compensation for chronic fatigue syndrome (CFS) caused by a flu vaccine and noting "a unique feature of CFS is the waxing and waning course of the disease") and Bryan, ECF 1:14-vv-898 136 (granting the petitioner's request for a life-care planner); G.C. v. Sec'y of Health & Human Servs., No. 15-773V, 2019 WL 4941087, at *10, 19-20 (Fed. Cl. Spec. Mstr. Sept. 5, 2019) (awarding compensation for the petitioner's vaccine-caused urticarial vasculitis, a chronic autoimmune disease which caused the petitioner "continue[d] . . . leg and joint pain, along with rash flare-ups and mouth ulcers").[7]

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[6] As of the time of oral argument on this motion for review, on December 9, 2020, counsel for Petitioner indicated that L.T. has experienced "more than two [recurrences] at this point, . . . and I don't have an exact number, but I believe she's probably up to four by now, maybe five." Oral Arg. Tr. 4.

[7] The Chief Special Master also appears to have concluded that there was an alternative cause for L.T.'s subsequent episodes -- finding her genetic pre-disposition more likely caused recurrences. See ECF No. 68 at 24 ("It is more likely that an individual's subsequent recurrences are attributable to the genetic susceptibility underlying AA."). In the Vaccine Program, once a petitioner has established causation, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." Althen, 418 F.3d at 1278 (alteration in original) (citation omitted). Here, the Government never argued a theory of alternative causation for L.T.'s AA recurrences, and the Chief Special Master never shifted the burden of proof to Respondent because he found that Petitioner failed to demonstrate Althen prong one -- that the HBV vaccine "could cause" recurrences of L.T.'s AA. But this finding contradicts the Chief Special Master's original

Forcing petitioners to sue over each recurrence of an episode of a vaccine-caused condition would spawn adverse ramifications for future Vaccine Act litigation. Aside from creating statute-of-limitations issues, this path would invite multiple litigations and increase the cost and complexity of pursuing these claims -- contrary to the purpose of the Vaccine Compensation Program. As the Federal Circuit explained in Knudsen v. Secretary of the Department of Health & Human Services:

> The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." The program is supposed to be "fair, simple, and easy to administer."

35 F.3d 543, 549 (Fed. Cir. 1994) (citations omitted); see also Koston v. Sec'y of Health & Human Servs., 974 F.2d 157, 161 (Fed. Cir. 1992) ("[The Vaccine Program] envisons that awards be made 'quickly, easily, and with certainty and generosity,' . . . even if this results in 'compensation to some children whose illness is not, in fact, vaccine-related.'" (quoting H.R. Rep. No. 908, 99th Cong., 2d Sess. 3, 18 (1986))).

Conclusion

Petitioner's motion for review is **GRANTED**, and this matter is **REMANDED** to the Chief Special Master for further proceedings consistent with this opinion**.** The Chief Special Master is directed to reopen the evidentiary record on remand and determine appropriate compensation for subsequent and future recurrences of L.T.'s AA.

s/Mary Ellen Coster Williams
MARY ELLEN COSTER WILLIAMS
Senior Judge

conclusion that the HBV vaccine could cause AA. Moreover, the Chief Special Master's introduction of genetic susceptibility alone as an alternative cause for L.T.'s recurrences is at odds with both expert opinions that a trigger, such as a vaccine or virus, in addition to genetic susceptibility must be at play in causing AA. See Entitlement Hr'g Tr. 42, 151.