

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-467V

(E-Filed: June 7, 2013)

* * * * *

DEMETRICE MATHIS, parent of
N.M., a minor,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

* * * * *

*
*
*
*
*
*
*
*
*
*
*

TO BE PUBLISHED

Special Master
Hamilton-Fieldman

Show Cause Order; Results of Genetic
Testing for SCN1A Mutation; Diphtheria
Tetanus Acellular Pertussis (DTaP)
Vaccine; Dravet Syndrome.

ORDER TO SHOW CAUSE¹

I. INTRODUCTION AND SUMMARY

On July 21, 2009, Petitioner Demetrice Mathis (“Petitioner”) filed a petition on behalf of her daughter, N.M., for compensation under the National Childhood Vaccine Injury Act of 1986 (the “Act”), 42 U.S.C. § 300aa-10 *et seq.* (2006).² The petition

¹ The undersigned intends to post this Order to Show Cause on the United States Court of Federal Claims’s 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 Order will be available to the public. *Id.*

² The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 *et seq.* (2006). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

alleged that N.M. suffered a seizure disorder as a result of receiving a diphtheria-tetanus-acellular pertussis (“DTaP”) vaccination on August 10, 2006. On March 22, 2010, Respondent (the “Secretary”) filed a report pursuant to Vaccine Rule 4(c), maintaining that compensation was inappropriate and that the Petition should be dismissed. Resp’t’s Rule 4(c) Rep. at 17-18, ECF No. 13.

The case was heard before Special Master Dee Lord in Boston, Massachusetts, on August 11, 2011. Following the hearing, the Court ordered that the parties collaborate to arrange for N.M. to undergo genetic testing. Order at 1, Aug. 12, 2011, ECF No. 50. In a Joint Status Report (“JSR”) filed on October 7, 2011, Petitioner notified the Court that “Demetrice does not consent to any further genetic testing on [N.M.]” JSR, ECF No. 53. Thereafter, the Court entered into the record Court Exhibits 1-4, and ordered the parties to file supplemental expert reports “discussing whether and to what extent [N.M.] meets the diagnostic factors for Dravet syndrome and describing the testing procedures that would have been used to determine whether [N.M.] has SCN1A gene abnormalities.” Order at 1, Nov. 21, 2011, ECF No. 55.

After reviewing those additional reports as well as the remainder of the record as it existed at that time, Special Master Lord held as follows:

In sum, Petitioner presented preponderant evidence in support of a theory that DTaP vaccine, and its pertussis component in particular, could have caused [N.M.]’s seizures. Petitioner also established an appropriate proximate temporal relationship between [N.M.]’s receipt of the DTaP vaccine and the onset of her initial seizure 36 hours later.

The evidence of a logical sequence of cause and effect showing that the vaccine caused [N.M.]’s injuries does not preponderate in Petitioner’s favor, however. Respondent’s expert asserted that [N.M.]’s symptoms were consistent with a genetic disorder caused by a point mutation in the SCN1A gene. Petitioner’s expert maintained that a genetic cause was unlikely, based on [N.M.]’s medical record, but agreed that the results of genetic testing could be relevant to his opinion.

I find that Respondent’s contention is reasonable in light of the facts of the case and the known causes of certain epileptic disorders in children. Accordingly, Petitioner must furnish evidence that [N.M.] does not have a point mutation of the SCN1A gene. Such testing results will determine whether the evidence preponderates in Petitioner’s favor under Althen Prong 2. Absent results of the genetic testing, which is readily available, minimally invasive, and will be paid for by Respondent, Petitioner has not provided necessary rebuttal evidence, and has therefore failed to make out her case-in-chief.

Order to Show Cause at 2, Sept. 18, 2012, ECF No. 61. Rather than arranging for N.M. to undergo this genetic testing, however, on October 18, 2012, Petitioner filed a Response to the Court's Show Cause Order, again arguing that "[N.M.] has provided preponderant evidence that [] she does not suffer an SCN1A mutation" and therefore no genetic testing is necessary. Pet'r's Resp. at 4, Oct. 18, 2012, ECF No. 67. Petitioner also conditioned her consent to the genetic testing as follows:

The petitioner is willing to move forward with genetic testing if there is assurance that this court will rely on the statements of the former special master in her September 18, 2012 order to show cause: If [N.M.] is tested and the evidence showed that she does not have an SCN1A genetic mutation, she will be found entitled to compensation.

Id., at 9.

The case was transferred to the undersigned on March 4, 2013,³ and by Scheduling Order dated March 21, 2013, Respondent was permitted to file a reply to Petitioner's Response. In her Reply, filed April 11, 2013, Respondent cites 42 U.S.C. §300aa-13(b)(1) in support of her argument that "[t]he Court is not bound by the genetic test result." Resp't's Reply at 6, Apr. 11, 2013, ECF No. 71. Respondent also argues that "both parties must be granted the opportunity to litigate the impact of the test result on this case through their respective expert's testimony," *id.*, and that the special master must then evaluate the record as a whole, including the testing, to determine whether Petitioner is entitled to compensation. *Id.*

DISCUSSION:

Proceedings under the Vaccine Act are intended to be user-friendly and less adversarial than other litigation. RCFC App. B, Rule 3(b)(2); *see also Rodriguez v. Sec'y of Dep't of Health & Human Servs.*, 632 F.3d 1381, 1385 (Fed. Cir. 2011) ("[T]he Vaccine Act provides petitioners with an alternative to the traditional civil forum, applies relaxed legal standards of causation, and has eased procedural rules compared to other federal civil litigation."). At the same time, each party to the proceedings must be afforded "a full and fair opportunity to present its case." RCFC App. B, Rule 3(b)(2). "In receiving evidence, the special master. . . must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties." RCFC App. B, Rule 8(b)(1). This mandate that a special master's decision should be premised on a complete record is also set forth in numerous cases. *See, e.g., Hines v. Sec'y of Dep't of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991)(stating that the special

³ Reassignment was as a result of the resignation of Special Master Dee Lord from service as a special master.

master is to consider the relevant evidence in the record as a whole); *Isaac v. Sec’y of Dep’t of Health & Human Servs.*, 108 Fed.Cl. 743, 768 (2013), *appeal docketed*, No. 08-0601V (Fed. Cir. April 2, 2013)(acknowledging that the special master did not exclude evidence, and “[i]ndeed. . .took the initiative to introduce [evidence]” and gave the parties opportunity to address the new material).

In the present case, Special Master Lord twice held that N.M. should undergo genetic testing to ascertain “whether [N.M.] has SCN1A gene abnormalities.” Order at 1, Nov. 21, 2011, ECF No. 55; Order to Show Cause at 2, Sept. 18, 2012, ECF No. 61. Twice Special Master Lord concluded, after thorough review and analysis, that “[t]esting is necessary in order to adjudicate the claim for compensation properly, complete the record and give each side a full and fair opportunity to litigate the issues.” Order to Show Cause at 30, Sept. 18, 2012, ECF No. 61; JSR at 1, Oct. 7, 2011, ECF No. 53. Nothing has changed in this case since these orders except the special master assigned to preside over it. That is not the kind of change that warrants providing Petitioner with a third bite of this particular apple. Without the test results and expert reports interpreting those results, the record is incomplete and does not support an award of compensation to Petitioner.

The Court also cannot provide Petitioner with the “assurance” she requests that “[i]f [N.M.] is tested and the evidence showed that she does not have an SCN1A genetic mutation, she will be found entitled to compensation.” Pet’r’s Resp. to Order to Show Cause at 9, Oct. 18, 2012, ECF No. 67.⁴ Just as “fundamental fairness to both parties,” RCFC App. B, Rule 8(b)(1), requires that “[i]f [N.M.]’s testing reveals a genetic mutation, Petitioner will have the opportunity to litigate the impact of the mutation on this claim,” Order to Show Cause at 30, Sept. 18, 2012, ECF No. 61, so too does it require that if N.M.’s testing does not reveal a genetic mutation, Respondent must be granted the opportunity to litigate the impact of that test result on the arguments she has advanced in this case. Only when the test results are available and both parties have had an opportunity to integrate those results into their respective experts’ testimony, will the record be complete and ripe for a decision on entitlement.

CONCLUSION/ORDER:

Petitioner shall file proof that she has submitted N.M. for SCN1A testing no later than Friday, July 5, 2013. By complying with this order, Petitioner is being given a final

⁴ Citing to Order to Show Cause at 28, Sept. 18, 2012, ECF No.61 (“If [N.M.] were tested and the evidence showed that [N.M.] did not have genetic mutation that could account for her condition, the evidence presented by Petitioner, although scant, would prevail.”) A special master is not required to adhere to her previous rulings in a case unless those rulings have been adopted, explicitly or implicitly, by an appellate court’s judgment. *Exxon Corp. v. United States*, 931 F.2d 874, 877 (Fed. Cir. 1991).

opportunity to “show cause” why her case should be allowed to continue. Failure to file such proof will result in the dismissal of Petitioner’s claim.

If Petitioner does proceed with testing, her expert report discussing the implications of the test results, along with the test results themselves and any exhibits and literature upon which the expert report relies, shall be filed no later than 35 days after Petitioner receives the results of the tests. Respondent’s responsive expert report, with exhibits and literature, shall be filed no later than 35 days after Petitioner’s expert report is filed. The record will then be complete, and the special master will take it under advisement for ruling.

IT IS SO ORDERED.

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