In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 12-87V

Filed: January 13, 2015

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LISA FAUP, parent of, A.F., a minor,	*	
	*	Special Master
Petitioner,	*	Hamilton-Fieldman
	*	
v.	*	
	*	Ruling; Motion for Summary
SECRETARY OF HEALTH	*	Judgment; Diphtheria-Tetanus-Acellular
AND HUMAN SERVICES,	*	Pertussis Vaccine ("DTap"), Inactivated
	*	Poliovirus Vaccine ("IPV"); Juvenile
	*	Idiopathic Arthritis ("JIA");
	*	Residual Effects for More Than Six Months.
Respondent.	*	
* * * * * * * * * * * * * * * * * * * *	*	

Christina Ciampolillo, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for Petitioner.
Jennifer L. Reynaud, United States Department of Justice, Washington, DC, for Respondent.

RULING DENYING RESPONDENT'S MOTION FOR SUMMARY JUDGMENT[1]

This matter is before the undersigned on Respondent's Renewed Motion for Summary Judgment filed on May 20, 2014 ("Renewed Motion"). In her Renewed Motion, Respondent argues that, even with the expert reports submitted by both parties, Petitioner is unable to prove by a preponderance of the evidence that A.F. suffered the residual effects of her alleged vaccine injury for more than six months after the administration of the vaccine. Renewed Motion at 3-4. Respondent further asserts that the abnormal values from A.F.'s lab test results, including those from September 16, 2009 and March 4, 2010, were, at best, the result of the medication A.F. was taking for her juvenile idiopathic arthritis ("JIA"), not from the JIA itself. *Id.* at 9, n.10. Therefore, Respondent argues, Petitioner "has failed to offer any evidence that A.F.'s test results

[1] Because this published ruling contains a reasoned explanation for the action in the case, the undersigned intends to post this ruling on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347 § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). As provided by Vaccine Rule 18(b), each party has 14 days within which to file a motion for redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). In the absence of such motion, the entire decision will be available to the public. *Id.*

indicate that she suffered the residual effects of her JIA for more than six months after she received the vaccinations on March 13, 2009," and Petitioner's claim must therefore be dismissed. *Id.* at 4.

Petitioner argues that the undersigned should reconsider the previous Special Master's ruling that the health effects and emotional distress associated with A.F.'s methotrexate treatment fail to satisfy the "more than six months of residual effects" requirement of §300aa-11(c)(1)(D)(i) of the Vaccine Act. [2] Petitioner's Opposition to the Respondent's Renewed Motion for Summary Judgment ("Response"), filed June 17, 2014, at 18-19, 21-22. Alternatively, Petitioner argues that the continued abnormal results from A.F.'s bloodwork represent residual effects of the underlying JIA disease, rather than artifacts of the methotrexate treatment, and therefore satisfy the more than six months residual effects requirement. Response at 19-21.

For the reasons set forth below, Respondent's Renewed Motion for Summary Judgment is DENIED.

I

PROCEDURAL HISTORY

On February 9, 2012, Lisa Faup ("Petitioner") filed a petition for compensation under the Vaccine Act, alleging that her child, A.F., developed a rheumatologic injury as a result of the diphtheria-tetanus-acellular pertussis ("DTaP") and inactivated polio ("IPV") vaccines administered on March 13, 2009. Petition ("Pet.") at 1.

Respondent filed a Rule 4(c) Report ("Resp't's Report") on June 18, 2012, recommending against compensation on the grounds that Petitioner had not established that A.F. "suffered the residual effects of her injury for more than six months after she received DTaP and IPV vaccinations on March 13, 2009." Resp't's Report at 1-2, 12.

Respondent reiterated the argument concerning the lack of six months of residual effects in her Motion for Summary Judgment ("Motion") filed on August 17, 2012. Motion at 1. Petitioner filed an Amended Petition and an Opposition to Respondent's Motion for Summary Judgment on October 5, 2012. Respondent filed a Reply on October 22, 2012.

The Chief Special Master, to whom the case was then assigned, issued a "Ruling on Respondent's Motion for Summary Judgment" ("Ruling") on February 26, 2013. The Chief Special Master found that "Petitioner cannot establish that A.F. suffered residual effects by pointing to either the health impact of A.F.'s prescribed medication or her attendant emotional response that manifested as a fear of receiving further shots." Ruling at 6. However, the Chief

[2] 42 U.S.C. §300aa-10, *et seq.* National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42. U.S.C. § 300aa (2006).

Special Master denied Respondent's Motion, finding that Petitioner was entitled to an opportunity to file a medical opinion concerning two unresolved issues of material fact: "(1) whether A.F.'s abnormal laboratory test results were indicative of ongoing problems with JIA; and (2) whether A.F.'s normal bone marrow biopsy constituted a surgical intervention under the Vaccine Act." *Id.* at 8.

Petitioner filed an expert report from pediatric rheumatologist Dr. Robert Sundel on September 12, 2013, and Respondent filed an expert report from pediatric rheumatologist Dr. Carlos Rosè on January 13, 2014. Petitioner's Exhibit ("Pet'r's Ex.") 20; Respondent's Exhibit ("Resp't's Ex.") A. During an April 22, 2014 status conference, Petitioner conceded that there was no surgical intervention in this case. Errata correcting Non-PDF Order, filed May 8, 2014.

Respondent filed her Renewed Motion on May 20, 2014, to which Petitioner responded on June 17, 2014. The matter is now ripe for ruling on the Renewed Motion.

II

FACTUAL BACKGROUND

A.F. was the first of three female triplets born on March 9, 2004. Pet'r's Ex. 1 at 1. Other than "an innocent heart murmur," her early medical history was unremarkable. *Id*. at 27-28. She had all of her early immunizations without incident. *Id*. at 2.

On March 13, 2009, A.F. had a kindergarten entrance physical examination. Pet'r's Ex. 14 at 1. During this examination, A.F. received the DTaP and IPV vaccinations at issue in this case. *Id.* Two days later, A.F. developed a fever of 104°F, a fever which lasted three days. Pet'r's Ex. 1 at 16. She also developed a rash, which became worse over the next few days, as well as elbow, ankle, and knee pain, and swollen joints. *Id*. Petitioner took A.F. to the pediatrician with these concerns on March 20, March 25, and March 27, 2009. *Id*. The pediatrician prescribed prednisone. *Id*.

On April 16, 2009, pediatric rheumatologist Yukiko Kimura, M.D., diagnosed A.F. with JIA. Pet'r's Ex. 5 at 1-2. After A.F. experienced a number of disease flare-ups and a severe complication of JIA known as macrophage activation syndrome ("MAS")[3], A.F. was started on a

[3] Macrophage activation syndrome is "a life-threatening complication of rheumatic disease that, for unknown reasons, occurs much more frequently in individuals with systemic juvenile idiopathic arthritis (SJIA) and in those with adult-onset Still disease. Macrophage activation syndrome is characterized by pancytopenia, liver insufficiency, coagulopathy, and neurologic symptoms and is thought to be caused by the activation and uncontrolled proliferation of T lymphocytes and well-differentiated macrophages, leading to widespread hemophagocytosis and cytokine overproduction." Macrophage Activation Syndrome, emedicine.medscape.com, http://emedicine.medscape.com/article/1380671-overview (Last visited December 29, 2014).

course of methotrexate[4] on June 16, 2009. *Id.*; Pet'r's Ex. 1 at 47.

A.F. had a follow-up visit with Dr. Kimura on August 27, 2009. Pet'r's Ex. 5 at 54-55. She noted that A.F. still had trace swelling in her ankle and had a low blood count. *Id.* Dr. Kimura did not decrease A.F.'s dosage of methotrexate at this time. *Id.* A.F.'s methotrexate dosage began to be tapered off December 1, 2009. *Id.* at 57-58. At a July 13, 2010 medical appointment with Dr. Kimura, A.F. was noted to have stopped taking methotrexate completely six weeks before the appointment. Pet'r's Ex. 5 at 65-67. A.F. was noted as functioning well without the medication; her lab results, however, continued to be abnormal. *Id.* at 65-67, 78-79.[5]

III

APPLICABLE LEGAL STANDARD

Pursuant to the Rules of the Court of Federal Claims ("RCFC") 56(a) and Vaccine Rule 8(d), the court shall enter judgment in favor of the moving party if there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. *See Jay v. Sec'y of Health & Human Servs.*, 998 F.2d 979, 982-83 (Fed. Cir. 1993). In ruling on a motion for summary judgment, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 982 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)).

Congress established the Vaccine Program in 1988. *See* 42 U.S.C. §300aa-1-34. The goals of the Vaccine Program were to "compensate vaccine-injured persons and to protect the nation's vaccine supply by limiting the exposure of vaccine manufacturers to resource-depleting lawsuits." *Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *5 (Fed. Cl. Spec. Mstr. Jan. 16, 2014). *See also Bruesewitz v. Wyeth LLC*, 131 S.Ct. 1068, 1072 (U.S. 2011).

To proceed with a claim for compensation under the Vaccine Act as originally enacted, a petitioner must have "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. § 300aa-11(c)(1)(D)(i). "Congress included the 6 month petition requirement 'to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine.' H.R.Rep. No. 100-391(I), at 699 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, -373 . . . [T]his provision, along with the other petition requirements, is intended to

[4] Methotrexate is defined as "a folic acid antagonist that acts by inhibiting synthesis of DNA, RNA, thymidylate, and protein . . . It is also used as an antipsoriatic and antiarthritic in the treatment of severe, recalcitrant, disabling psoriasis and severe rheumatoid and psoriatic arthritis." Dorland's Illustrated Medical Dictionary 1151 (32d ed. 2012).

[5] As noted in the earlier Special Master's "Ruling on Respondent's Motion for Summary Judgment" in this case, "A.F.'s white blood cell count (WBC) and creatine (CREA) levels were low, and her lactate dehydrogenase (LDH) levels were high." Ruling at 4.

restrict eligibility to the compensation program." *Cloer v. Sec'y of Health & Human Servs.,* 654 F.3d 1322, 1335 (Fed. Cir. 2011) (en banc*), aff'd*, 133 S.Ct. 1886 (2013).

The current version of the Vaccine Act has two avenues for living vaccinees to establish eligibility for compensation under the Act: either the vaccinee "(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine," or the vaccinee "(iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention." 42 U.S.C. §300aa-11(c)(1)(D)(i)-(iii).

A petitioner must satisfy the requirement of more than six months of residual effects or of surgical intervention coupled with inpatient hospitalization, as "a condition precedent to filing a petition for compensation." *Cloer*, 654 F.3d at 1335. As with all elements of a vaccine claim, the conditions precedent must be proven by preponderant evidence. 42 U.S.C. § 300aa-13(a)(1)(a); *Black v. Sec'y of Health & Human Servs.*, 93 F.3d 781, 785-87 (Fed. Cir. 1996). "A potential petitioner must do something more than merely submit a petition and an affidavit parroting the words of the statute" to go forward with a claim under the Act. *Black v. Sec'y of Health & Human Servs.*, 33 Fed. Cl. 546, 550 (1995), *aff'd*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted). "He or she must submit supporting documentation which reasonably demonstrates" that the injury or its sequelae lasted more than six months, or that surgical intervention and inpatient hospitalization took place. *Id*.

IV

ANALYSIS

The parties submitted expert reports in response to the previous Special Master's ruling on Respondent's First Motion for Summary Judgment. Based on those reports, the undersigned concludes that the abnormal bloodwork results were not a symptom of A.F.'s underlying JIA condition. However, in light of the significant new evidence presented in the expert reports, the undersigned also finds that this conclusion is not dispositive of the parties' dispute regarding the more than six months requirement. Both experts discussed the medical necessity for the methotrexate treatment, and agreed that once A.F. had responded to the treatment, "the primary goal of treatment [was] to make sure that the disease [did] not relapse, as such recurrences of arthritis may fail to respond to previously effective treatments." Pet'r's Ex. 20 at 3-4; *see also* Resp't's Ex. A at 10 ("[t]he possibility of developing another episode of MAS or of evolving to severe erosive disease is the main reason why this reviewer agrees with Dr [sic] Kimura's insistence on keeping the drug on for one year despite absence of symptoms or laboratory abnormalities"). Dr. Rose noted that "[a]lthough effective therapy is recommended to control the disease as early as possible, we don't know if such intervention has anything to do with the achievement of remission, yet most of us agree that judicious use of a medication like Methotrexate is necessary simply because we do not know who, at disease onset, is earmarked to follow a more or a less favorable course." Resp't's Ex. A at 10. Finally, Dr. Rose agreed with Dr. Sundel that the methotrexate treatment "contributed to control [A.F.'s] symptoms and to prevent the developing of permanent joint damage." *Id.* at 14. Neither expert opined that A.F.'s JIA had been "cured" at six months post-vaccination.

Because determining the existence, or lack thereof, of clinical symptoms of a disease is the most obvious and logical means of evaluating the duration of the "residual effects or complications" of that disease, it is understandable that the concepts are often conflated. However, "residual effects or complications" and "symptomatic" are not synonymous; one can suffer from a disease without exhibiting any clinical signs thereof. In this case, the experts agree that A.F. was not exhibiting symptoms of JIA more than 6 months post-vaccination at least in part because she was medicated to prevent the occurrence of those very symptoms. Under those circumstances, the undersigned concludes that the ongoing need for medication to prevent symptoms and/or relapse of the alleged vaccine-caused illness constitutes a residual effect or complication of that illness.[6] The undersigned finds that A.F.'s need for the medication existed for more than six months after the administration of the vaccines that allegedly caused her illness. Respondent's Renewed Motion for Summary Judgment is therefore denied.

V

CONCLUSION

Pursuant to the foregoing discussion, **Respondent's Renewed Motion for Summary Judgment is DENIED**. The undersigned's chambers will contact counsel to schedule a status conference to determine the appropriate next steps in the case.

IT IS SO ORDERED.

/s/ Lisa D. Hamilton-Fieldman
Lisa D. Hamilton-Fieldman
Special Master

[6] The previous Ruling focused on the side effects of the methotrexate, and distinguished between those side effects as "subsequent treatment of the injury" and "the ongoing health impact of a vaccine injury." Ruling at 6. The expert reports submitted in response to that Ruling make it clear that A.F.'s treatment with methotrexate is an "ongoing health impact" of her alleged vaccine injury.