

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: September 8, 2022

FREDERICK AND LISA ROOT,
as parents of M.A.R.,

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No. 16-20V

Petitioners,

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Special Master Sanders

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

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Dismissal; Insufficient Proof; Human
Papillomavirus (“HPV” or “Gardasil”)
Vaccine; Premature Ovarian Failure/
Insufficiency (“POF/POI”)

Respondent.

Mark T. Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for Petitioners.
Dorian Hurley, U.S. Department of Justice, Washington, DC, for Respondent.

DISMISSAL DECISION¹

On January 5, 2016, Frederick and Lisa Root (“Petitioners”) filed a petition for compensation on behalf of their minor daughter, M.A.R., under the National Vaccine Injury Compensation Program² (“Vaccine Program” or “Program”). 42 U.S.C. § 300aa-10 to 34 (2012). Pet. at 1, ECF No. 1. The petition alleges that the human papillomavirus (“HPV” or “Gardasil”) vaccinations M.A.R. received on January 21, 2013, March 8, 2013, and August 26, 2013, caused her to suffer from premature ovarian failure (“POF/POI”). *Id.* The information in the record, however, does not show entitlement to an award under the Program.

On August 25, 2016, Respondent filed his Rule 4(c) report. Resp’t’s Report, ECF No. 15. Respondent argued that Petitioners have not satisfied their burden of proof under *Althen*, as they “failed to proffer a medical opinion or theory sufficient to establish a logical cause and effect relationship between [M.A.R.’s] vaccinations and [] injury.” *Id.* at 5. Petitioners’ case was

¹ This Decision shall be posted on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the I agree that the identified material fits within the requirements of that provision, such material will be deleted from public access.

² National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 (“the Vaccine Act” or “Act”). Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

consolidated with several other POI matters to determine if any of the cases could proceed in light of the causation theory proposed in the petitioners' cases. *See, e.g.*, ECF Nos. 17, 32–34, 61. On December 6, 2019, I held a status conference with the parties in the consolidated POI matters to discuss the presentation of the parties' arguments with respect to the viability of a causation theory pursuant to *Althen* prong one. *See* No. 15-183V, ECF No. 80; *see also* Min. Entry, docketed Dec. 6, 2019. Petitioners filed a brief on *Althen* prong one on June 18, 2020. No. 15-183V, ECF No. 86. Respondent submitted a response on September 22, 2020, and Petitioners filed a reply on November 20, 2020. No. 15-183V, ECF Nos. 88, 90.

I issued a ruling on *Althen* prong one on August 30, 2021, finding that the petitioners in the consolidated POI cases have presented a causation theory that, while not applicable to all of them, does survive *Althen* prong one under limited, specific circumstances. *See* Findings of Fact at 24, ECF No. 80. On December 14, 2021, I held a status conference in this matter to discuss whether preponderant evidence has been submitted showing that M.A.R. suffers from POI with an autoimmune etiology so that Petitioners may proceed under *Althen* prongs two and three. Sched. Order at 1, ECF No. 82. Petitioners requested sixty days to file updated medical records, including updated antibody test results, and a status report indicating whether this case will proceed or be dismissed, and I granted their request. *See id.*

Petitioners filed an unopposed motion for a sixty-day extension of time to file updated medical records or a status report indicating how they wish to proceed on February 14, 2022. ECF No. 83. I stayed Petitioners' motion and ordered them to file a status report indicating whether the case will proceed with expert reports on *Althen* prongs two and three or be dismissed; and/or an explicit motion to supplement Petitioners' request for sixty days to file medical records containing additional objective testing, including a timeline for the collection and submission of such filings. ECF No. 84.

On March 15, 2022, Petitioners filed a supplemental motion for an extension of time to file a motion to dismiss or a status report indicating how they wish to proceed. ECF No. 85. In support of their motion, Petitioners indicated that “[i]nitially, [M.A.R.] wanted to undergo additional testing, as her older sister suffers from an autoimmune disorder.” *Id.* at 1 (citing Pet’r’s Ex. 3 at 34). Petitioners continued that “[h]owever, due to documented severe psychiatric comorbidities experienced by [M.A.R.], her providers did not see how this would aid her in her treatment and in fact determined that it may hinder her psychiatric health.” *Id.* Petitioners requested additional time to determine how they wish to proceed. *Id.* at 2. I held a status conference with the parties on August 4, 2022, and noted that there remain unresolved issues relating to the factors set forth in my ruling on *Althen* prong one that would aid in my determination of vaccine-causation pursuant to prongs two and three. ECF No. 87. I also noted concerns about proceeding with this matter, given the mental health implications experienced by M.A.R. as a result of her condition. *Id.* Petitioners then filed an unopposed motion for a decision dismissing their petition. ECF No. 88.

To receive compensation under the Program, Petitioners must prove either (1) that M.A.R. suffered a “Table Injury”—i.e., an injury falling within the Vaccine Injury Table—corresponding to the vaccination, or (2) that M.A.R. suffered an injury that was actually caused by a vaccine. *See* §§ 13(a)(1)(A), 11(c)(1). An examination of the record did not uncover persuasive evidence that M.A.R. suffered from a “Table Injury.” Further, the record does not contain persuasive evidence

that M.A.R.'s injuries were caused-in-fact by her HPV vaccinations, as she cannot show by a preponderant standard that her POI is autoimmune in nature.

Under the Act, Petitioners may not be given a Program award based solely on their claims alone. Rather, the petition must be supported by medical records or the opinion of a competent physician. § 13(a)(1). In this case, the medical record is insufficient to prove Petitioners' claim, and at this time, Petitioners have not filed sufficient supporting evidence. Therefore, this case must be **dismissed for insufficient proof. The Clerk shall enter judgment accordingly.**³

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master

³ Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.