

**In the United States Court of Federal Claims**  
**OFFICE OF SPECIAL MASTERS**  
**No. 16-864V**  
(to be published)

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I.J.,

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Chief Special Master Corcoran

Petitioner,

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v.

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Filed: January 4, 2022

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SECRETARY OF HEALTH AND  
HUMAN SERVICES,

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Respondent.

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*Robert J. Krakow*, Law Office of Robert Krakow, P.C., New York, NY, for Petitioner.

*Catherine Stolar*, U.S. Dep’t of Justice, Washington, DC, for Respondent.

**RULING ON REMAND GRANTING ENTITLEMENT**<sup>1</sup>

Isaac Jones filed a petition on July 21, 2016, seeking compensation under the National Vaccine Injury Compensation Program (“Vaccine Program”).<sup>2</sup> ECF No. 1. Mr. Jones alleged that he developed transverse myelitis (“TM”) due to the Tetanus-Diphtheria-acellular-Pertussis (“Tdap”) vaccine he received on July 22, 2013.

A two-day hearing was held in this matter on October 22–23, 2019. Initially I denied entitlement, finding that although Petitioner had preponderantly established that he likely experienced TM, insufficient evidence supported the conclusion that the Tdap vaccine *can cause*

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<sup>1</sup> This Decision will be posted on the Court of Federal Claims’ website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen 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 whole Decision will be available to the public in its current form. *Id.*

<sup>2</sup> The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10–37 (2012) (hereinafter “Vaccine Act” or “the Act”). Individual section references hereafter shall refer to § 300aa of the Act.

TM, or that it did so in this case. *I.J. v. Sec’y of Health & Hum. Servs.*, No. 16-864V, 2021 WL 1232733 (Fed. Cl. Spec. Mstr. Jan. 4, 2021) (the “Entitlement Decision”). However, Petitioner sought review of the Entitlement Decision, and the Court subsequently vacated my prior determination, remanding the matter for my determination a second time. *J. v. Sec’y of Health & Hum. Servs.*, 155 Fed. Cl. 20 (2021) (the “Remand Decision”).

I thereafter ordered Respondent to Show Cause why, in light of the Remand Decision’s findings, entitlement should not be found for Petitioner, and both parties have briefed the issue. Respondent’s Brief, dated September 20, 2021 (ECF No. 136) (“Resp. Show Cause”); Petitioner’s Response, dated Oct. 14, 2021 (ECF No. 138) (“Pet. Response”); Respondent’s Reply, dated Nov. 12, 2021 (ECF No. 140) (“Reply”).<sup>3</sup> Now, for the reasons stated below, I find that Petitioner has carried his burden of proof, and is therefore entitled to damages.

### **BRIEF PROCEDURAL HISTORY**

#### *The January 2021 Entitlement Decision*

As noted, this matter was tried over a two-day period in the fall of 2019. At trial, I heard testimony from the Petitioner himself plus a total of four medical experts. My Entitlement Decision observed that the parties primarily disputed the classification of Petitioner’s injury. Entitlement Decision, 2021 WL 1232733, at \*28. Indeed, Petitioner’s three experts all focused on this subject. I found, however, that although there was evidence on both sides of the question, and resolution of the matter presented a close call, Petitioner’s showing was ultimately preponderant, establishing that TM was the diagnosis best supported by the record. *Id.* at \*29.

Regarding the *Althen* prongs, however, I found that Petitioner had not preponderantly established that the Tdap vaccine likely caused his TM, since only one of the three prongs had been satisfied. Petitioner demonstrated that he experienced onset of his TM in a medically-acceptable timeframe (measured from the date of vaccination) consistent with his causation theory for how long it would take an autoimmune, vaccine-driven process to occur. Entitlement Decision,

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<sup>3</sup> The filing date for this Ruling admittedly falls outside the 90 days set by the Vaccine Rules for a special master to act on a remanded matter (since the action was remanded to me on July 6, 2021—meaning acting on the remand should have occurred on or before October 4, 2021). *See* Vaccine Rule 28(b). However, the Court of Federal Claims has previously observed that “the Vaccine Act does not identify any consequences for a special master’s failure to complete the task directed by the court on review within the statutory ninety-day remand period.” *Greene v. Sec’y of Health & Human Servs.*, No. 11-631V, slip. op., at 3 (Fed. Cl. May 30, 2018). In addition, even if my ruling (now in Petitioner’s favor) had been issued within that 90-day timeframe, the case’s *final* and complete disposition would still remain for a later date, since the parties must now undergo the meticulous process of determining damages in a case involving a plainly-catastrophic injury—and experience tells that the damages calculation process will surely take far longer than 90 days. Otherwise, my show cause order that prompted briefing on the remand issue was published in July 2021, with both parties subsequently requesting (and receiving) extensions of time to file their respective briefs. As a result, delay in issuance of this ruling prejudices neither party.

2021 WL 1232733, at \*34. But in my determination Petitioner had not preponderantly demonstrated that the Tdap vaccine had caused his injury, since there was very little evidence of an aberrant immune-driven reaction. *Id.* at \*32. Suspicion by treaters that a *different* vaccine, not received by Petitioner, was causal was not in my estimation strong treater support. *Id.* at \*33.

More importantly, I did not find that the first, “can cause” prong was satisfied. Entitlement Decision, 2021 WL 1232733, at \*29–33. In so determining, I focused on the limited showing made by Petitioner’s primary expert, Dr. Scott Zamvil, observing that he relied on evidentiary categories not subject to great weight (e.g., case reports, or the discredited theory that adjuvants in the vaccine prompt an aberrant immune response), and also placed emphasis on molecular mimicry—a reliable scientific theory by itself, but one which did not automatically carry the day for claimants simply in its invocation. *Id.* at \*32. I also noted that although many prior Program decisions found a Tdap-TM association, more recent determinations might reflect a change in the scientific view on the subject. *Id.* at \*31. Finally, I gave weight to a scientific case series study offered by Dr. Zamvil, Baxter,<sup>4</sup> in which no association was observed between the Tdap vaccine and TM, based on numerous vaccination events specific to the Tdap vaccine. *Id.* Dr. Zamvil emphasized that Baxter observed a greater risk between Tdap and a *different*, but related, neurologic demyelinating injury, but attempted to downplay Baxter’s Tdap-specific finding, and I faulted his opinion for ignoring the facial and negative implications of this item of literature he otherwise highlighted. *Id.*

### *The Remand Decision*

The Court’s Remand Decision made a number of legal and factual findings that resulted in granting the motion for review and remanding the matter to me. First, the Court held that I misapplied the legal standard applicable to the first *Althen* prong. Remand Decision, 155 Fed. Cl. at 43. The Federal Circuit had characterized that standard over ten years ago, in *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1375 (Fed. Cir. 2009), as only requiring a showing of “biological plausibility.” *Id.* A more recent Circuit decision seemed to emphasize that this framing no longer held sway, noting that “a ‘plausible’ or ‘possible’ causal theory does not satisfy the standard.” *Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019). But then, in a nonprecedential decision issued earlier this year, a different Circuit panel indirectly addressed *Boatmon*—and in the view of the Court herein held that *Boatmon* had not rejected the view that proof of an “exact biologic mechanism” was never required in establishing the first *Althen* prong. *Kottenstette v. Sec’y of Health & Hum. Servs.*, No. 2020-2282, 2021 WL 2434329, at \*6 (Fed. Cir. June 15, 2021). The Court interpreted this to mean that *Boatmon*’s articulation of preponderance as governing the prong one evidentiary standard had not, in fact, rejected or overturned the prior statement of mere plausibility in *Andreu*—and therefore I applied preponderance to the first prong in error. Remand Decision, 155 Fed. Cl. at 44.

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<sup>4</sup> Baxter’s full cite is set forth in the Entitlement Decision.

Second, the Court determined that several of my fact determinations were arbitrary and capricious. Regarding evidence offered for the first prong, the Court addressed in great detail the findings in the Baxter study. It determined that I misread Baxter’s findings regarding the association between TM and the Tdap vaccine, and also that I overvalued Baxter’s weight generally (especially to the extent I cited other decisions relying on it, but which had in the Court’s view also relied on the *Boatmon* standard for the first *Althen* prong), or had given it different weight in other cases. Remand Decision, 155 Fed. Cl. at 46–47. I otherwise was ordered to re-evaluate the weight of Petitioner’s showing on the “can cause” prong (including how I evaluated molecular mimicry as a mechanistic explanation for vaccine causation) in light of the *Andreu* plausibility standard. *Id.* at 50.

Finally, the Court ruled that I erred in determining that the second *Althen* prong was not met. Despite my finding that there was little in the medical record leading up to Petitioner’s presenting symptoms seventeen days post-vaccination (*see* Entitlement Decision at \*1–2, 33), the Court emphasized the record of evidence of inflammation *thereafter* (around the time of Petitioner’s initial treatment) as supportive of the Petitioner’s claim, and thus contrary to my more blanket statement that “hardly any” testing evidence established pre-onset inflammation. Remand Decision, 155 Fed. Cl. at 54. The Court also found that even if treaters had mischaracterized the specific identity of the purportedly-causal vaccination at issue, the fact they suspected *some* prior vaccination could be causal was still worthy of weight, although it left resolution of how much weight to give this evidence to remand. *Id.* at 55–56.

## PARTIES’ ARGUMENTS

### *Respondent*

After the Court’s issuance of the Remand Decision, I ordered Respondent to Show Cause why entitlement should not now be entered for Petitioner. Order, dated July 8, 2021 (ECF No. 131). Respondent contested the Court’s reliance on *Kottenstette* as stating the proper evidentiary standard under the *Althen* test, emphasizing that this specific Circuit opinion was by its own terms nonprecedential. Resp. Show Cause at \*3. Thus, Respondent maintained that I had correctly determined that the “causal theory was neither sound nor reliable.” *Id.* But Respondent then argued that despite the Court’s determinations about the proper weight to be given to certain evidence, there remained insufficient proof upon which to find that Petitioner had satisfied the first two *Althen* prongs. *Id.* at \*4.

Regarding the first *Althen* prong, Respondent argued that mere mention of molecular mimicry generally could not amount to preponderant evidence in a specific case. Resp. Show Cause, at \*4–5. Otherwise, Petitioner’s expert, Dr. Zamvil, had failed to provide a sound and

reliable explanation for how the Tdap vaccine could cause TM. *Id.* at \*5. While Dr. Zamvil tried to establish that the mechanism of molecular mimicry could instigate immune-mediated disease processes, he had offered little in the way of evidence directly connecting the Tdap vaccine to TM in this manner. *Id.* And online database searches showing homology between amino acid sequences in the proteins found in the vaccine's antigens and self protein structures was inadequate to establish preponderance. *Id.*

Respondent next maintained that Petitioner had not met his burden as to *Althen* prong two, observing the absence of evidence "of any autoantibodies that might arguably be associated with the asserted TM cross-reaction." Resp. Show Cause at \*6 (citing Entitlement Decision, 2021 WL 1232733, at \*43). He also emphasized the importance of my finding that there was not excessive or unusual inflammation even with the little evidence of some post-vaccination. Resp. Show Cause at \*6–7. Respondent also questioned the value of treater speculation in this case, noting that treating physician opinions "are not sacrosanct, and can be rebutted and found unreliable or not dispositive by a special master based on the record as a whole." *Id.* at \*7; Section 13(b)(1); *Snyder v. Sec 'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (Fed. Cl. 2009) (citations omitted). In this case particularly, treaters had not even properly identified the vaccine received by Petitioner. Resp. Show Cause at \*7.

On reply, Respondent reiterated prior arguments. Case reports purportedly associating the Tdap vaccine with TM via molecular mimicry were in Respondent's view distinguishable or provided no detail as to a possible mechanism. Reply at \*1–2. Otherwise, the acceptance of molecular mimicry in different vaccine injury cases does not render the theory dispositive or persuasive herein, absent evidence connecting TM to the mechanism, or a showing how the Tdap vaccine could instigate a cross-reaction due to molecular mimicry. *Id.* Respondent further argued that the lack of studies connecting Tdap and TM weighed against causation. *Id.* at \*3. And even if some of Petitioner's treaters had referenced *some* vaccine as possibly causal, they did not implicate the Tdap vaccine, and the basis for their conclusions was not otherwise evident in the medical record, with no real explanation for Petitioner's TM ever agreed upon or identified. *Id.* at \*4.

#### *Petitioner*

Petitioner emphasizes the Court's embrace of "biologically plausible" as the *Althen* prong one standard, arguing that it has been met herein. Pet. Response at \*3. A connection between the Tdap vaccine and TM has been repeatedly linked in literature and prior cases, via molecular mimicry, noting also that sufficient homology for a cross-reaction to occur was proven. *Id.* at \*3, 7. Petitioner also restates the criticisms leveled against the Baxter study by the Court, and hence why I erroneously viewed it as undercutting the strength of Petitioner's *Althen* one showing. *Id.* at \*4. Petitioner otherwise tried to bulwark Dr. Zamvil's theory and use of other scientific studies. *Id.* at \*5–6.

## ANALYSIS

In any remanded case, the special master is bound by the determinations of the Court on matters of law and fact. *Rickett v. Sec’y of Health & Hum. Servs.*, 468 F. App’x 952, 959 (Fed. Cir. 2011) (quoting *Hanlon v. Sec’y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (Fed. Cl. 1998)). Given the notably extensive and painstaking nature of the Court’s Remand Decision, and after consideration of the briefs filed in response to my Order to Show Cause, I find that Respondent has not identified grounds for a second entitlement determination consistent with my first.

First, the Court’s embrace of a plausibility evidentiary standard for *Althen* prong one—a standard I am compelled to apply herein<sup>5</sup>—effectively obligates me to find on the present record that Petitioner has offered in this case a plausible medical theory that the Tdap vaccine “can cause” TM. Dr. Zamvil, a qualified expert, certainly proposed a reliable mechanism (molecular mimicry) to explain how components of the vaccine could cross-react with homologous amino acid sequences making up nerve myelin, and in turn cause an autoimmune attack leading to TM. He also demonstrated how antigenic components of the vaccine could mimic self amino acid

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<sup>5</sup> I must accept the Court’s interpretation of the law on this matter and apply it in my remand determination. But having reviewed *Boatmon* and *Kottenstette* in detail, I am far less certain than the Court that the two are actually in opposition, with the latter rejecting the former (as the Court has concluded). *Kottenstette*’s discussion of *Boatmon* was limited to the fact that the three-judge *Boatmon* panel found the deciding special master in that case had effectively applied the wrong evidentiary burden. *Boatmon*, 941 F.3d at 1359 (“[t]he Special Master deviated from the correct “reputable,” “sound and reliable” standard and articulated a lower “reasonable” standard. . . **We have consistently rejected theories that the vaccine only “likely caused” the injury and reiterated that a “plausible” or “possible” causal theory does not satisfy the standard**”) (emphasis added). The *Kottenstette* panel, by contrast, found that the special master in question (whose initial decision in the claimant’s favor was overturned before the matter was remanded to a different special master (because the prior special master had retired)), had articulated the *proper* overall preponderant requirement—and thus in the *Kottenstette* panel’s view had not committed the error identified in *Boatmon*. *Kottenstette*, 861 F. App’x at 440–41. The *Kottenstette* panel otherwise does not characterize the *Boatmon* articulation of the first *Althen* prong standard to be erroneous. And merely noting, as *Kottenstette* does, that a specific biologic mechanism need not be offered to establish causation, or that scientific certainty is not the evidentiary standard overall, *is not equivalent to finding that claimants need not prove the Althen one causation prong by a preponderance of the evidence*.

I urge the Court in future cases to reconsider whether in fact the Federal Circuit’s facially non-precedential *Kottenstette* decision is controlling and/or eliminates what the Circuit has previously said about the first *Althen* prong (and what the special masters have collectively understood the standard to be—now, for many years). Purely from the standpoint of the Vaccine Program, a standard of mere plausibility would effectively mean that claimants could *always* satisfy the first prong, simply by pointing out the plausibility of molecular mimicry instigated by the immune system as a mechanism for autoimmunity—and thus the distinction between Table claims (in which the Government concedes causation) and non-Table would be obliterated. I also note that holding claimants to a preponderant showing on the “can cause” prong does not work an injustice, or elevate their burden unreasonably. There is no dispute that petitioners may offer a variety of evidence to prove their claim—they are not required to offer epidemiologic proof, for example—and thus the existing evidentiary system employed in the vast majority of vaccine claims takes into account the lack of a requirement of medical certainty.

structure/sequences. Although the theory was mostly provided in an outline form, without much in the way of direct evidence establishing the actual capacity of the Tdap vaccine to prompt demyelination in the manner proposed, I cannot dispute the *plausibility* of the contention. Indeed—nearly *any* vaccine could plausibly cause demyelination by instigating a cross-reaction, assuming a sufficient degree of sequential and structural homology.

I must also now give Baxter limited weight, if any, in contrast to my prior determination. It remains the case that Dr. Zamvil specifically invoked Baxter even though it was facially at odds with his very theory, since the article’s findings favorable to Petitioner involve a *different* injury, acute disseminated encephalomyelitis (“ADEM”)—while Baxter’s authors plainly *discount* the TM-Tdap association. Entitlement Decision, 2021 WL 1232733, at \*31. However, the Court has articulated a number of sound reasons for placing less faith in Baxter’s findings.<sup>6</sup> In addition, no epidemiologic study can ever “disprove” the possibility of causation (something I have myself recognized repeatedly in the past),<sup>7</sup> and the Court noted that the trial record did not evaluate Baxter’s findings specifically enough from all sides to permit it being deemed wholly reliable or persuasive. On remand, I determine that although Baxter *still* merits some evidentiary weight, in the context of this case—where Petitioner’s prong one showing was overall a bit more all-inclusive than Respondent’s—it was not by itself enough to rule against Petitioner on the “can cause” prong. Baxter alone does not eliminate the plausibility (applying the Court’s *Althen* prong one standard) of the causation theory.

Importantly, certain *other* items of evidence offered by Petitioner in support of his causation theory remain in my estimation underserving of evidentiary weight, and I am comfortable so finding *despite* the constraints of the Remand Decision. Thus, I do not find that the case reports offered by Petitioner (such as those referenced in Agmon-Levin—an oft-criticized review article summarizing a number of case reports) are persuasive evidence to any degree, and therefore offer limited support for his contentions.<sup>8</sup> Indeed, if I over-valued Baxter (which certainly involved thousands of vaccinations, even if the precise number I cited was incorrect), then it would have to be similarly erroneous for me to deem *four* documented case reports of post-vaccination TM to be especially probative—since the same evidentiary criticisms raised against

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<sup>6</sup> The Court has also correctly observed that I myself have not deemed Baxter dispositive, or particularly persuasive, on the subject of the TM-Tdap link, in every case. Remand Decision, 155 Fed. Cl. at 47–48, *citing McGrail v. Sec’y of Health & Hum. Servs.*, No. 17-926V, 2021 WL 1728706, at \*1 (Fed. Cl. Spec. Mstr. Apr. 23, 2021).

<sup>7</sup> *See, e.g., Kelly v. Sec’y of Health & Hum. Servs.*, No. 16-878V, 2021 WL 5276373, at \*26n.24 (Fed. Cl. Spec. Mstr. Oct. 10, 2021), *appeal docketed*, Nov. 17, 2021 (Fed. Cl.).

<sup>8</sup> Entitlement Decision, 2021 WL 1232733, at \*11 (Agmon-Levin referenced only four instances of post-Tdap-comparable TM); *see also Pearson v. Sec’y of Health & Hum. Servs.*, No. 16-9V, 2019 WL 3852633, at \*14 (Fed. Cl. Spec. Mstr. July 31, 2019) (giving low weight to Agmon-Levin in case alleging that flu vaccine caused TM, since Agmon-Levin referenced only two post-flu vaccine TM cases—based on a review of 39 *years* of published case reports).

the reliability of Baxter’s findings go double for anecdotal reports of temporal associations between vaccination and injury. And I am not at all persuaded by Dr. Zamvil’s adjuvant arguments either, for reasons I previously articulated. Entitlement Decision, 2021 WL 1232733, at \*32.

Nevertheless, Dr. Zamvil’s showing was *still* more comprehensive than Respondent’s rebuttal. Petitioner in this case endeavored to offer proof for how the Tdap vaccine could be causal of TM, and this coupled with the fact that the theory has been found persuasive in numerous prior cases (even if those cases, like *Raymo v. Sec’y of Health & Hum. Servs.*, 11-654V, 2014 WL 1092274 (Fed. Cl. Spec. Mstr. Feb. 24, 2014), were explicitly decided without the benefit of more comprehensive studies like Baxter) is enough for me to find that a plausible “can cause” theory was advanced. This is especially so since (a) both experts were roughly comparable in expertise, and (b) I do not find that Respondent’s sole expert, Dr. Alexander, rebutted Dr. Zamvil’s overall contentions, preferring instead simply to deny causation (to the extent he addressed it at all).<sup>9</sup> I have found in other cases that even a lackluster showing by Petitioner can establish causation where Respondent chooses not to defend or does so ineffectually. *See, e.g., Barone v. Sec’y of Health & Hum. Servs.*, No. 11-707V, 2014 WL 6834557, at \*9 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (petitioner prevailed on *Althen* one showing despite some thinness of contentions, since Respondent offered no expert to rebut Petitioner’s showing).

Accordingly, I find sufficient evidence was offered herein by Petitioner to meet the plausibility standard applied by the Court on the first *Althen* prong—and it was not rebutted by Respondent. In a different case, where an immunologist (for example) testifying for the Respondent made more specific rebuttal points (beyond Baxter) showing how the Tdap vaccine likely could not cause TM, my conclusion could well be different. But here (especially since the parties’ experts predominantly focused their testimony on the diagnostic debate), the fact that the overall record was globally sparse on causation means that what Petitioner *did* offer ended up being sufficient. I will remain open in future cases to find that the Tdap vaccine cannot likely cause TM—but *on this record* I am comfortable concluding that Petitioner *plausibly* established it can.

Second, I find on this record that the “did cause” prong of *Althen* has also been established. Here, there is no question raised by the parties (or the Court) that a preponderant showing is required—and although Petitioner’s case was (again) not especially robust, it was enough to cross the preponderant line. As the Remand Decision observes, there *was* evidence of post-vaccination

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<sup>9</sup> Indeed—Dr. Alexander’s first report said nothing about causation. *See* Report, dated February 28, 2018, filed as Ex. A (ECF No. 41-1). His second report only contested the evidentiary value of Agmon-Levin (Report, dated September 20, 2019, filed as Ex. N (ECF No. 79-1) at 3)—a proposition I wholly embrace, but something that does not defeat Petitioner’s “can cause” showing. And his final supplemental report (Report, dated December 26, 2019, and filed as Ex. O (ECF No. 107-1)) was prepared post-hearing and intended only to comment on MRI findings discussed at hearing by Dr. Watanabe.

inflammation,<sup>10</sup> and no other possible explanation for TM identified by treaters. This, plus Dr. Zamvil’s reasoned opinion vouching for the vaccine’s causal role in propagating Petitioner’s TM, was enough to establish that the vaccine likely caused the injury.

The overall brevity of my Remand Ruling is a product of my desire to bring this matter (which is now more than five years old) to a conclusion. It is in the interests of the Program (and its policy goals of swift resolution of vaccine injury claims) not to further delay resolution of this case with even more detailed analysis of the success of the evidentiary showing made herein. As my original Entitlement Decision set forth, the Petitioner unquestionably *did* succeed in carrying several of his evidentiary burdens, despite the fact that the parties hotly disputed the nature of Petitioner’s injury. Upon reflection, it appears that their joint zeal in debating the injury (the subject that took up the majority of trial time, and which involved *all four* testifying experts) may have distracted both from giving the same attention to the other *Althen* prongs—resulting in insufficient attention being paid to these equally-vital issues, and opening the door to my initial determination that important causation matters were not adequately established.

The Court has now performed its own exacting review and weighing of the evidence, concluding that a different outcome is favored. There is, of course, still some room for a more detailed explication of certain topics. I could, for example, order both sides to offer epidemiologic expert testimony to delve into the intricacies of Baxter, with the goal of clearing up some of the questions raised about the weight its findings should receive. A whole additional hearing day, or more, could be devoted to the inquiry, and there are no doubt experts (whether or not their expertise arises from epidemiologic matters) that could provide views on both sides of the topic.<sup>11</sup>

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<sup>10</sup> Of course, in *any case* alleging an auto-inflammatory neuronal illness, there will inherently be evidence of inflammation specific to the injury (since this is an essential driver of the disease process)—suggesting that it is somewhat circular to conclude that proof of the process directly resulting in injury alleged (and from the very time the disease was first observed clinically) stands as weight-deserving proof of causation. It is for this very reason that I typically look for *other* corroborative evidence that the vaccine caused the injury—evidence of autoantibodies associated with the pathogenesis of the disease, for example, or some kind of testing result that suggests a process *leading* to the injury was underway, even before onset’s outward manifestation. The Remand Decision found this evidence of inflammation especially compelling herein, however, and so it binds my determination.

<sup>11</sup> See, e.g., *Smith v. Sec’y of Health & Hum. Servs.*, No. 14-848V, 2018 WL 3991386 (Fed. Cl. Spec. Mstr. July 5, 2018). In *Smith*, a special master determined that the Hepatitis B vaccine was not demonstrated to have likely caused a claimant’s TM. There, the Respondent’s expert offered Baxter to contest Petitioner’s prong one arguments, and in so doing he deemed Baxter “‘by far, the best’ of the papers that he looked at because ‘the [sample size] is the largest and the analysis is really well done,’” along with the fact that the total number of vaccination incidents considered was “‘less subject to underreporting than a typical study.’” *Smith*, 2018 WL 3991386, at \*18. That expert also considered Baxter deserving of weight despite the fact that no epidemiologic evidence could completely rule out vaccine causation, given the total number of vaccination occurrences considered weighed against the handful of instances of post-vaccination TM. *Id.* at \*19. Of course, none of this vouching is in evidence herein—but I reference it to underscore the fact that skepticism of Baxter is not necessarily well-founded, and certainly could be the subject of reasoned disagreement.

But rather than prolong the case with a second round of findings that, however well-reasoned, would surely become fodder for additional appeal, judicial prudence—plus concern for fairness to the Petitioner, who unquestionably *did* experience a post-vaccination injury, regardless of how causation is resolved, and who has brought this claim in evident good faith—counsels me to bring this matter to an end, if possible.

### CONCLUSION

Petitioner has satisfied his burden in establishing that the Tdap vaccine caused his TM, entitling him to damages. A damages order shall issue separately.

**IT IS SO ORDERED.**

/s/ Brian H. Corcoran  
Brian H. Corcoran  
Chief Special Master