

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. 02-1014V

Filed: June 22, 2006

NOT TO BE PUBLISHED

JANINE PANDOLFINO, for herself and on behalf *
of GIANNA PANDOLFINO, a minor, *

Petitioners, *

v. *

SECRETARY OF THE DEPARTMENT OF *
HEALTH AND HUMAN SERVICES, *

Respondent. *

Entitlement; Unsupported By
Medical Record or Medical
Opinion

Thomas M. Bond, The Kaplan/Bond Group, Boston, MA, for Petitioner.

Michael Milmo, United States Department of Justice, Washington, D.C., for Respondent.

DECISION¹

GOLKIEWICZ, Chief Special Master

Petitioner filed on August 20, 2002, on behalf of her daughter, Gianna, for compensation

¹ Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). 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 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). Otherwise, "the entire" decision will be available to the public. Id.

under the National Vaccine Injury Compensation Program² (“the Act” or “the Program”). Petitioner alleged that within three days of Gianna’s childhood immunizations “she experienced seizures and has been diagnosed with encephalopathy with intractable seizures.” Petition (“Pet.”) at 1. Due substantially to the undersigned’s determination of critical factual issues, petitioner’s allegations are unsupported by either the medical records or a medical opinion. Thus, this case must be dismissed.

Unless otherwise noted, the fundamental facts of this case are not in dispute. Gianna Pandolfino was born on July 9, 2000.³ Petitioner’s Exhibit (“P. Ex.”) 1; Pet. at para.1. Dr. Nancy Rosselot, Gianna’s pediatrician, examined Gianna on July 21, 2000, and noted that she was “well,” “healthy,” “happy baby,” and “very good.” P. Ex. 2 at 3. On September 11, 2000, Gianna was administered her childhood immunizations. See P. Ex. 3 (Vaccine Administration Record); see also P. Ex. 2 at 3. On October 1, 2000, Gianna experienced three episodes of tonic/clonic seizure activity and was admitted to the hospital. P. Ex. 4 at 158. She was started on the seizure medication, Phenobarbitol, with the suggestion “to maintain this dose of steady level for three or four months at which time, if there were no further seizure problems, this medication could be discontinued.” Id. Gianna was discharged on October 4, after doing well in the hospital with no further seizure activity. Id. Of note in the histories taken during Gianna’s hospitalization is that the “parents first noticed legs and lower body twitching during 2nd wk of life but did not connect to seizures and only in lower body.” P. Ex. 4 at 173; see also Id. at 169; P. Ex. 2 at 59.

The medical records document further seizure activity on October 12 and November 13. P. Ex. 2 at 4. In response to the seizure activity on the 13th, Gianna’s anticonvulsant medication was increased. Id.

On November 20, 2000, Gianna was administered her second set of childhood immunizations. P. Ex. 3; see also P. Ex. 2 at 6. According to the Petition, “[o]n or about November 23, 2000 Gianna suffered post-vaccination seizures, which petitioner, Janine Pandolfino, described as being “violent” and “severe” and unlike anything Gianna had experienced before.” Pet. at para. 6; see also Affidavit at para.6. The medical records do not document “violent” and “severe” seizures on November 23, but note in an entry made on November 27 that over the weekend Gianna suffered “2 szs. (2 min.each)”. P. Ex. 2 at 6; see also Id. at 60.

On December 18, 2000, Gianna was admitted to Children’s Hospital in Boston, where she

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.A. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) (“Vaccine Act” or the “Act”). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

³The first three paragraphs of the Petition contain errors in the dates; the years are incorrectly recorded as “2002”. The correct year is “2000”.

remained until December 29. P. Ex. 6. On January 4, 2001, Gianna was re-admitted to Children's Hospital for increasing seizure activity. R. Ex. A at 9. Gianna's condition took a devastating turn for the worse. She was intubated, placed on life support and put in a drug-induced coma. Id. at 9-14. According to an evaluation by the Multidisciplinary Cerebral Palsy Clinic on March 1, 2002, Gianna was assessed with "[p]robable acquired encephalopathy with intractable seizures, extrapyramidal syndrome, and significant developmental delay of unclear etiology despite multiple extensive evaluations." P. Ex. 8 at 299.

BACKGROUND

After completing the filing of the relevant medical records in this case,⁴ the parties engaged in a cooperative effort to gather further information from six of Gianna's treating doctors. See Joint Status Report, filed Aug. 20, 2003. This difficult and lengthy process culminated in two letters from treating doctors. Gianna's pediatrician, Dr. Rosselot wrote on August 18, 2003:

Gianna Pandolfino, DOB 7/9/00, has an intractable seizure disorder and severe global developmental delay. An underlying etiology for her condition has not been determined despite extensive evaluation as detailed in her medical records. Gianna's first seizure occurred on 10/1/00 although her parents reported unusual body movements as early as one to two weeks old. I cannot attribute a causal relationship between Gianna's condition and immunizations received.

Petitioner's Notice of Filing, filed Oct. 14, 2003.

Dr. Riviello, one of Gianna's treating neurologists, responding to a letter prepared by counsel for the undersigned's signature, wrote that he did "not recall ever discussing immunizations with [Gianna's] mother", is "not aware that [Gianna's condition] is considered an immunization-related disorder", "there is no notation in the initial note about any immunizations", "[t]here was concern about possible abnormal movements by 1 to 2 weeks of age", and, finally, "[b]ecause of my peripheral role, and lack of information about the child, I have no definite conclusion about the relationship between immunizations and an underlying neurologic disorder." Court's April 5, 2004 Order filing Dr. Riviello's February 8, 2004 letter.

After exhausting the collection of outstanding medical records and information from the treating doctors, petitioner was ordered to file an expert report in support of her case. Id. After several extensions, petitioner reported that the parties agreed to petitioner "prepar[ing] and submit[ting] a written settlement proposal to Respondent's counsel in an effort to avoid further costs and litigation expenses." Order, filed Aug. 11, 2004 (filing by court's leave petitioner's August 5, 2004 Status Report.); see also Petitioner's September 13 and October 18, 2004 Status

⁴Respondent is commended for its efforts in assisting petitioner with the collection of the medical records. See Status Report, filed Dec. 2, 2002.

Reports.

In an effort to construct a settlement proposal, petitioner reported that the medical records were sent to a medical expert, Dr. Thomas Schweller for an opinion. See Order, filed Dec. 7, 2004. Dr. Schweller's report was sent to respondent by letter dated December 15, 2004. Petitioner's January 4, 2005 Status Report. At a status conference held on January 24, 2005, it was determined that settlement would not be fruitful. Expert reports were ordered to be filed. Order, filed Jan. 25, 2005. Petitioner filed the expert report of Dr. Schweller on January 27, 2005; respondent filed the expert report of Dr. Bennett L. Lavenstein on May 19, 2005.

The Expert Reports

After summarizing the basic factual information, Dr. Schweller opined that Gianna's second set of immunizations given on November 20, 2000 aggravated her existing seizure disorder.⁵ It is clear from his opinion that this finding is based upon the timing of the seizures following the second set of vaccinations and an alleged change in the severity of the seizures compared to the seizures experienced prior to the second vaccinations. Critical to Dr. Schweller's opinion is that the "mother . . . reported on November 23, 2000 that Gianna had violent seizures unlike those she had experienced before." Schweller report at 2. This information is not in the medical records, but is contained in the mother's affidavit. See P. Ex. 5 at para. 6.

Dr. Lavenstein saw no causative role for Gianna's vaccinations . Dr. Lavenstein noted the suspected seizure activity at two weeks of life, opined that there was no evidence of an encephalopathy following the first set of vaccinations, and based upon the medical records, stated that Gianna's seizures worsened in October and early November, the period between the two sets of vaccinations, not after the second set of immunizations as opined to by Dr. Schweller. R. Ex. B. Dr. Lavenstein indicated that Gianna's clinical picture is "in fact indicative of a primary neurodegenerative disorder which has resulted in the clinical outcome of this child." Id.

The Hearing

At a status conference conducted on June 6, 2005, the parties agreed with the undersigned

⁵It should be noted that Dr. Schweller did not implicate the first set of vaccinations given on September 11 with Gianna's injuries. See generally Schweller report. This is not surprising to the undersigned given the lack of temporal relationship between the immunizations and Gianna's seizure activity. Respondent's expert, Dr. Lavenstein, discussed the lack of causal evidence following the first set of immunizations. R. Ex. B at 3; see also Transcript ("Tr.") at 50-51 (mother described Gianna after the first set of immunizations as "happy, healthy baby" and noted no change in her behavior).

that significant factual issues needed to be resolved prior to taking testimony from the experts.⁶ Specifically, the allegation that Gianna suffered “violent seizures” within three days following her second set of immunizations given on November 20, 2000 is not documented in the medical records. Thus, a hearing was conducted on October 12, 2005 solely for the purpose of eliciting factual testimony. An in-person hearing was conducted in petitioner’s home and testimony was heard from both parents and Gianna’s grandmother. See Transcript of Hearing conducted on October 12, 2005.

Fact Ruling

On March 1, 2006, the undersigned issued a Fact Ruling and Order. The findings and the undersigned’s reasoning will not be reiterated herein, but are incorporated by reference. For ease of understanding this Decision, the summary is repeated. It states as follows:

In summary, the undersigned finds that the medical records are to be relied upon primarily for the facts of this case. Further, there is no support in either the medical records or the fact testimony for the mother’s statement in her affidavit that Gianna “suffered post-vaccination seizures, which were violent and severe and unlike anything Gianna had experienced before.” The fact testimony from mom and the grandmother indicate that while there was concern about the seizures the concern was not that great because mom had been through this before. That indicates consistency in the seizures, not a change. And if there was any doubt, the father, Paul, confirmed that in fact Gianna suffered the same type of seizure approximately two weeks after the first vaccination, which was about one week prior to the hospitalization on October 1. Taken together, it is abundantly clear that there is no factual support for Dr. Schweller’s statement that “there was an increase and more seizure (sic) that occurred within three days of the second set of immunizations.”

Fact Ruling and Order, filed Mar. 1, 2006 at 5. Following the issuance of the ruling, petitioner was ordered to schedule a status conference “to discuss what future proceedings are necessary to resolve any outstanding issues.” Id.

Further Proceedings

A status conference was conducted on March 29, 2006 during which petitioner reported that petitioner’s expert, Dr. Schweller, could not support petitioner’s causation claim based upon

⁶ This is a process commonly utilized in vaccine cases. Rather than have the expert pick and choose amongst conflicting factual information, the special master first resolves the factual issues, after which the expert offers an opinion based upon those facts. This saves time and money since the expert’s opinion is only as good as the factual foundation supporting it and if the expert’s opinion is based upon facts ultimately rejected by the special master, the expert’s efforts are wasted.

the facts as found by the undersigned. Petitioner also stated that she disagreed with the undersigned's factual ruling. Accordingly, the undersigned gave petitioner an additional two weeks to indicate in writing how she wished to proceed in the case, and gave respondent ten days to respond. Order, filed Mar. 30, 2006. Petitioner filed her response on April 13, 2006, which again states her disagreement with the undersigned's factual ruling and requests a final decision from which an appeal can be taken. Petitioner's Response to March 30, 2006 Order. Given petitioner's response to the court's Order, respondent contacted my office to state that no response would be filed.

FINAL RESOLUTION

It is axiomatic that an expert's opinion is only as good as the facts upon which it is predicated. See Murphy v. Secretary of HHS, No. 90-882V, 1991 WL 74931, at *3 (Fed. Cl. Spec. Mstr. (Apr. 25, 1991), aff'd, 23 Cl. Ct. 726, 730 (Cl. Ct. 1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992), cert. denied, Murphy v. Sullivan, 506 U.S. 974 (1992). Dr. Schweller's November 30, 2004 opinion that Gianna's second set of immunizations significantly aggravated her existing seizure disorder was based upon factual information supplied by petitioner, Gianna's mother. The critical aspect of that factual information, that Gianna suffered after her second set of immunizations "violent and severe [seizures] unlike anything Gianna had experienced before," P. Ex. 5 at para. 6, was not corroborated by the medical records. In addition, the undersigned found that the lay witness testimony from the mother and grandmother did not support a change in seizure severity, and in fact, the father testified to similar seizure activity following the first set of immunizations. Fact Ruling at 3-5. In the undersigned's Fact Ruling, the undersigned ultimately found that "it is abundantly clear that there is no factual support for Dr. Schweller's statement that 'there was an increase and more seizure (sic) that occurred within three days of the second set of immunizations.'" Fact Ruling and Order at 5. Accordingly, the factual underpinnings for Dr. Schweller's opinion, in the undersigned's view, no longer existed. Without a factual basis, it follows that the opinion itself lacks credibility.

Of additional note is the undersigned's finding that Ms. Pandolfino's "memory of events cannot be relied upon for accuracy." Fact Ruling at 2. The undersigned did not attempt to show every discrepancy in Ms. Pandolfino's testimony to discredit her, but instead gave a couple of examples. Id. at 2-3. It is important to note that there were a number of additional problems with mom's testimony. For example, Ms. Pandolfino testified that after Gianna was put on phenobarbitol following her October 1 hospitalization, she did not see anymore seizures up until Gianna's vaccinations on November 20. Tr. at 12. This testimony is contradicted by the medical records, and specific information in those records attributed to Ms. Pandolofino. See P. Ex. 2 at 4. Secondly, Ms. Pandolfino testified that Gianna's phenobarbitol was not increased until after the second set of immunizations. Tr. at 16. Again, however, the medical records indicate clearly an increase in Gianna's phenobarbitol after the November 13 seizure event. P. Ex. 2 at 4. When shown the medical records, Ms. Pandolfino acknowledged, contrary to her prior testimony, the seizures occurring on November 13 and also the increase in phenobarbitol. Tr. at 45.

Lastly, Ms. Pandolfino’s belief that Gianna’s seizures were far different in severity immediately following the second set of immunizations is belied by the medical records, her husband’s testimony and her own testimony. When asked to describe how the seizures following the November 20 immunizations differed from the October seizures, Ms. Pandolfino stated that “it affected her extremities, upper and lower. . . . Whereas before, it was more of her eyes deviating to the left or to the right.” Tr. at 23⁷ However, Ms. Pandolfino earlier described the October seizures as “her eyes rolled in the back of her head and **her whole body was just shaking.**” Tr. at 10 (emphasis added.) In addition, the medical records for November 13 record a “full” tonic-clonic seizure.⁸ Thus, contrary to the statement in her affidavit that the seizures following the November 20 immunizations were “violent and severe and unlike anything Gianna had experienced before”, the evidence, including Ms. Pandolfino’s testimony, indicates that Gianna’s seizures prior to the November 20 immunizations were similar to the post-November 20 seizures or had already begun worsening. Dr. Lavenstein opined that “[t]he patient had a worsening of seizures in October and early November apart from the time of administration of the second set of immunizations.” R. Ex. B at 3. The increase in phenobarbital on November 13 would support that observation. See P. Ex. 2 at 4. At the very least, there is no credible support for the allegation that the seizures were “unlike anything Gianna experienced before” following the November 20 immunization. The father’s testimony alone negates that proposition.

The Vaccine Act provides that the Special Master or Court cannot make a finding for compensation based solely upon the claims of petitioner. The claim must be supported by either medical records or a medical opinion. § 13(a)(1). As the record stands, petitioner’s case is neither supported by the medical records nor, because of the undersigned’s factual ruling, a medical opinion. Accordingly, this case must be dismissed. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master

⁷The answer continues with “it more affected her whole body.” Tr. at 23. Read in context, this clause describes the seizures following the November 20 immunizations, not the October event.

⁸Tonic-clonic seizures involve a loss of consciousness followed by a repetitive jerking movement of the limbs. GERALD M. FENICHEL, M.D., CLINICAL PEDIATRIC NEUROLOGY, at 32 (2d ed. 1993).

