In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 07-261V
Filed: October 29, 2009

TO BE PUBLISHED

JOHN STAVRIDIS, parent of WILLIAM STAVRIDIS, a minor,	*	
Petitioner,	*	Six-month residual effects rule; Surgical intervention; DTaP autoimmune hemolytic anemia
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald Homer, *Conway, Homer & Chin-Caplan, Boston, Massachusetts, for Petitioner.*

Rebecca Trinrud, *United States Department of Justice, Washington, D.C., for Respondent.*

DECISION [1] [2]

GOLKIEWICZ, Chief Special Master

On April 26, 2007, John Stavridis filed this Petition on behalf of his son, William, for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 to

[1] This document constitutes a final "decision" in this case pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Unless a motion for review of this decision is filed within 30 days, the Clerk of the Court shall enter judgment in accord with this decision.

[2] The undersigned intends to post this decision on the United States Court of Federal Claims's 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.

-34 (hereinafter "Vaccine Act" or "the Act"). The Petition alleged that William suffered a vaccine-related injury, autoimmune hemolytic anemia (hereinafter "AIHA"), following a diphtheria, tetanus, and acellular pertussis (hereinafter "DTaP") vaccination administered on November 21, 2005. Pet. at 1. For the reasons discussed herein, the undersigned must deny compensation.

FACTUAL HISTORY

The essential facts are not in dispute. William was born on July 19, 2005. Although William's medical record was uneventful prior to his second set of vaccinations,[3] his mother has a mild form of von Willebrand disease.[4] Pet. at 2-3; P Ex 4 at 21-23. Due to his mother's condition, William was monitored for bleeding tendencies. Pet. at 3; P Ex 4 at 21-23. He was evaluated at a hematology clinic on September 20, 2005, and no abnormal bleeding conditions were discovered at that time. Pet. at 3; P Ex 6 at 54-55, 73.

Subsequently, William received a second set of vaccinations on November 21, 2005, which petitioner alleges caused William's AIHA. Within days, William's mother and an acquaintance noticed a change in William's coloring. Pet. at 4; P Ex 7 at 2. After developing a low grade fever and being examined by his pediatrician, William was hospitalized on December 1, 2005, and the diagnosis of AIHA followed shortly thereafter. Pet. at 5-6; P Ex 7 at 3. Among other efforts, his condition was treated with intravenous steroids and a blood transfusion. P Ex 6 at 61-62, 80, 95. William responded to treatment and, after four days of hospitalization, was released home on oral steroid medication. P Ex 6 at 85, 106.

Following his release from the hospital, William was seen by doctors at the hematology clinic on an outpatient basis. P Ex 6. By March 10, 2006, approximately four months after his vaccination, William's doctors felt he was doing well enough to discontinue the oral steroids within a week. P Ex 6 at 78. At a March 31, 2006 visit, the medical record notes that William was no longer on the oral steroids. P Ex 6 at 9. In an August 25, 2006 letter to William's pediatrician, Dr. Altura, a physician at the hematology clinic, stated, "[f]or the last four months, he has been off treatment and he has had no recurrence of his anemia . . . Given the normalization of his blood counts and the hemoglobin stability off medication, we do not feel that further blood counts are necessary and will discharge him from the hematology clinic." P Ex 5 at 71. Petitioner's filings reference William's fluctuating, low white blood cell count after his release from the hematology clinic. E.g., P "Response to the Court's Order of September 5, 2007 and the Respondent's Report and Motion to Dismiss," at 10 n. 8, filed March 19, 2008 (hereinafter "P Response"). However, as discussed above, the record indicates William was not treated for a hemolytic injury longer than six months. Also, petitioner himself points out that other post-hospitalization white blood cell counts

[3] William received his first set of vaccinations on September 19, 2005. Pet. at 2.

[4] Von Willebrand's disease is "a congenital bleeding disorder, usually of autosomal dominant inheritance, characterized by deficiency of von Willebrand's factor, with prolonged bleeding time . . . associated with epistaxis and increased bleeding after trauma or surgery . . . ." Dorland's Ill. Medical Dictionary (30th ed. 2003).

were within the normal range. See P Response at 10 n. 8.

PROCEDURAL HISTORY

As stated previously, this Petition was filed on April 26, 2007. Respondent filed her Rule 4(c) Report and a Motion to Dismiss on July 30, 2007 (hereinafter "R Report"). Respondent challenged petitioner's claim, stating the statutory requirements of the Act were not met. Specifically, respondent claimed petitioner had not shown "William suffered residual effects of his alleged vaccine-related injuries for more than six months," as required by 42 U.S.C. § 300aa-11(c)(1)(D)(i). R Report at 6. Respondent further argued petitioner did not meet the Act's alternative requirement, that the alleged vaccine-related injury required hospitalization and surgical intervention. R Report at 6 (referencing 42 U.S.C. § 300aa-11(c)(1)(D)(iii)). Finally, assuming petitioner met either the six-month or surgical intervention requirements, respondent challenged petitioner on the issue of causation as well. R Report at 7-11.

Petitioner naturally countered, claiming William's injury did indeed meet the statutory requirements found in 42 U.S.C. 300aa-11(c)(1)(D). P Response. Petitioner claimed William's condition surpassed the six month requirement, evidenced by his fluctuating, low white blood cell count. P Response at 13-15. Second, petitioner argued William's treatments of intravenous steroids and a blood transfusion constituted surgical intervention. Petitioner acknowledged the Federal Circuit has yet to address the scope or definition of "surgical intervention" but urged consideration of the Act's underlying objectives and proffered dictionary definitions of surgical intervention in support of his position. P Response at 15-23. Regarding the causation challenge posed by respondent, petitioner offered a legal argument while conceding he had no direct evidence of causation. P Response at 23-31.

Respondent again countered, arguing William's medical records failed to show the hemolytic injury lasted more than six months, R Response, filed May 1, 2008, and presenting a medical opinion that William's treatments are not considered surgical intervention. R Ex A, filed July 9, 2008.

Between September 2007 and September 2009, these issues were addressed. Order, filed September 5, 2007; Minute Entry, entered September 11, 2007; Order, filed February 8, 2009. Most relevant to this decision, petitioner was ordered to produce expert evidence on both or either of the means a petitioner may utilize to meet the statutory requirement of 42 U.S.C. 300aa-11(c)(1)(D). Order, filed April 10, 2009. This Order stated, "[i]n light of Dr. Altura's letter and in the absence of medical records stating that William's injury has persisted, subclinically or clinically, petitioner must present an expert opinion on this issue." Order at 2, filed April 10, 2009. Also, "[g]iven the lack of guidance on this issue and in light of Dr. Arceci's statement, petitioner must provide more than a dictionary definition to support [his "surgical intervention"] argument." Order at 2, filed April 10, 2009.

To date, petitioner has not provided evidence from a treating physician or an expert regarding whether William's fluctuating white blood cell count shows the alleged vaccine injury persisted for more than six months. Nor did petitioner provide a proper rebuttal opinion regarding what treatments constitute surgical intervention or that William's treatments specifically constitute

surgical intervention. Petitioner twice affirmatively declined the opportunity to present expert opinions. P Status Report, filed May 11, 2009; Minute Entry of telephonic status conference, entered September 10, 2009. Therefore, this matter is ripe for decision.

DISCUSSION

Pursuant to the Act, the petitioner must demonstrate that his son received a vaccine covered by the Act, 42 U.S.C. 300aa-14(a); that his son sustained an injury that was caused-in-fact by the vaccine or had an injury significantly aggravated by the vaccine; *and* that his son either "(i)suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or . . . (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).[5] Petitioner must prove his case "by a preponderance of the evidence," 42. U.S.C. 300aa-13(a)(1)(A), and a finding cannot be made based upon unsupported claims of the petitioner alone. 42 U.S.C. 300aa-13(a)(1).

There are two decisive issues working against petitioner in this case: first, whether William's condition lasted more than six months, and second, whether his treatments constitute surgical intervention.[6] Both are pertinent to this decision and they will be addressed separately.

Six-month Requirement, 42 U.S.C. § 300aa-11(c)(1)(D)(i)

Petitioner alleges his son sustained a vaccine-related hemolytic injury, AIHA, from a DTaP vaccine. Pet. at 1. The Petition is challenged by respondent, who points to William's own medical records, stating there is no support that the hemolytic injury lasted longer than six months as required by the Act. R Report at 6. Petitioner responded, presenting the argument that William's fluctuating, low white blood cell count was a "clear indication he was still suffering from a hemolytic injury." P Response. Subsequently, petitioner argued that William's condition, although not expressed on a clinical level, persisted *subclinically*. P "Response to the Court's February 8, 2008 Order and the Respondent's Reply of April 17, 2008," at 2-3, filed May 1, 2008 (hereinafter "P Reply"). Since proper evaluation of petitioner's arguments requires appropriate medical knowledge and expertise, the undersigned directed petitioner to file an expert report supporting his contention that William's low white blood cell count was evidence of a subclinical hemolytic injury, related to the immunization. Order, filed May 8, 2008. As discussed previously, petitioner twice declined presenting evidence from an expert or treating physician on this issue. P Status Report, filed May

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[5] This case does not involve a "Table Injury," which is the avenue for receiving compensation under the Act other than proving causation-in-fact. A Table Injury is found if a petitioner is able to prove "(i) that the injury suffered is one listed in the Vaccine Injury Table . . .; (ii) that the injury occurred within the time provided within the Table; and (iii) that the injury meets the requirements of section 300aa-14(a)" Capizzano v. Sec'y of Health and Human Services, 440 F.3d 1317 (Fed. Cir. 2006)(citing Munn v. Sec'y of Health and Human Services, 970 F.2d 863, 865 (Fed. Cir. 1992).

[6] Since this case is resolved on petitioner's failure to meet § 300aa-11(c)(1)(D), it is unnecessary to address the causation issue presented in this case.

11, 2009; Minute Entry of telephonic status conference, entered September 10, 2009.

Petitioner "bears the burden of proving by a preponderance of the evidence that [his son] suffered the residual effects or complications . . . for at least [six] months." Song v. Sec'y of Health and Human Services, No. 92-279, 1993 WL 534746 (Fed. Cl. Spec. Mstr. Dec. 15, 1993), *aff'd* 31 Fed.Cl. 61 (Fed. Cl. 1994), *aff'd* 4 F.3d 1520 (Fed. Cir. 1994)(unpublished table decision). In Song, although the petitioner was able to prove the child suffered a vaccine-related injury, the petitioner could not show the vaccine-related injury lasted longer than six months as required by the Act. Accordingly, the petition in Song was dismissed.

In the present case, petitioner claims his son suffered AIHA, lasting more than six months subclinically. However, in a March 10, 2006 letter, Drs. O'Brien and Altura stated, "Over the last four months, William has done well, we have been able to wean his steroids. He did receive one dose of IV IG in January 2006 in an attempt to hasten the weaning of steroids. We plan on discontinuing his steroids in another week." P Ex 6 at 78. In fact, a letter from Dr. Altura dated August 25, 2006, confirms William's anemia did not last longer than six months. "For the last 4 months, he has been off treatment and has had no recurrence of his anemia. . . . Given the normalization of his blood counts and the hemoglobin stability off medication for the last 4 months, we do not feel that further blood counts are necessary and will discharge him from the Hematology Clinic." P Ex 6 at 71; P Ex 5 at 16.[7] Petitioner's son was vaccinated on November 21, 2005, thus the evidence must show William's injury persisted beyond May 21, 2006. The medical record states that William was "now off steroids" on March 31, 2006. P Ex 6 at 9. In the August 2006 letter, Dr. Altura confirmed Williams had been off treatment for four months. P Ex 5 at 71. Dr. Altura's narrative places the latest date of William's injury in April 2006, still short of May 21, 2006. Petitioner did not contest the information in the medical records.

Although given ample opportunity, petitioner was either unable or unwilling to produce an opinion from a treating physician or medical expert opining that William's alleged injury persisted subclinically beyond six months. Taken by itself, petitioner's argument is insufficient to prove this medical issue. "The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13. As discussed above, the medical records establish William's injury lasted less than six months. Therefore, the undersigned finds the petitioner failed to carry the burden required of him under 42 U.S.C. 300aa-11(c)(1)(D(i).

[7] Petitioner's argument that William's fluctuating low white blood cell count was evidence of an ongoing or subclinical AIHA was specifically discussed in a status conference. Minute Entry, entered May 20, 2008. The undersigned expressed to petitioner the need for a physician to state that petitioner's argument is medically correct. Order, filed May 8, 2008. Without that medical statement, petitioner's arguments were unsubstantiated. As stated above, petitioner declined submitting a medical opinion. P Status Report, filed May 11, 2009; Minute Entry of telephonic status conference, entered September 10, 2009. Thus, the medical records, which indicated the length of time William suffered the alleged injury, went unrebutted. See 42 U.S.C. § 300aa-13(a)(1) (a finding cannot be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.").

Surgical Intervention, 42 U.S.C. § 300aa-11(c)(1)(D)(iii)

Petitioner's alternative argument is that William's treatments, specifically the intravenous steroid treatments and blood transfusion, qualify as surgical intervention. In his response to the Rule 4(c) Report, petitioner recited the overarching objectives of the Vaccine Act and its year 2000 amendment, which expanded the Act to compensate individuals who required hospitalization and surgery due to their vaccine-related injury. P Response at 16-19. Also in support of his argument, petitioner provided the dictionary definitions of the terms surgical, surgery, operation and intervention from the Online Medical Dictionary at the Center for Cancer Education from the University of Newcastle.[8] P Response at 22.[9] Petitioner's proposed definition defines surgical intervention as the "'methodical action of the hand . . . with instruments' on William's body, . . . to 'produce a curative . . . effect' and [that] 'interfer[ed] so as to modify' his condition . . ." P Response at 22. If petitioner's cobbled-together definition were accepted, it seems a great number of minor procedures would qualify as surgical intervention. However, since this definition would plausibly include William's treatments, the undersigned ordered respondent to present a medical opinion. Order, filed May 8, 2008.

Respondent offered the opinion of Dr. Robert J. Arceci regarding whether William's treatments constitute surgical intervention. R Ex A, filed July 9, 2008. After reviewing petitioner's medical records and commenting that the treatments were suitable for William's diagnosis, Dr. Arceci stated, "[a]s hematologists, we, and our colleagues in pediatrics, would not consider such treatments surgical in nature." R Ex A at 2. Furthermore, "I see patients with hemolytic anemia routinely as a primary disease or secondary complication in my subspecialty of Pediatric Hematology [and] Oncology. The treatment of such patients does not require surgeons or surgical intervention." R Ex A at 2. Dr. Arceci also referenced the International Classification of Disease, ICD-9CM, which classifies blood transfusions and intravenous delivery of medication under "other *nonoperative* procedures." R Ex A at 2 (emphasis added). Petitioner was offered the opportunity to respond, which petitioner declined, and Dr. Arceci's opinion evidence went unrebutted. See P Status Report, filed May 11, 2009; Minute Entry of telephonic status conference, entered September 10, 2009.

In 2000, the Act was amended to include compensation for persons who required "inpatient hospitalization and surgical intervention." 146 Cong. Rec. H8206-06 (2000). "Surgical intervention" is not defined in the Act. This phrase was specifically added to compensate persons

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[8] As provided in petitioner's Response, filed March 19, 2008, the definitions he presents are: "Surgical: 'Of, pertaining or correctable by surgery.' Surgery: 'An operation.' Operation: 'Any methodical action of the hand, or of the hand with instruments, on the human body, to produce a curative or remedial effect, as in amputation, etc.' Intervention: 'The act or fact of interfering so as to modify.'"

[9] Petitioner also referenced the Decision of Judge Firestone in Hocraffer v. Sec'y of HHS, 63 Fed. Cl. 765 (Fed. Cl. 2005). In Hocraffer, Judge Firestone requested "briefs on the issue of Petitioner's claim for relief based on a hospitalization and surgical intervention." 63 Fed. Cl. at 768 n. 4. The scope of what constitutes surgical intervention was not discussed because Judge Firestone found the issue was conceded when the "Respondent did not object to Petitioner's characterization of her lumbar puncture as a 'surgical intervention.'" Id.

injured by the rotavirus vaccine who did not otherwise meet the Act's six month requirement. See, e.g., 145 Cong. Rec. S15213-03 (1999).[10] In the case of rotavirus vaccine injuries, petitioners were suffering intussusception, a condition where the intestine prolapses into the lumen of an immediately adjoining section of intestine. Dorland's Ill. Medical Dictionary (30th ed. 2003). Some cases of intussusception are treated with surgery and these patients recover before the six-month requirement is met. 145 Cong. Rec. S15213-03 (1999).

When this amendment was proposed, Congress acknowledged the legislative intent behind the requirements of 42 U.S.C. 300aa-11(c)(1)(D). "[P]arameters were established to permit claims for those *serious adverse events* that were known to be associated with those vaccines . . . The statutory proxy for a serious injury is that the residual effect from the injury must be of six months' duration or longer."[11] 145 Cong. Rec. S15213-03 (1999)(emphasis added). The amendment allowed petitioners another method of proving they were entitled to compensation for a serious adverse event: that they were hospitalized and received surgical intervention. Petitioner reiterates this point, "[b]y amending the Vaccine Act in 2000 to allow compensation for injuries resulting in inpatient hospitalization and surgical intervention, [C]ongress intended to permit recovery for other types of *serious* injuries." P Reply at 4 (emphasis added). Although petitioner is correct that this amendment expanded the scope of compensable vaccine injuries, P Response at 18-21, that scope is limited to those injuries requiring "hospitalization and surgical intervention."

In Abbott v. Sec'y of Health and Human Services, the court examined the meaning of a word in the Act, "sequela." Abbott v. Sec'y of Health and Human Services, 27 Fed. Cl. 792 (Fed. Cl. 1993), *aff'd in part, rev'd in part*, 19 F.3d 39 (Fed. Cir. 1994)(upholding the analysis of the Court of Federal Claims as it pertained to the term "sequela").

> In determining the meaning of this phrase, we start with the proposition that the intention of a statute is to be found in the words that it contains. Unless the context shows otherwise, words of everyday usage are to be accorded their ordinary and everyday meaning; similarly, "where Congress has used technical words or terms of art, 'it [is] proper to explain them by reference to the art or science to which they [are] appropriate.'"

Abbott v. Sec'y of Health and Human Services, 27 Fed. Cl. at 793 (citing Avery v. Commissioner,

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[10] During discussions of this amendment, it was said that "[t]o our knowledge, the amendment would only apply to circumstances under which a vaccine recipient suffered from intussusception as a result of the . . . rotavirus vaccine. The amendment is not intended to expand jurisdiction to other vaccines listed in the Program's Vaccine Injury Table." 145 Cong. Rec. S15213-03 (1999). However, another reference in the Congressional Record does not refer to a rotavirus vaccine-related injury as the only vaccine injury entitled to compensation under this amendment. 146 Cong. Rec. H8206-06 (2000). Notably, the final language of the amendment does not restrict this section to persons whose injury results in inpatient hospitalization and surgical intervention only due to the rotavirus vaccine.

[11] Petitioners are also entitled to compensation if the vaccinated person dies from the vaccine-related injury, 42 U.S.C. 300aa-11(c)(1)(D)(ii), a requisite that is not at issue in this matter.

292 U.S. 210, 214(1934); Corning Glass Works v. Brennan, 417 U.S. 188, 201 (1974)(quoting Greenleaf v. Goodrich, 101 U.S. 278, 284 (1880))).

It is apparent from Dr. Arceci's report that petitioner's definition casts too wide a net even though it is taken from a medical dictionary. Dr. Arceci's report clearly and unequivocally states that William's steroid treatments and blood transfusion would not, in his experience, be considered surgeries. R Ex A at 2. In addition, Dr. Arceci referenced the ICD-9CM for further support, which classifies these treatments as nonoperative. Id. Despite opportunities to do so, petitioner neither took issue with Dr. Arceci's report nor took advantage of the opportunity to rebut it.

Even if the undersigned were to analyze the phrase "surgical intervention" from its "ordinary and everyday meaning," Abbott, 27 Fed. Cl. 792, 793 (citing Avery v. Commissioner, 292 U.S. 210, 214 (1934)), most lay persons would not find injections of medication or blood transfusions to constitute surgical intervention.[12]

Finally, given the unrebutted opinion from Dr. Arceci, petitioner's proposed medical definition of surgery must be rejected. It is foreseeable that numerous cases will present before this court, challenging the breadth of procedures that constitute "surgical intervention." One can imagine a potentially large gray area between treatments that are definitively considered "surgical intervention" and those that are not. Support from medical treatises or doctors will be needed to determine the appropriate boundaries of what constitutes surgical intervention. Petitioner's unsupported presentation through his legal argument is neither persuasive nor statutorily permissible. 42 U.S.C. 300aa-13(a)(1). Thus, the undersigned finds petitioner has not presented a cogent argument for including William's treatments even within the boundary of this foreseeable gray area. As uncomfortable and daunting as these treatments likely were for a young child, the undersigned finds petitioner's intravenous treatments and blood transfusions do not constitute surgical intervention under § 300aa-11(c)(1)(D)(iii) of the Act.

CONCLUSION

The court has reviewed the record and finds that due to the lack of supportive medical records or an expert opinion, petitioner has failed to establish a prima facie case required by 42 U.S.C. § 300aa-11(c). The court must deny compensation. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

s/Gary J. Golkiewicz
Gary J. Golkiewicz
Chief Special Master

[12] Indeed, with the popularity of television surgery programs and medical documentaries, the undersigned believes the average television viewer who is tuning into a program about surgical intervention would be disappointed and perhaps confused to simply see patients lying in beds with IVs in their arms.