In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: March 4, 2016

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DREYTON JAKES,	*	
	*	No. 06-831V
Petitioner,	*	
	*	Special Master Hamilton-Fieldman
v.	*	
	*	Exclusion of evidence; onset
SECRETARY OF HEALTH	*	determination.
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
* * * * * * * * * * * * * * * * * *		

ORDER DENYING MOTION TO EXCLUDE AND FINDING OF FACT CONCERNING ONSET OF SYMPTOMS[1]

On December 7, 2006, Carol Jakes filed a petition on behalf of her minor son, Dreyton Jakes ("Petitioner"),[2] pursuant to the National Vaccine Injury Compensation Program.[3] Ms. Jakes, who was *pro se*, alleged that Dreyton received an influenza ("flu") vaccination on

[1] Because this published order contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this order on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, (codified as amended at 44 U.S.C. § 3501 note (2012)). As provided by Vaccine Rule 18(b), each party has 14 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 entire order will be available to the public. *Id.*

[2] Petitioner was a minor at the time of the filing, and his mother filed the action on his behalf. Once he reached the age of majority, the caption was amended to name Dreyton Jakes as the petitioner. *See* Order, filed June 18, 2015.

[3] The National Vaccine Injury Compensation Program is set forth in 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.A. § 300aa-10-§ 300aa-34 (2012) ("Vaccine Act" or the "Act"). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

December 12, 2003, and that the flu vaccination caused him to suffer from neurological injuries. The case is presently before the undersigned on Petitioner's Motion to Exclude Portions of Medical Records ("Pet. Mtn."), filed October 14, 2015, and for resolution of the underlying factual dispute concerning onset of the symptoms of Petitioner's alleged vaccine injury.

A detailed procedural history of the case was set forth by the undersigned in an Order to Show Cause filed June 4, 2015. The portions of that history relevant to the present dispute concerning reliability of medical records and onset of symptoms are repeated herein to provide context for the present findings and orders:

During a status conference conducted on August 12, 2013 by Special Master Zane (who previously presided over this matter), Petitioner's counsel, Mr. Fialkow, advised that Petitioner "was not prepared to proceed to hearing with her current expert." See Order, dated August 13, 2013, at 1. Mr. Fialkow "advised that[,] based upon review of[,] and upon discussions with[,] her expert regarding Respondent's expert's opinion [regarding] the temporal relationship between the receipt of the vaccination and the onset of injury, [an injury onset of] less than 24 hours was too short to have been due to autoimmune response." Id. Mr. Fialkow instead wished to proceed by exploring other potential theories of neurotoxicity or allergic response. Id. Special Master Zane granted Petitioner additional time to explore a new theory and directed her to file a supplemental expert report by no later than November 29, 2013. Id. at 1-2. Mr. Fialkow made and withdrew a request to depose Respondent's expert; Special Master Zane explained that such depositions are unusual in the Vaccine Program, and that Mr. Fialkow's request was premature. Id.

This case was subsequently reassigned to the undersigned. See Order Reassigning Case, dated September 4, 2013. Petitioner failed to file a supplemental expert report by November 29, 2013, and filed nothing further until January 10, 2014, when the undersigned issued an Order to Show Cause why the case should not be dismissed for failure to prosecute. Petitioner's response to the Show Cause Order was due no later than February 7, 2014. See Order, filed January 10, 2014, at 1. Petitioner ultimately filed a timely request for, and was granted, an extension to file her expert report, see Petitioner's Status Report, filed January 22, 2014, and Non-PDF Order, filed January 23, 2014, which was ultimately filed on March 19, 2014. See Pet. Ex. A, filed January 23, 2014. Petitioner's new expert, Dr. Evgeny Tsimerinov, opined that "the Influenza vaccination triggered a molecular response of not only against the [sic] Influenza vaccine antigen but also against the native brain and spinal cord myelin antigen, which led to the patient's neurological symptoms." Id. at 5. Dr. Tsimerinov appears to have believed that D.J.'s vaccine-caused injury was acute disseminated encephalomyelitis ("ADEM"). Id. at 3.

Respondent filed a second expert report, authored by Dr. Sriram, on June 17, 2014. See Resp. Ex. C. Dr. Sriram again opined that D.J. had pre-clinical MS at the time of vaccination,

not ADEM, and that it was not biologically plausible for the vaccine to have aggravated his condition. Id. at 3-4.

During a status conference conducted on July 23, 2014, Mr. Fialkow renewed his previous request to depose Respondent's expert. Noting that discovery generally is not permitted in the Vaccine Program, the undersigned denied Mr. Fialkow's request, but granted him the opportunity to follow up with a written motion. See Order, filed July 24, 2014, at 1-2. The undersigned also directed Petitioner to file, by no later than August 20, 2014, a status report containing a deadline for the filing of his supplemental expert report (or proposing an alternative schedule). Id. The undersigned granted Petitioner until August 6, 2014, to file a discovery motion, but no such motion was ever filed. Id.

Petitioner subsequently requested and was granted an opportunity to file a second amended petition. See Petitioner's Motion, filed August 8, 2014; Non-PDF Order, filed August 12, 2014. Petitioner's new petition alleged that the onset of D.J.'s injury had occurred as of December 15, 2003, three days post-vaccination, when D.J.'s teacher reported to his parents "a decrease in visual acuity in that [D.J.] seemed to be having a hard time seeing the board." Second Amended Petition, filed August 18, 2014, at 1.

Another status conference took place on August 19, 2014, during which the undersigned directed Respondent to file a status report documenting whether she agreed with Petitioner that the onset of D.J.'s injury onset took place within 48-52 hours of vaccination. See Non-PDF Order, filed August 19, 2014. Respondent took the position that, in light of the contemporaneous medical records, the onset of D.J.'s injury had occurred on December 12, 2003, the same day as the vaccination. See Status Report, filed October 3, 2014, at 2-3. Respondent argued that the undersigned could make such a finding without holding a fact hearing. Id.

The undersigned conducted a third status conference on October 21, 2014. See Order, dated October 23, 2014, at 1. The undersigned agreed with Respondent's assessment of the onset date, but granted Mr. Fialkow the opportunity to conduct further investigation into the date of onset. Id. In order to prove that D.J.'s symptoms began on December 15th, not December 12th, Mr. Fialkow wished to obtain D.J.'s school attendance records and to interview the teacher who purportedly observed D.J.'s symptoms on the relevant date(s). Id. The undersigned granted Mr. Fialkow additional time to locate the teacher and the records, but ordered that, in the event that he was able to locate the teacher, he not speak with her. Id. Instead, a fact hearing would be held so that the undersigned could observe the teacher's demeanor when questioned about her ability to recall events from 11 years earlier, including D.J.'s symptoms. Id. The undersigned ordered Mr. Fialkow to file a status report regarding the progress of his investigation by no later than December 16, 2014. Id.

On December 16, 2014, Mr. Fialkow filed a status report in which he requested additional time to locate the teacher, whom he had recently been able to identify. The undersigned granted this request and directed Mr. Fialkow to file another status report by February 17, 2014. See Order, filed December 17, 2014, at 1. On February 24, 2015, Mr. Fialkow reported that, although he had the teacher's name, he had yet to locate her. See Status Report, filed February 24, 2015, at 1-2. Mr. Fialkow made no mention of school attendance records. Id. He reiterated his request that the undersigned revisit prior rulings. Id.

The undersigned conducted another status conference on April 7, 2015, during which the parties agreed to collaboratively compose a letter to D.J.'s teacher regarding her memory of the events at issue. See Order, filed April 8, 2015, at 1. Mr. Fialkow indicated that he had had difficulty obtaining D.J.'s school attendance records, and the undersigned suggested that he request subpoena authority. Id. The undersigned also directed Mr. Fialkow to file declarations from any other relevant fact witnesses. Id.

Since that time, the undersigned has convened a number of status conferences. Petitioner has filed several hundred pages of records obtained pursuant to a subpoena served on Petitioner's elementary school. *See* Petitioner's Exhibit ("Pet. Ex.") 29. He has also filed a letter from Ms. Julie Bogetti, which was the result of Petitioner's attempts to locate the first grade teacher who contacted his mother during the disputed time period concerning Petitioner's loss of vision and inability to see the board. *See* Pet. Ex. 30. Ms. Bogetti's letter stated that she had not been Petitioner's teacher. *Id.*

Petitioner's Motion to Exclude included a "Memorandum of Points and Authorities" paginated consecutively with the Motion. Petitioner also filed the Declaration of Carol Jakes, his mother ("Decl. Carol Jakes") and the Declaration of Andre Jakes, his father ("Decl. Andre Jakes") on October 14, 2015. Respondent's Response to the Motion was filed November 13, 2013 ("Resp. Response"); Petitioner's Reply was filed November 19, 2015 ("Pet. Reply").

MOTION TO EXCLUDE

In his Motion, Petitioner seeks to exclude

> any and all evidence, references to evidence, testimony or argument relating to the following portions of the medical records originally filed by Petitioner which inaccurately and incompletely refer to the onset of DJ's medical condition, namely: (a) at page 762 "mother has noticed at home past couple of days sitting too close to television unable to see" and "three days ago"; (2) at page 770 "Initial consult states onset of visual loss is uncertain. First noticed by teacher on December 12, 2003, the same day he received his influenza vaccine" and "on Sunday afternoon he complained about being tired and that

> his leg hurt and his mother asked why he was sitting close to the T.V., then reported that he had told he had trouble seeing the T.V. and then Sunday went to sleep"; (3) at page 789 "His teacher noted decreased vision on Friday and moved closer to the board"; and (4) at 856 "the patient's teacher noted the patient having difficulties with vision on Friday, 12/12/2003. Over the weekend, the patient's family also noted the patient having increasing trouble seeing, complaining of inability to see the clock or the television."

Pet. Mtn. at 1.

Petitioner's first argument in favor of exclusion is that the records he seeks to exclude are hearsay, or hearsay within hearsay, citing Federal Rules of Evidence ("Rules") 801(a), 802, and 805. Mtn. at 3-4. He asserts that the records are "inaccurate and incomplete" and should therefore be excluded in favor of later medical records which are supported by the affidavits of his parents filed with his Motion. Pet. Mtn. at 3.

The Federal Rules of Evidence do not apply in Vaccine Program cases. *See* RCFC App. B, Rule 8 (b)(1) ("In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties."); *see also* 42 U.S.C. §300aa-12(d)(2)(B)(standards applicable to admissibility of evidence in Vaccine Act cases are to be "flexible and informal"). Even assuming for sake of argument that the Federal Rules of Evidence applied in Vaccine Program cases, Rule 803(4) provides an exception to the hearsay rule, regardless of the availability of the declarant, for "Statement[s] Made for Medical Diagnosis or Treatment," including statements "made for – and reasonably pertinent to – medical diagnosis or treatment," and statements that "describe[] medical history; past or present symptoms or sensations; their inception; or their general cause." This exception was adopted "in view of the patient's strong motivation to be truthful," Rule 803, advisory committee's note to 1972 proposed rules of evidence, and clearly encompasses the records at issue here. Thus, the evidence Petitioner seeks to exclude is admissible under the Federal Rules of Evidence, and should not be excluded on that basis.

Under the rules governing cases brought pursuant to the Vaccine Act, the same standards concerning reliability of medical records created contemporaneously with the illness or injury they address apply. In *Cucuras v. Secretary of Health and Human Services,* 933 F.2d 1525, 1528 (Fed. Cir. 1993), the Federal Circuit found this category of evidence reliable, explaining that medical records "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions …. [w]ith proper treatment hanging in the balance, accuracy has an extra premium."

Petitioner asserts that the records he seeks to exclude are inaccurate and incomplete because, in essence, his mother says they are. *See, e.g.*, Pet. Mtn. at 3 *quoting* Decl. Carol Jakes at 4 ("[Ms. Jakes] never told anybody that Dreyton's [sic] had any visual problems that started on Friday or that he had any problems on Friday, because he didn't …. [Ms. Jakes] looked at the medical records and they are not very precise and at times they are inaccurate."). While this argument can certainly be considered in determining what weight to give to these records vis-à-vis the remaining medical records, it provides absolutely no legal basis for excluding the records from consideration at all.

Finally, Petitioner's Motion to Exclude Records does not comport with either the letter or the spirit of the Vaccine Act, which requires that complete medical records be filed with the petition, 42 U.S.C. §300aa-11(c)(2), requires the special master to consider the record as a whole, 42 U.S.C. §300aa-13(a)(1), and mandates "flexible and informal standards of admissibility of evidence." 42 U.S.C. §300aa-12(d)(2)(B).

For the reasons set forth above, Petitioner's Motion to Exclude Records is DENIED.

FINDING OF FACT CONCERNING ONSET

Turning now to the underlying issue of onset, the issue as framed by the parties is this:

Did Petitioner develop symptoms of his alleged vaccine-caused neurological injuries, specifically, problems with his eyesight, within 24 hours or less of receiving the vaccine, i.e., December 12, 2003, or did those problems only begin to develop Sunday night, December 14, 2003, approximately 48 to 52 hours after vaccination? Petitioner argues in favor of the latter, later onset, Petitioner's Motion to Exclude and Memorandum of Points and Authorities; Respondent in favor of the former, earlier onset. *See* Respondent's Status Report concerning onset filed October 3, 2014.

There is no dispute that Petitioner received a flu vaccine on December 12, 2003. There is also no dispute that the medical records from Monday, December 15 and Tuesday, December 16, 2003, when Petitioner first presented to medical professionals with vision problems, state that the problems began on Friday, December 12, 2003. These are the records that Petitioner seeks to exclude, excerpts of which are set forth at some length below. Petitioner disputes the accuracy and completeness of those medical records, and asserts that in making her factual determination concerning onset, the undersigned should rely instead on medical records created approximately 90 days after onset, beginning March 17 and March 20, 2004, and on the affidavits of Petitioner's parents filed in conjunction with his Motion.

The undersigned agrees with Petitioner that the *Cucuras* presumption in favor of the accuracy and reliability of medical records prepared contemporaneously with the events being described in those records is a rebuttable one. 993 F.2d 1525, 1528 (Fed. Cir. 1993); s*ee also Camery v. Sec'y of Health & Human Servs.,* 42 Fed. Cl. 381, 391 (1998) (the rule set forth in *Cucuras* "should not be applied inflexibly, because medical records may be incomplete or inaccurate"); Pet. Mtn. at 4. The undersigned has, for example, found that a vaccine was administered even in the absence of a contemporaneous record documenting the vaccination. *See Figueroa v. Sec'y of Health & Human Servs.*, No. 10-750V, 2014 WL 6819494, at *4 (Fed. Cl. Spec. Mstr. Nov. 7, 2014). In the present case, however, there is not just one missing or anomalous record. There are at least four different records, from at least four different medical professionals, from at least two different medical facilities (Kaiser Stockton and Dameron Hospital), setting forth the history of onset beginning December 12, 2003, in different yet consistent terms. The relevant passages from those records are as follows:

> Pet. Ex.[4] at 762, Kaiser Permanente Manetca Nursing Record, dated "12/15/03": "progressive visual decline. Teacher called mother today [and] told her the vision has deteriorated so much that he is unable to participate in class. Here today. Child is c/o unable to see board. Mother has noticed @ home past couple days, sitting too close to television c/o unable to see. Appt w/ DR. Estrada today @ 3:30 pm"
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> Pet. Ex. at 762, Kaiser Permanente Manetca Nursing Record, dated "12/15/03", immediately below the preceding passage, but in different handwriting: "Attending Note: S: [circled] c/o last night couldn't see TV. 'Can't see.' Difficulty dressing. Teacher called Mom telling Pt. couldn't see board to participate. 3 days ago, couldn't see board. No hst of vision problem."
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> Pet. Ex. at 789, Smart Tool – Ophthalmology – Stockton, dated "12-15-03": "Pt's teacher noted ↓ VA on Friday. Moved closer to board. Today, seemed even worse. Mom states he also couldn't see TV this weekend. Both eyes affected. C/o being tired lately, ØHA, ØN/V."
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> Pet. Ex. at 789, Smart Tool – Ophthalmology – Stockton, dated "12-15-03", further down the page from the preceding passage, possibly

[4] On December 1, 2009, Petitioner filed 961 pages of medical records, none of which were labeled with exhibit numbers. These records were filed on paper only, and have not been uploaded to the electronic record. The undersigned will refer to these medical records by page number only, e.g., "Pet. Ex. at 1."

another different scribe: "Mom states pts 12 yo brother also c̄ ↓VA → advised she bring him tomorrow also. Has been excessively sleepy last week & over weekend → sleeps right after school. Yesterday was ok, slept at [illegible] times. Ø unusual behavior, listlessness, speech problems, HA or N/V."

Pet. Ex. 29 at 398, Dameron Hospital Association Progress Record, dated "12-16-03" at "3:30 p.m.", under a heading that states "HOSPITAL REGULATION: All Positive and Important Negative Findings Shall Be Recorded": "6 yo ♂ c̄ Loss of vision ON – onset not certain teacher noted on Friday 12/12/03 that pt had trouble seeing board. Symptoms worsened on Friday. Seen in Manteca 12/15 c̄ ↓VA noted ON. Seen by opth [illegible] on 12/15 & 12/16. Pt c̄ ↓VA to CF ON. Swollen optic nerve head OD, ON pallor c̄ retrobulbar swelling on CT scan os. Mother denies other current c/of x̄ leg pain"

Pet. Ex. at 856, typed, History and Physical, Dameron Hospital, Stockton, California, dated "12/16/2003", also date stamped "DEC 16 PM":[5] "The patient is a 6 year old African-American male with a history of loss of vision in both eyes. The date of onset is not ["100%" is crossed out and "entirely" is handwritten beside it] certain, however, the patient's teacher noted the patient having difficulties with vision on Friday, 12/12/2003. Over the weekend, the patient's family also noted the patient having increasing trouble seeing, complaining of inability to see the clock or the television.

. . .

The history also is significant in that the patient received the flu shot on Friday. He has not had a change in mental status, although the mom states that earlier in the week, he seemed excessively sleepy and was going to sleep immediately after school and sleeping through the night. However, as of Sunday, he had been sleeping a normal amount and had resumed his normal activities.

[5] This may be a typed version of the passage from Pet. Ex. 29 p. 398, as some of the language is very similar, although as Petitioner notes some of the language also appears to be taken from Pet. Ex. at 789 (see Decl. Carol Jakes ¶20), so it could be a combination of the two records, combined for purposes of dictation.

Over the last two days, he has also developed some leg pain, the etiology of which is unclear."

The first record that provides a history of onset different than that set forth above is a typewritten record dated and date stamped March 17, 2004, from the office of Richard L. Friederich, M.D. Pet. Ex. at 770-71. This record provides a very detailed history in which the scribe notes parenthetically that "Mother is giving the story in very great detail, much more detail than reported here, and very rapidly." *Id.* at 771. This is the first record that places "onset approximately 3 days after receiving influenze [sic] immunization." *Id*. at 770. The discrepancies in the histories are noted: "Initial consult states onset of visual loss is uncertain, first noticed by teacher on 12Dec03, the same day he received his influenza vaccine, vision loss subsequently confirmed by parents over the next couple days. . . .Other reports state he awoke with abruptly decreased vision." *Id*. The record from Dr. K. M. Saba relates a history of "sudden, painless bilateral vision loss on December 15, 2003," Pet. Ex. at 315, and a nurse's admission record from the Kaiser Foundation Hospital, Dr. Siciliano, dated "3/23/04," notes a medical history obtained from "Mother" and states: "Oakland Kaiser since 3/20/04. December 12, 2003, -- Blindness Ⓛ side paralysis 12/15/04 (sic) admitted to the hospital 12/20/03." Pet. Ex. at 219. Thereafter, there are no further references to a December 12, 2003 onset.

The undersigned understands that Ms. Jakes remembers talking with more than one person when she and Dreyton arrived at Kaiser. Dec. Carol Jakes at 4. The undersigned also has no doubt that Ms. Jakes' recollection is that she did not tell anyone that Dreyton had visual problems starting on Friday December 12. *Id*.

The accounts set forth in the medical records from December 15 and 16, 2003, are different in a number of ways, but as to their description of the date of onset, they are essentially consistent. They were recorded by several different medical professionals, at different medical facilities, in several different formats. Based on the undersigned's extensive experience reviewing medical records, it is simply not plausible that that many different people at different times in different contexts while performing one of the essential functions of the medical profession (taking/recording history and symptoms) could have made the same basic, and potentially critical, mistake. Based on the foregoing analysis and a review of the record as a whole, the undersigned FINDS that the date of onset of Petitioner's vision problems was December 12, 2003.

ORDER

This case is now ten years old. Petitioner has been afforded abundant opportunity to present his case; the undersigned will brook no further delays. **No later than 63 days from the date of this Order, by April 29, 2016, Petitioner shall file an expert report that includes a**

causation theory consistent with the onset ruling set forth herein. Failure to file such an expert report will result in dismissal of Petitioner's vaccine claim.

IT IS SO ORDERED.

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