

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-332V

(Not to be Published)

SEAN SICARD,

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Chief Special Master Corcoran

Petitioner,

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Dated: January 13, 2021

v.

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SECRETARY OF HEALTH AND

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HUMAN SERVICES,

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Respondent.

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Andrew D. Downing, Van Cott & Talamante, Phoenix, AZ, for Petitioner.

Ryan Daniel Pyles, U.S. Dep’t of Justice, Washington, DC, for Respondent.

DECISION DISMISSING PETITION¹

On March 15, 2016, Dorothy Sicard filed a petition seeking compensation under the National Vaccine Injury Compensation Program (“Vaccine Program”),² on behalf of S.S., her minor child. Sean Sicard (previously identified by his initials) was thereafter substituted in as the

¹ Although this Decision has been formally designated “not to be published,” it will nevertheless be posted on the Court of Federal Claims’ website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012).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. *Id.*

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter “Vaccine Act” or “the Act”). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

named Petitioner on June 12, 2018, after reaching the age of majority. *See* ECF No. 57. Petitioner alleged that he developed antiphospholipid antibody syndrome (“APS”) and/or systemic lupus erythematosus (“SLE”) as a result of receiving his third human papillomavirus (“HPV”) vaccination on March 15, 2013. *See generally* Petition (ECF No. 1).

During the case’s life, Petitioner filed medical records from various treating physicians in support of his claim. *See e.g.*, ECF No. 7, Ex. 1–8. Respondent filed a Rule 4(c) Report on October 25, 2016, recommending that compensation was inappropriate in this matter, and that the case should be dismissed. ECF No. 18. Petitioner filed additional medical records on November 17, 2017. Ex. 10–13 (ECF No. 20); Ex. 13–14 (ECF No. 23). Petitioner also filed supporting medical literature through February and March of 2017, plus an initial expert report from his expert, Dr. Yehuda Shoenfeld. *See* ECF Nos. 28, 30–33; Report, dated January 17, 2017, filed as Ex. 13 (ECF No. 23-1) (“Shoenfeld First Rep.”). Respondent filed expert reports from Dr. Lindsay Whitton, an immunologist, and Dr. Carlos Rose, a rheumatologist, as well as supporting medical literature on May 8, 2017. Resp. Ex. A (“Whitton First Rep.”); Ex. A, Tabs 1–9 (ECF No. 34); Ex. A, Tabs 10–16 (ECF No. 35); Ex. B, Tabs 1–9 (ECF No. 36); Ex. B, Tabs 10–11 (ECF No. 37); Ex. C–D (ECF No. 38). In response, Petitioner filed supplemental expert reports from Dr. Shoenfeld and Dr. Thomas Zizic as well as supporting literature. *See* Report, dated March 7, 2017, filed as Ex. 15, (ECF No. 30-1) (“Shoenfeld Supp. Rep.”); Report, dated October 10, 2018, filed as Ex. 92 (ECF No. 59-1) (“Zizic First Rep.”); ECF Nos. 45–48, 50. *See* Ex. 49; Report, dated November 4, 2019, filed as Ex. 95 (ECF No. 78-1) (“Zizic Supp. Rep.”).

After numerous status conferences and an interim attorney’s fees award, the case was transferred to me from Special Master Roth on July 30, 2020. *See* July 30, 2020 Docket Entry Order. I held a status conference on September 28, 2020, at which time Petitioner acquiesced to my proposal that the case be resolved via ruling on the record. He filed his brief in support on November 30, 2020. ECF No. 93.

On December 11, 2020 however, Mr. Sicard filed what he styled a “Motion for a Decision Dismissing his Petition.” (ECF No. 94) (“Mot.”). In it, Petitioner requests that I dismiss his claim prior to issuance of a full written decision, based on his expressed desire to opt out of the Program and “pursue a third party action in district court” against the manufacturer of the HPV vaccine. Mot. at 2. He also requested that his November 2020 Motion for Decision on the Record be stricken as moot. *Id.* On December 28, 2020, Respondent filed a 24-page brief in reaction to Petitioner’s Motion (ECF No. 95) (“Resp.”). Respondent did not contest the relief sought in the Motion, but nevertheless felt compelled to provide a detailed, record-referencing explanation of his assessment for why the case should be appropriately dismissed on the merits with prejudice. Response at 1. Specifically, Respondent argued that Petitioner could not preponderantly establish all three of the required showings for a causation-in-fact vaccine injury claim under *Althen v. Sec’y of Health &*

Human Servs., 418 F.3d 1247 (Fed. Cir. 2005).³

PETITIONER'S CLAIM

Prior to evaluating the merits of Petitioner's motion to dismiss the case, some brief consideration of the evidentiary support for this claim is required—for the claim's course was rocky, and overall outlines circumstances in which a petitioner and his experts struggled to articulate a clear causation theory that had a chance of ultimate success.

In his initial expert report filed in this case, Dr. Shoenfeld opined that Petitioner's third dose of Gardasil precipitated his SLE and APS. First Shoenfeld Rep. at 9-15. Dr. Shoenfeld posited two possible mechanisms by which this may have occurred: (1) "Autoimmune Syndrome Induced by Adjuvants," or "ASIA", (Ex. 15 at 2), an unproven syndrome created by Dr. Shoenfeld,⁴ and (2) molecular mimicry due to homology between the vaccine's antigenic components and self amino acid sequences (Ex. 15 at 21). Special Master Roth subsequently noted that Dr. Shoenfeld's report cited eighty-six articles and ordered Petitioner to pare down the literature to "those that have a connection to the issues in this case." Order, dated Feb. 8, 2017, (ECF No. 24).

On February 20, 2017, Petitioner filed an amended report from Dr. Shoenfeld (Ex. 15) as well as thirty-three additional supporting citations as Exhibits 16–48 (refiled on March 7, 2017). Respondent's expert reports (from Drs. Whitton and Rose) were filed not long after. Both of Respondent's experts concluded that Petitioner's condition had no relationship to his Gardasil/HPV vaccine vaccination. In addition, Respondent filed an April 18, 2013 white paper from Dr. Whitton, titled "Review of the ASIA Hypothesis," as Exhibit C, as well as an April 29, 2013 white paper from medical toxicologist Edward W. Cetaruk, M.D., titled "ASIA – Dr. Shoenfeld's Theory of Vaccine-Induced Autoimmune Disease" as Exhibit D. On October 4, 2017, Petitioner filed a supplemental report from Dr. Shoenfeld, addressing Dr. Whitton's report. Ex. 49.

³ In particular, Respondent argued that Petitioner had not established by preponderant evidence that the HPV vaccination can cause Petitioner's condition in general. Resp. at 19. Petitioner also could not demonstrate a logical sequence of cause and effect showing that the HPV vaccine was the reason for his condition. *Id.* at 21. And Petitioner was unable to establish a medically-acceptable temporal relationship between vaccination and the onset of his alleged condition. *Id.* at 22. In addition, Respondent discussed the shortcomings of the initial and supplemental expert reports filed by Petitioner's expert, Dr. Shoenfeld, as well as the lack of new ground covered by Petitioner's supplemental expert, Dr. Zizic. *Id.* at 3.

⁴ I have repeatedly expressed skepticism as to the scientific reliability of ASIA as a vaccine injury causation theory. *See, e.g., Yalacki v. Sec'y of Health & Human Servs.*, No. 14-278V at *11 (Fed. Cl. Spec. Mstr. Jan. 31, 2019), *mot. for review den'd*, 146 Fed. Cl. 80 (2019); *Johnson v. Sec'y of Health & Human Servs.*, No. 14-254V, 2018 WL 2051760, at *7 n.11, *26 n.35. (Fed. Cl. Spec. Mstr. Mar. 23, 2018). I would have rejected it in this case as well for the same reasons, since it does not appear from the present record to be better supported than in prior actions. *Johnson*, 2018 WL 2051760, at *7 n.11, *26 n.35.

On October 23, 2017, Petitioner filed a second supplemental report from Dr. Shoenfeld addressing Dr. Rose's report. Ex. 50. On March 6-7 and 26, 2018, Petitioner filed forty-one additional literature citations as Exhibits 51-91. On April 19, 2018, Respondent filed supplemental reports and additional medical literature. *See* Ex. E; Ex. F; Ex. G.

In reaction to the foregoing, Special Master Roth noted in a June 2018 Order that

[d]espite the best efforts of petitioner's counsel and specific orders from the Court, petitioner's expert, Dr. Shoenfeld, has been unable to focus on the specific issues in this matter. During the conference today, petitioner's counsel was offered the opportunity to find another expert who would address the issues in this case. Petitioner's counsel advised that he has been working with a new rheumatologist who he believes can author an opinion in support of petitioner's claim and address the issues. It was agreed that petitioner should proceed with a new expert.

Based on the contemporaneous medical records, it appears that onset of [petitioner's] symptoms occurred in November or December of 2013. Accordingly, petitioner's new expert should explain how [petitioner's] receipt of the third HPV vaccine allegedly caused him to develop APL and SLE eight months after vaccination.

On October 10, 2018, Petitioner filed a report from a new expert rheumatologist Dr. Zizic. Dr. Zizic opined that Petitioner's ailments were the result of a biologic mechanism that was vaccine-induced and resulted in autoinflammatory/autoimmune disease. *Id.* at 38. This produced yet another round of expert filings from Respondent. *See* Report, dated March 11, 2019, filed as Ex. H (ECF No. 63-1) ("Whitton Second Rep."); Report, dated March 11, 2019, filed as Ex. I (ECF No. 64-1) ("Rose Rep."). On April 28 and May 4, 2020, Petitioner filed Dr. Zizic's literature citations as Exhibits 96-114. On June 23, 2020, Respondent filed a third supplemental expert report Dr. Whitton. Report, dated June 23, 2020, filed as Ex. J (ECF No. 88-11) ("Whitton Third Rep.").

ANALYSIS

The specific provisions under the Vaccine Rules for ending a case *before* a decision has been issued are largely inapplicable herein. Petitioner may no longer avail himself of Vaccine Rule

21(a)(1)(A), which governs voluntary dismissals before service of the Rule 4(c) Report (since that report was filed more than four years before), and Respondent has not stipulated to dismissal under Rule 21(a)(1)(B). In addition, even if the parties had so stipulated, Petitioner seeks entry of a judgment, whereas Vaccine Rule 21(a) would only result in an “order concluding proceedings.” Rule 21(a)(3).

Accordingly, the only remaining channel for the relief Petitioner requests is a “motion seeking dismissal”—an informal mechanism for ending cases developed in the Program that other petitioners have used, either because they have determined that the claim cannot succeed or simply because they choose not to continue with the claim (but arrive at that conclusion after the time for Rule 21 dismissal has passed). *See, e.g., Goldie v. Sec’y of Health & Human Servs.*, No. 18-1476V, 2019 WL 6045647, at *1 (Fed. Cl. Spec. Mstr. Oct. 11, 2019). Petitioners who wish to dismiss a case under these circumstances usually include in their dismissal motion an acknowledgement that the claim cannot succeed. These words are missing from Petitioner’s Motion—on the contrary, he takes pains to emphasize his view that the claim *could* be substantiated. Motion at 2. Petitioner does, however, acknowledge that any Decision dismissing the case at this point will not only be adverse to any parallel claim seeking relief in the Program, based on this vaccination, but also may well include some comment on the evidence filed. *Id.* at 2–3.

Thus, although it is true that the present circumstances do not afford Petitioner a means of dismissal directly under the Vaccine Rules, dismissal of petitions *can* still occur at this point in the claim’s life. Indeed, the rules of the Court of Federal Claims (which are properly applied herein)⁵ permit dismissal of claims at a petitioner/plaintiff’s request and “on terms that the court considers proper.” RCFC 41(a)(2).

I find Petitioner’s Motion is appropriately granted, even though it does not contain the customary acknowledgement that the claim cannot succeed in the Program. Expediency, judicial efficiency, and providing fairness to Vaccine Program claimants—values that constantly inform the work of special masters in deciding vaccine injury claims—all support allowing dismissal when requested by a petitioner. Dismissal of the case will obviate the need to write a lengthy decision, and cut off the prospect of future appeal as well (at least on matters not pertaining to attorney’s fees), thus further preserving judicial resources.

However, and in accordance with RCFC 41(a)(2), this Decision shall include an express

⁵ The Vaccine Rules specifically stated that the Rules of the Court of Federal Claims “apply only to the extent they are consistent with the Vaccine Rules,” and otherwise empower special masters to “regulate the applicable practice” under the Vaccine rules “[i]n any matter not specifically addressed” therein. Vaccine Rule 1(b) and (c). Here, I find that permitting dismissal—in the form stated in this Decision—based on a rule of the Court of Federal Claims is fully consistent with the Vaccine Rules, given that language of Vaccine Rule 21 does not cover voluntary dismissal by court order, whereas RCFC 41 does cover voluntary dismissal by court order. Thus RCFC 41(a)(2) addresses a situation not contemplated by Vaccine Rule 21.

limitation in order to make it conform to the requirements of Section 12(d)(3) of the Act. In particular, the matter is dismissed *with prejudice*. Rule 41(a)(2) gives the Court of Federal Claims discretion as to whether a dismissal should be with or without prejudice. *See Giesecke & Devrient GmbH v. United States*, 146 Fed. Cl. 631, 641 (Fed. Cl. 2020) (“[u]nder Rule 41(a)(2), a voluntary dismissal by court order is ‘without prejudice’ unless the court finds that the defendant will suffer legal prejudice, such as when a plaintiff ‘does not seek dismissal until a late stage’ in the litigation”). There are three factors to consider on whether a dismissal should be with or without prejudice: “(i) the burden on the defendant if the case were to be dismissed without prejudice; (ii) the progress of the litigation; and (iii) the diligence and good faith of the plaintiff.” *Klamath Irrigation District v. United States*, 116 Fed. Cl. 117, 119 (Fed. Cl. 2014).

Here, the late stage of the litigation—a case pending for over four years, featuring multiple experts and reports, full filing of relevant records and other proof, and ample briefing - weighs in favor of dismissal with prejudice. The case simply has advanced too far to be permitted to be dismissed at this late date, only to come to life possibly later if Petitioner or his counsel later have second thoughts about dismissal. I also dismiss with prejudice because this case, like others in which Mr. Downing is counsel, is yet another Program case involving the HPV vaccine being dismissed largely to avoid the possibility of an adverse determination by the Office of Special Masters. Although I do not find the Court Rules, the Vaccine Rules, or the Act itself prevent a petitioner from requesting eleventh-hour dismissal of their claim, the fact that this has become a trend in many of Mr. Downing’s cases (a fact he does not deny) means that he and his clients cannot expect the claim to have any possible “future” in the Program once dismissed under these circumstances.

Whether the present claim could have met the preponderant evidentiary standard required for a positive entitlement determination presents a more difficult question.⁶ In other HPV vaccine cases brought by Mr. Downing that he subsequently asked to be dismissed, my extensive familiarity with the causal theory in question (due to ruling on the same kind of claim previously) permitted me to state readily that the claim would not have succeeded. *See, e.g., Otto v. Sec’y of Health & Hum. Servs.*, No. 16-1144V, 2020 WL 4719285 (Fed. Cl. Spec. Mstr. June 17, 2020) (case dismissed after holding two-day trial, but noting that petitioner had not successfully met his burden of proof). This case, however, involves a different injury and theory, and it is evident from the claim’s history (in particular after the retention of Dr. Zizic) that Petitioner sought to improve and refine his claim, away from Dr. Shoenfeld’s largely-discredited ASIA theory.

Respondent certainly has pointed out numerous problems in the claim that I would have

⁶ I note that Respondent has not conceded that the claim possessed reasonable basis, and therefore may challenge any final fees request in this matter on that ground, although Petitioner clearly maintains the contrary. In addition, I will take into account the eleventh-hour abandonment of the claim in determining fees, as it is not a practice that should be rewarded in the Vaccine Program.

addressed had I been required to issue an entitlement decision. And an initial view of the filings and expert reports provides me with some doubt that Petitioner would have prevailed herein.⁷ Nevertheless, the primary similarity between this case and the prior HPV vaccine cases I have dismissed is the HPV vaccine. This is insufficient grounds for me to reasonably determine on dismissal that Petitioner could not have succeeded.

Despite the above, I do not find that granting dismissal obligates me to make an entitlement finding or even a “suggestion” of how I might have ruled. The Vaccine Rules empower special masters to dismiss cases for lack of prosecution, “for failure to prosecute or comply with these rules or any order of the special master or the court.” Rule 21(b)(1). No entitlement determination need be made under such circumstances. Here, Petitioner has expressly and on the record indicated he does not intend to pursue the claim, despite my prior ruling on the record order, as well as prior orders in this case (issued by two special masters) about the showing he would need to make. In effect, he has indicated an intent no longer to prosecute the claim—and therefore it is properly dismissed, despite an unwillingness to acknowledge that the claim was not likely to succeed.

CONCLUSION

Accordingly, and for the aforementioned reasons, Petitioner’s Motion for a Decision Dismissing the Case is hereby GRANTED, and the Petition is dismissed **with prejudice**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court **SHALL ENTER JUDGMENT** in accordance with the terms of this decision.⁸

IT IS SO ORDERED.

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

⁷ As acknowledged by Petitioner’s expert, Dr. Zizic, the causes of SLE remains unknown. Zizic First Rep. at 35. However, Dr. Zizic proffers the theory of molecular mimicry as causal of Petitioner’s conditions without presenting much evidence that HPV vaccine can trigger SLE, whether or not through molecular mimicry—or even that it can trigger *any* autoimmune disease (a contention that has not been evidentially-supported in other HPV vaccine cases I have decided). Dr. Zizic also argues that Petitioner is genetically susceptible to SLE, a point not disagreed with by Respondent’s experts. Whitton Rep. at 6. However, as Respondent’s expert Dr. Whitton points out, the safety of quadrivalent HPV vaccine in adolescents who already had SLE (and who would be most likely to develop a flare if HPV vaccine triggers the disorder) was evaluated, but it was concluded that even in these SLE-predisposed individuals, HPV vaccine was generally safe and well tolerated, with no increase in disease activity. *Id.*

⁸ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.