In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-0187V

Filed: 19 January 2010

* * * * * * * * * * * * * * * * *

JOLEE CUSTER, mother and legal representative of the estate of JORDON CUSTER,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* * * * * * * * * * * * * * * * *

UNPUBLISHED

Curtis R. Webb, Esq., Webb, Webb & Guerry, Twin Falls, Idaho, for Petitioner;
Michael Patrick Milmoe, Esq., U.S. Department of Justice, Washington, District of Columbia, for Respondent.

ENTITLEMENT RULING[1]

ABELL, Special Master:

On 7 March 2006, Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[2] alleging that Jordon's 16 December 2004 vaccination was followed within four hours by anaphylaxis meeting the Table definition, and that such anaphylaxis led inexorably to Jordon's death that night. After a period of several filings by both parties, including expert reports, the Court convened a hearing on the issues affecting entitlement on 17 April 2008, which was followed by several months of briefing on those issues. Hearing Transcript ("Tr.") at 1. Subsequent to that hearing, the parties filed closing briefs with the

[1] Petitioners are reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this ruling 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" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 et seq. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C. §300aa.

Court. Following thereafter, the Court issued an oral Bench Ruling on 18 December 2009, which is reprinted (in relevant part) below.

As a preliminary matter, the Court notes that Petitioner had satisfied the pleading requisites found in § 300aa-11(b) and (c) of the statute, by showing that: (1) she is the real party at interest as the mother and natural guardian of Jordon, the injured party; (2) the vaccine at issue is set forth in the Vaccine Injury Table (42 C.F.R. § 100.3); (3) the vaccine was administered in the United States or one of its territories; (4) no one has previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. Additionally, the § 16 requirement that the Petition be timely filed have been met. On these matters, Respondent tenders no dispute.

The Vaccine Act authorizes the Office of Special Masters to make rulings and decisions on petitions for compensation from the Vaccine Program, to include findings of fact and conclusions of law. §12(d)(3)(A)(I). In order to prevail on a petition for compensation under the Vaccine Act, a petitioner must show by preponderant evidence that a vaccination listed on the Vaccine Injury Table either caused an injury specified on that Table within the period designated therein, or else that such a vaccine actually caused an injury not so specified. § 11(c)(1)(c).

It is axiomatic to say that a petitioner bears the burden of proving, by a preponderance of the evidence – which this Court has likened to fifty percent and a feather – that a particular fact occurred or obtains. Put another way, it is required that a special master, "believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." *In re Winship*, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring). Moreover, mere conjecture or speculation does not meet the preponderance standard. *Snowbank Enterprises v. United States*, 6 Cl. Ct. 476, 486 (1984).

This Court may not rule in favor of a petitioner based on his asseverations alone. This Court is authorized by statute to render findings of fact and conclusions of law, and to grant compensation upon petitions that are substantiated by medical records and/or by medical opinion. §§ 12(d)(3)(A)(i) and 13(a)(1).

Contemporaneous medical records are afforded substantial weight, as has been elucidated by this Court and by the Federal Circuit:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary of HHS, 993 F. 2d 1525, 1528 (Fed. Cir.1993).

Medical records are more useful to the Court's analysis when considered in reference to what they include, rather than what they omit:

> [I]t must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant.

Murphy v. Secretary of HHS, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F. 2d 1226 (Fed. Cir. 1992), *cert. denied sub nom. Murphy v. Sullivan*, 113 S. Ct. 263 (1992) (citations omitted), citing *Clark v. Secretary of HHS*, No. 90-45V, slip op. at 3 (Cl. Ct. Spec. Mstr. March 28, 1991).

THE COURT'S BENCH RULING

All right. First let's start with the obvious issue. This is a Table case, not an actual causation case. Therefore, Petitioner does not need to prove the vaccine caused anaphylaxis, anaphylactic shock or death as a sequela. All Petitioner has to prove to succeed is that by a preponderance Jordon experienced anaphylaxis according to the Table definition as they claim within four hours of vaccination and that death was a sequela of the anaphylactic condition. I may have mis-spoken a minute prior, but that's since been corrected.

Respondent can undo Petitioner's position in a Table case and prevail only if they can prove that in this case Jordon's death was actually caused by a factor unrelated, presumably either that there was an anaphylaxis that was caused by something else or that there was no anaphylaxis, but something else unrelated to the vaccine. As we will know eventually, what Respondent was claiming was positional asphyxiation or, if you prefer, SIDS or atypical SIDS. The Court is wrapping that all up into one, however you wish to analyze that.

Now, as an aside, but is requisite, Petitioner has satisfied the other elements of the case showing: 1) She is the real party at interest as the mother and natural guardian of Jordon, the injured party in this case, deceased; the vaccine at issue is set forth in the Vaccine Injury Table; the vaccine was administered in the United States or one of its territories; 4) No one has previously collected an award or settlement of a civil action for damages; 5) No prior civil action has been filed in this matter. Additionally, the Section 16 requirement that the petition be timely filed. These have all been met. On these matters, Respondent tenders no dispute.

Now if we go to the Table definition for anaphylaxis and anaphylactic shock, and the Court wishes to emphasize these are two different items both under the same rubric. Anaphylaxis and anaphylactic shock mean an acute, severe and potentially lethal systemic allergic reaction that occurs within four hours of vaccination. Of course, eventually we will get into specifically the panting issue as whether that either is part and parcel and therefore would be the first indicium or it would not be.

Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and -- how do I pronounce this -- dyspnea. Does anybody know?

MR. WEBB: Yes, you got it right.

THE COURT: Dyspnea? Okay. I want to be certain you guys are listening. That's why I'm asking. All right. And dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx or trachea and minimal findings of eosinophilia in the liver, spleen and lungs.

Now, facts from the medical records. Jordon was born 22 June 2004. He was seen on 11 August 2004, taken to the doctor for wheezing while at home, especially while sleeping. He got his first DTaP on 27 August 2004, along with several other vaccinations. The same medical records note: Child's lungs are entirely clear, and there's some discussion about what could have caused the wheezing, but no conclusions.

That record also notes, if I'm pronouncing it correctly, torticollis, blaming it on congenital issues. Torticollis only comes up a couple times in this hearing, but inasmuch as it's not a common matter the Court should refer to Dorlands Medical Encyclopedia.

Torticollis: "Wryneck; a contracted state of the cervical muscles producing twisting of the neck and an unnatural position of the head." Congenital, which is what appears to be found in these medical records. Congenital torticollis: "Torticollis due to injury to the sternocleidomastoid muscle on one side at the time of birth and its transformation into a fibrous cord which cannot lengthen with the growing neck."

The Court also finds that ultimately, although the matter is discussed, no one really concluded that torticollis was causative, although it's theoretically possible. The Court isn't finding that, but it's possible that in some fashion it could have contributed, but that's obiter dicta, gentlemen.

Now, the main day in question is 16 December 2004 when Jordon got his second DTaP shot. On that morning his history noted a chest cold that had persisted for the preceding two to three days. He had no fever. He was growing well, developing normally. There were some notes in the examination about some nasal congestion, lung congestion, but it's also noted he had no respiratory distress or wheezing in the lungs at the doctor's office that day.

The next actual medical record is the coroner's report as he was found dead the next morning. The pathological findings included bronchopneumonia, acute tracheitis – that's inflammation of the trachea -- and pulmonary edema with a cause of death of atypical SIDS. Now, the death certificate lists probable streptococcal pneumonia. That would be bacteriological in origin.

Also, there is no pathological evidence of the presence of strep bacteria, and the absence of a fever on the preceding morning probably militates against bacterial infection. That is, ultimately the Court must find that that is conjectural because although there's a question mark and it's mentioned on the death certificate, there is no evidence to support the contention.

I should mention that when the treating doctor for Jordon met with the parents on 23 February after Jordon had died he told them that the SIDS diagnosis was being withdrawn because the pathological picture was more consistent with apnea related to infection than suffocation and/or SIDS. At the meeting, the parents actually began to wonder about the possible effect of the vaccine.

Then presumably after speaking with the coroner, Dr. Selove, the treating doctor noted that Dr. Selove had gone back to SIDS, albeit atypical SIDS, because "the pulmonary inflammation and pneumonitis present wasn't adequate or extensive enough to be the cause of death," so that's how it was written up on the death certificate.

The attending pathologist found focal bronchopneumonia and edema in the microscopic exam of the lungs. The attending pathologist described the findings from the microscopic exam of the larynx as focal severe acute inflammation of mucosa at vocal cord region of trachea, that is the larynx. However, there was no redness or swelling of the pharynx or epiglottis upon gross examination.

Now, fact findings I have already decided. Jordon was six months old at the time of question, large for his age, healthy. He had already learned to crawl, could crawl backwards, could roll over from front to back and back to front and crawled around during the day quite extensively, and on the morning of the 16th of December he was in good health and happy disposition.

After he received the vaccination he was then taken home or I guess first to the home of the maternal grandmother. Anyway, the mother described the panting spells at that time, the first of which they observed -- I guess that's the grandmother as well -- closely at the grandmother's house as three to six quick panting breaths, which she had not heard Jordon do before nor any other child. It should be noted that the mother works at a daycare.

The panting itself did not appear to bother Jordon. He seemed to welcome the attention. He did not appear distressed, but the Court finds that significant that

these spells were not like any prior panting spells. It was not like the wheezing that was noticed at a prior medical record. These are unique; sui generis, if you will.

The actual first panting spell the parents saw was around 12:15, which presumably would be Post Meridiem, or 12:30-ish at the grandmother's house, which of course is roughly one, one and a half hours postvaccinal. Mother said he went through that breathing routine several times that afternoon and going to bed that night, the last of which was perhaps an hour before they put him to bed at 11 p.m.

Jordon apparently had some other indicia that are noted by the parents but do not appear to be relevant for the purposes of our hearing today, but they should be noted. He was lethargic, loss of appetite for solid food, fussiness and irascibility at bedtime. Usually he was a happy child, good eater, would go right to bed. Instead, as reported by the parents, he was very different that day, that night. His urination and urine output, however, appeared normal.

When they did put him to sleep, they left him to cry to sleep. There was a blanket that was just draped over him, but not wrapped around his body or tucked in on the end of the mattress. The father said he laid Jordon on his back, and of course we know that he eventually wound up on his stomach. That suggests that he rolled over at least once.

When the mother went in the next morning, 8:00, 8:30 a.m., he was stiff. She immediately picked him up and started CPR. Now, of course, that suggests to the Court if he was stiff he had died some hours before, whatever that is, because he's stiff now.

He was found lying on his stomach with his head turned to the right. The blanket was over his back with part of it extending over the back, top and some of the front of his head. It extended over the top of his head, partially covered some of his face, but as was noted by the esteemed member of the judiciary that made the bench ruling heretofore, "The blanket was over the top of the head and perhaps part of the side of the head, but not the whole head. The way she indicated would be the back of the head. She's not indicating the right front face."

All right. What are our issues as the Court perceives it? What is not at issue? Neurologic components to death are absent. There was some discussion by that perhaps by Dr. Anderson. The Court finds that is a red herring. That's why Dr. Rorke-Adams was brought into it. At some point everyone agreed that there's nothing in the brain for our purposes to help us out. Petitioner's experts and Respondent's experts seem to concur on that.

Also what is not at issue: Jordon died of some fashion of asphyxiation. What should not be at issue, but perhaps is: SIDS, from my perspective, even the atypical variety, cannot be a cause of death as a factor unrelated as a matter of law, and I

would cite the case of Perez, P-E-R-E-Z, v. HHS, which was my case, which is why I'm quoting it, Case No.05-1261, filed in March 2008.

What is at issue: Was what asphyxiated Jordon anaphylaxis, anaphylactic shock, positional asphyxiation -- that is, smothering -- or something else? First issue: Did Jordon suffer from anaphylaxis within four hours of the vaccination? With an onset within four hours I should say.

Second issue: Did the anaphylaxis cause Jordon's death? Third: Was it SIDS or positional asphyxiation -- positional asphyxiation for contention is a legitimate factor unrelated -- that actually killed Jordon instead of the anaphylaxis as claimed?

Now, the first medical witness was Dr. Brady, Petitioner's pathologist, board certified in anatomic pathology, clinical pathology, forensic pathology, certainly very qualified. He has done autopsies on kids whose death was SIDS, as well as kids who died from sequela to anaphylaxis. As an aside, I would note that Dr. Rorke-Adams admits she's never done an autopsy on anaphylaxis victims. I think that's transcript at 101.

Dr. Brady saw no evidence of long-term chronic disease or abnormality in the autopsy results. Now, that's contra to Respondent's experts who did see chronic lung problems. Dr. Brady's review of the medical records did not review a history of chronic lung problems.

What Dr. Brady did see was changes in the child's lung in the small airways -- bronchioles, if I'm pronouncing it correctly -- where he found a bunch of eosinophils, that is "cells that are seen frequently, perhaps arguably diagnostically in cases of anaphylactic reaction or allergic reactions, and there very definitely were more eosinophils, enough eosinophils to cause me to focus on those."

Also in the bronchioles he saw changes in the smooth muscle beneath the lining membrane of these small air passages. These smooth muscles were contracted. There were areas in which the air passages were infolded, which means that I believe there was a muscular spasm to this involuntary muscle. As a consequence of this spasm, some of these small air passages were clearly constricted or were smaller than they would normally be.

Based on the following four observations, Dr. Brady concluded that an anaphylactic response to some material was a reasonable and medically likely cause of the changes in the child's respiratory system: 1) The presence of eosinophils; 2) Presence of trapped air in small air spaces within the lung; 3) Infolding of smooth muscle ostensibly due to spasms; 4) There was not the amount of fluid/edema/congestion of the lungs that is typical in cases labeled as SIDS.

Why else he thinks this was not a SIDS case: He thinks the enlarged thymus theory is junk science, has been rebutted. He doesn't think the kid, Jordon, rolling over would suffocate him spontaneously. He could be suffocated by somebody else, by another human, but not just alone in his bed.

Next, there was alveolar dilation and tearing, as Dr. Rorke-Adams pointed out, sure, but that only tells us he asphyxiated to death. Dr. Brady points out what's important I think certainly to Dr. Rorke and to myself is what was not there, and very clearly she and I and Dr. Selove, the pathologist, failed to see the amount of congestion and edema that is regularly, arguably diagnostically present in what we would -- some people -- call the sudden infant death syndrome.

He also points out that Dr. Rorke-Adams appears to ignore "the infolding and the eosinophils that I believe are important here, but whether this is simply something she failed to mention or not I don't know, sir." He mentions petechial hemorrhages on the thymus are present, but that only tells us he asphyxiated. It is not specific to SIDS.

The Court should mention what is atypical SIDS. He discussed some of this. It's already a catch all basket for the uncategorizable, so atypical SIDS is not an outlier to something uncategorizable. Dr. Brady says it is a clear message from the attending pathologist that this is a complete toss up diagnostically.

THE COURT: Okay. I don't know if it's important, but Dr. Brady makes a good point that Respondent's expert glossed over somewhat lividity on the left side of Jordon's face tells us only "the position that the body was in after the child died. That tells us not necessarily what he was when he died, but it tells us very clearly what position he remained in after his heart failed to continue to beat." The lividity only tells us the final resting position immediately following death.

Now, the Court should mention that Dr. Brady the Court finds was helpful and professional. He also indicated in reference to the Respondent's reports, "I respect their reports and their work and their experience. I think the reality of it is that all of us kind of focuses on different areas of the work that we do, and mine certainly is not the focus on neuropathology."

Next we go to Dr. Tilleli, Petitioner's clinician, board certified pediatrics, emergency medicine, pediatric emergency medicine, pediatric critical care medicine and in medical toxicology, and in his fields he's highly qualified. In fact, the Court recalls hearing Dr. Tilleli as a witness 18 years ago.

He admits that anaphylaxis is very rare in children under six months old. He has treated children experiencing anaphylaxis. He went into a long description of allergic exposure, the meaning of that, how this is not a roller coaster going downhill,

but rather it has ups and downs, at least from his experience and analysis; that is, anaphylaxis and/or allergic response. He discussed allergic response quite a bit.

He does not characterize the panting as distressed breathing, but counted it relevant because it was unique change in respiratory pattern. Remember, both parents said it was unlike anything they had ever heard Jordon or any other child do before. He thought it would be speculative to say too much beyond that. However, he would generalize by calling it respiratory difficulty and these as respiratory symptoms.

He also felt that he could not actually blame death on anaphylaxis as such on its own, but that it is useful in corroborating the pathological findings of which the presence of eosinophils is the most supportive of anaphylaxis because those are the inflammatory mediator cells.

So Dr. Tilleli said that the clinical evidence allowed him to say that Jordon suffered respiratory symptoms that could be characterized as allergic/anaphylactic. He also differentiated between anaphylaxis and anaphylactic shock. Assuming that the autopsy findings point to anaphylaxis, he felt the panting episodes were its onset.

In sum, Dr. Tilleli described Jordon's death as death from airway occlusion as evidenced by mild respiratory distress, more likely than not as a manifestation of an allergic response to the immunization, and of course allergic response, that language, is actually used in the Table definition of anaphylaxis, that is as an allergic reaction. This testimony presumably from his perspective goes towards rebutting Respondent's factor unrelated defense.

He also noted there's a striking absence of systemic or constitutional systems that are associated such as cardiovascular collapse or arrythmia, but the respiratory symptoms that are asserted in many ways comport with the pathologic findings that have already been testified.

Specifically, there's evidence of airway occlusion in both the large and small airways, and the prior pathologic testimony of bronchospasm would comport with the definition. There was evidence of alveolar overexpansion and an eruption, which would indicate that there was airway occlusion with enlargement of the alveoli and subsequent rupture, so the pathologic data comports and the symptomatology represents that onset of symptoms that would comport once again with his definition.

He reiterates that Dr. Brady mentioned the big thymus theory as a debunked myth. However, petechiae on the thymus and other solid organs represents a significant finding that would correlate representing airway occlusion.

Summing up on how it meets the Table's definition, he says the real issue is "whether or not the symptoms as described by the family represent the initiation" --

that is the onset -- "of a pulmonary pathology that would have terminated in the child's death later that evening.

"And in my opinion, absent a more thorough physical examination by a professional, which we'll never be able to have happen, one would have to I think reach the conclusion that this represents the initiation of those symptoms that would be associated with an allergic response that would in fact cause the symptoms that the Special Master elaborated when reading the definition of anaphylaxis."

And in response to a query proffered by the Court he said "by a preponderance of the evidence onset began minutes to a few hours after exposure" in the form of panting and hyperventilation.

Dr. Tilleli said it could not be SIDS from a pediatrician's perspective in that most of the SIDS deaths occur before the age of six months inasmuch as most of the time those deaths occur in a child who is developmentally incapable of rolling back or turning his head side to side, and that's in such tiny infants why that can happen, and of course we know that is not the case in Jordon's case because he was developmentally quite capable of doing those things.

So therefore, he felt it certainly not characteristic of classic SIDS inasmuch as Jordon could roll over. "The character and the classic definition of SIDS is not applicable under these circumstances." Dr. Tilleli did not see any "serious respiratory complaints" in the medical records for the period leading up to the vaccination. However, after the shot, in the autopsy there was reported swelling of the airway, glottis and muscle spasm/airway collapse by his reading.

He does concede that the autopsy evidence of asphyxiation by airway occlusion does not tell us what occluded the airway. He also mentioned that the small amount of vomitus that was found in the bed, but not in the airway, doesn't really help either perspective because we don't know if he choked on the vomit or vomited when he started choking, a natural response. The fact that it was not in the airway makes it less likely that he choked on it.

Ultimately his bottom line was allergic or anaphylactic response provides swelling to the airway, provides airway occlusion, leads to asphyxiation. Again, he continually used the terms allergic response. He also felt that the presence of eosinophils is Petitioner's smoking gun for the anaphylactic or the inflammatory reaction which Dr. Brady says that he saw.

We next move to Dr. Anderson, Respondent's pediatric pathologist, board certified anatomic pathology, clinical pediatrics, pediatric pathology. She addressed several red herrings at the outset. One was the discussion about whether there was a neurologic hemorrhage in the brain. She asks Dr. Rorke-Adams for a reading on that. Dr. Rorke-Adams said it was nothing.

She asked about focal bronchial pneumonia, but it was so mild that it could not have resulted in death. The Court would only proffer, and I guess this really is obiter dicta, the rhetorical query could it have weakened or constricted his breathing, and that's a question mark because nobody answered it and probably nobody knows.

Dr. Anderson agrees that Jordon died as a result of airway occlusion and concedes that the autopsy report recounts focal severe acute inflammation of mucous tissues in the area of the larynx within the trachea.

She said her review of the autopsy slides led her to find both acute and chronic inflammation of the airway in the larynx, the voicebox. She thought it looked like it had been there since before the vaccination. She also opined that he probably had some croup in the past.

Croup, as you know, is a pathological condition of the larynx, especially in infants and children, characterized by respiratory difficulty and a hoarse, brassy cough. However, there's no mention of croup, chronic or otherwise, to be found in any of the medical records or discussions.

The Court finds that an interesting opinion, but only can view it as an opinion that is certainly less than 50 percent because there's a lack of other evidence to support that contention, and the Court feels that probably Dr. Anderson was not coming to that conclusion by a preponderance of the evidence. If she did, it was error because the Court cannot.

Now, she agreed with Dr. Brady about hyperaeration in the alveoli, that is the smallest lung units, and that this indicates a struggle to breathe during asphyxiation. However, she attributes this asphyxiation to positional asphyxiation as seen in SIDS "because the infant was found in prone position and there was lividity on the left side of his face."

She thinks that the hyperaeration could have come from resuscitation efforts, blowing too much air into his lungs, adding, "I really feel that you can't die without being resuscitated, and the act of resuscitation can cause some of these artifacts which I am familiar with." I'm not quite certain what she meant by that.

However, the Court must conclude, because of the stiffness of Jordon when found by his mother, he had been dead for some time and, yes, if she had tried to resuscitate him -- I believe she did -- he died without resuscitation being attempted because he was already dead, so therefore that doesn't really make sense on her theory of that.

She agrees with Dr. Rorke-Adams that positional asphyxia was the most likely cause of death, but once the brain was eliminated as a cause of my concern I felt more comfortable declaring this atypical SIDS because of the presence of some

mild inflammation in the lungs, but it was insufficient to cause death. That also leads probably to issues of more discussion, none of which took place.

Now, Dr. Anderson at first said she did not see eosinophils in the lungs or any airway serration to indicate bronchospasms, and then she said right after that, "I was not impressed in any way with the eosinophils in this case, but the sampling of the lymphoid tissue was very limited so I really can't comment on that any further," which raises an issue. Eosinophils? If she wasn't impressed by them that suggests that perhaps there were some.

Anyway, later she said regarding the presence of eosinophils in the bone marrow that Dr. Rorke-Adams initially saw that, "The only disagreement I had, I did not see eosinophils in the bone marrow so I was not in any way impressed with any kind of eosinophils anywhere in this case. I think you could say that there was some eosinophilic cells present, but I interpret them differently from Dr. Rorke-Adams. That was my only disagreement with her in that regard."

Well, one could interpret that as a rather pregnant statement. If there were no eosinophils but she interpreted them differently, that doesn't make sense unless she is conceding, and I think she is, that there are some present. By the way, I should harken back to the Table definition where it says on autopsy minimal findings of eosinophil, liver, spleen, lungs, et cetera.

So there appears to be some minimal findings even under Dr. Anderson's definition. Anyway, she interprets them differently. She felt the thymus was too big, but she disregarded that and the other organ weights and felt that he was in relatively good health. She saw no evidence of anaphylaxis in the case.

Evidence that she said would need to be present to find anaphylaxis would be "some eosinophilia somewhere because that's a prime responder in anaphylaxis." As mentioned, she seems to suggest that there was some. However, when differentiating her views from those of Dr. Rorke-Adams she said: "The only disagreement I had, I did not see eosinophil in the bone marrow. I was not in any way impressed with any kind of eosinophils anywhere in this case. I think you could say that there was some eosinophilic cells present, but I interpreted them differently from Dr. Rorke. That was my only disagreement with her."

Now, that statement is self-contradictory, but the Court must conclude that in some fashion she saw some type of eosinophils present. She also again mentioned croup as a possibility in the past and that that could cause some inflammation to the vocal cords. However, the Court cannot concur by a preponderance of the evidence that croup ever occurred.

There was also a fair amount of discussion about items for anaphylactic shock, and presumably everything discussed by Drs. Anderson and Rorke-Adams is

correct, but that also can be viewed in part as a straw man because it is not averred that Jordon died from anaphylactic shock, but anaphylaxis. The anaphylactic shock is really the extreme form of the anaphylaxis as the Court understands it.

At one point in response to Respondent's own counsel:

"Q Did you see any evidence of shock here?"

"A No. There's no edema anywhere."

Okay. But the Court notes that the autopsy report does describe edema on microscopic and gross examination, Petitioner's Exhibit 7 at 2, and I think it's on several other pages, so therefore that's not quite an accurate statement.

She continually spoke strongly for SIDS, saying prone position probably was what asphyxiated him; because of his torticollis his ability to move his head and take control was undoubtedly affected by his neurologic condition. I'm not quite certain what she meant. What's the neurologic condition, because torticollis I don't believe is a neurologic condition. It is neuromuscular. I presume she meant the torticollis, but I don't know that.

Eventually on page 86 of the transcript Dr. Anderson indicated I think the age range for SIDS is appropriate, so based on these arguments she concludes that SIDS is the most likely cause of death as a factor unrelated. It is patently insufficient as a matter of law, by the way, according to the Davis case and in the Court's own Perez case, that SIDS in and of itself can be accepted as a factor unrelated. Positional asphyxia is acceptable.

In fact, one could even construe that the Court tried to clear that up with her and even assist her with her own definitions of positional asphyxia. Eventually she said:

"There has been a lot of terminology problems, if I may say so, in how this case is viewed, and I think it's testament to the confusion about how this could happen and the tragedy of it, and that's really what led to the whole concept of SIDS in the first place. It's not a specific diagnosis. It's the context in which an infant is not able to defend his airway and becomes asphyxiated."

Well, actually if you use that definition of SIDS it's not inconsistent with anaphylaxis and that raises other interesting queries, but we need not get into those. Dr. Anderson agrees that Jordon died as a way of airway occlusion and concedes that the autopsy report recounts focal severe acute inflammation of mucous tissues in the areas of the larynx within the trachea. She concedes that such findings do not support her opinion that Jordon died of SIDS, but makes, the Court might add, the Procrustean argument that because this was not typical SIDS therefore it's atypical SIDS, and the only way she seems to be able to explain the laryngeal inflammation

is by relating it to a chronic problem. However, if the inflammation is acute it would actually corroborate anaphylaxis.

Now, Lucy Rorke-Adams, and I personally have a lot of respect for Dr. Rorke-Adams. I think I've listened to her probably longer than I have Dr. Anderson. I'm thinking I may have heard Dr. Rorke-Adams 15, 16 years ago, perhaps more. All right. First she ruled out any brain injury or evidence of trauma. In her initial expert report she found "a few granules of hemosiderin and chronic inflammatory cells, including rare eosinophils," and her microscopic examination of the rib with marrow included prominence of eosinophils.

In her supplemental expert report she notes, interestingly, that she does not know what Dr. Selove meant in his diagnosis of atypical SIDS. She also could not ever recall seeing a case of anaphylactic death in a child of any age. I believe she said she had never done an autopsy on a child that she concluded or understood was anaphylactic.

Now, at the hearing she repeated the bit about seeing hemosiderin in the strips of the dura, but left off noticing eosinophils there as well, except by implied general reference to "chronic inflammatory cells." And as for the observation of the prominence of eosinophils in the rib marrow she stated, "I have to admit, quite honestly, that I don't spend much time looking at bone marrows so I obviously made an error there, but in terms of the other findings they represent what I saw on the slides." The Court could conclude as an aside that the only part where she made error was when she disagreed with Respondent's other pathologist, but everything else is okay, and the Court raises its eyebrow to that.

This child "did indeed die as a consequence of asphyxia, and if one takes into consideration the position of the child" -- I guess near blankets -- "and the other factors which are mentioned" -- presumably torticollis – "it's quite consistent to come to the conclusion that this child died as a consequence of positional asphyxia." Obviously the mention of the blankets and the torticollis were added by this Court.

She repeats Dr. Anderson to say that the autopsy did not show any evidence of anaphylaxis. There was no edema, no infiltration of the eosinophils. And again there was a long discussion about anaphylactic shock, but Petitioner does not aver this was a case of anaphylactic shock.

She also mentioned the petechial hemorrhages, fairly common in findings in sudden infant unexpected death. They're associated with asphyxia. They do not need to be present. On cross-examination she conceded that the signs she pointed out are not specific on positional asphyxiation, but generally confirmatory of asphyxial death. Furthermore, she agreed "a child who died as a result of an airway obstruction caused by anaphylaxis might have those same findings."

She also indicated she'd never seen an anaphylactic shock, so she deferred to Dr. Anderson. And with atypical SIDS, which Dr. Rorke-Adams seemed to take great exception to, she's not certain what the term means and therefore the meaning is to be based upon her having heard Dr. Anderson's testimony. Of course, it is a diagnosis by exclusion.

Now we move on to Dr. Lynne Maxwell, Respondent's clinician, who practices pediatric anesthesiology and team medicine, board certified pediatrics and anesthesiology. She does not actually work in the ER, which is where anaphylaxis cases generally would come.

There was some discussion about latex allergy. She doesn't really treat anaphylaxis very much because she doesn't work in the ICU and that's where they would be treated. There was also from her part a lot of discussion about anaphylactic shock, but this is not a case averring anaphylactic shock.

She says for Jordon to have airway symptoms of anaphylaxis "the signs of anaphylaxis in an infant would be a result of swelling of the mucosa of the upper airway and that would be severe, noisy breathing, respiratory distress with if it continued tiring and respiratory failure."

Actually, a great deal of that seems to be exactly what Petitioner is arguing with the panting. She said that the panting wasn't anaphylaxis and she can't relate the panting to any symptoms of anaphylaxis. She simply doesn't know what it was.

By the way, I should mention this is almost from the wayside. There was some discussion about an article of medical literature discussing anaphylaxis by Respondent, but the article saw anaphylaxis that affected at least two body systems as I understand it. Of course, that's because they only study people with at least two body systems affected by the anaphylaxis as part of their ground rules. I don't know if that's selection bias or not.

Dr. Maxwell concedes that the study's definition is different from the Table definition, and that becomes in its own way puissant. There are obvious disagreements between Drs. Maxwell and Tilleli. Tilleli mentioned that this is not a roller coaster going downhill, the symptomatology, but it has ups and downs. Dr. Maxwell felt that it was really something that once it started it continued. The Court can only mention Dr. Tilleli actually treats these kind of infants or young children. Dr. Maxwell does not.

Dr. Maxwell also mentioned that edema, which is one of the hallmarks of anaphylaxis, was missing in this case, but of course edema is mentioned in the medical records in the autopsy, Exhibit 7 at 3, 4 and 6. Dr. Maxwell ultimately opined:

"Anaphylaxis itself, as I said before, causes leakiness of the blood vessels and losing the fluid in the blood vessels itself leads to shock, so usually when you see anaphylaxis you see low blood pressure, shock, poor profusion in addition to the airway swelling. Airway swelling itself doesn't cause shock, which is low blood pressure, but airway swelling or airway obstruction can cause, you know, low oxygen, which can cause heart arrhythmia and death, but the mechanism isn't shock."

Now, all of us must remember that for Table purposes Petitioner just has to show the occurrence of anaphylaxis or anaphylactic shock, either one, so discounting the shock does not eviscerate Petitioner's case and a discussion or the airway swelling from anaphylactic response is actually in line with Petitioner's theory.

Dr. Maxwell also raised the possibility that Jordon choked on his own vomitus, a trace amount of which was found on the pillow. The Court must construe this as a red herring ultimately because there was none found in the airway when he was found or mentioned on autopsy. It's more probable that he vomited a bit when he was struggling to breathe/ asphyxiating.

To take it a step further, it would be quite a feat for him to have the vomit lodge so securely in his airway that coughing, et cetera, would not dislodge it, but that it would simply run out after he died.

And ultimately, of course, Dr. Maxwell concludes it is impossible to know what the mechanism of Jordon's death was, but it sounds like from the pathologic findings there was some cause of airway obstruction. She also discussed SIDS and atypical SIDS and that this case seemed to fall into that rubric.

She cited a study that gave an age range of SIDS unexplained deaths which included Jordon's age range. However, the Court must conclude that this evidence is unreliable since it included all unexplained deaths -- failure to thrive, et cetera -- not just asphyxial deaths, which even Respondent's experts agree is a subject of SIDS death and it's only asphyxial deaths that we're concerned with here.

Now, there's a certain discussion here of statistical prevalence, but remember as a matter of law as per the Knudsen case statistical prevalence is not a sufficient or even viable guide to what happened in an individual case. In the individual case the evidence of the case is what the Court is to focus on.

Here there is scant evidence of asphyxiation by gastro-esophageal reflux, so its relative prevalence in other cases is de minimis here. Of course, she also indicated again she is a pediatric anesthesiologist so she isn't treating illnesses.

All right. Ultimately the Court must rule. Jordon died an asphyxial death. The question is what caused him to asphyxiate? Several nonspecific pathological

findings support the conclusion, including petechial hemorrhaging on certain organ surfaces.

The Court finds by a preponderance of the evidence that the panting spells were indicia of the anaphylaxis onset, insufficient in and of themselves to implicate anaphylaxis, but corroborated by the pathological findings. They were the onset of something that proved to be "acute, severe and potentially lethal" even if such a level was not reached at the onset, but obviously mere hours later.

Jordon's panting spells following his vaccination were qualitatively different from other respiratory symptoms he had experienced previously for which he had been to the doctor's months prior. What began as nondistressed panting spells appears to have crescendoed to a more severe and sinister anaphylaxis in the late night hours following the onset. The anaphylactic reaction was severe enough to obstruct Jordon's airway, even if it did not have opportunity to cause multi-organ damage or full-on shock.

Edema was present in Jordon's lungs and elsewhere. By the way, it's not a necessary finding, but it could be and therefore that means it's conjectural, that any prior airway problems, whether the chronic inflammation that Respondent's expert saw were just irritation from the recent upper respiratory infection he was recovering from or even his torticollis may have left him vulnerable to suffocate from even less airway occlusion than might otherwise have been necessary to asphyxiate another child.

Now, that's not my conclusion, but I raise that as an interesting possibility. At any rate, eosinophils were noted by Dr. Brady and initially by Dr. Rorke-Adams before she was coached. The only pathologist who stated independently and originally that there were no eosinophils was Dr. Anderson, although she seemed to change her story on this point to acknowledge that she did notice eosinophils, but just didn't think they were relevant.

Thus, death was a sequela of the anaphylaxis. SIDS was not a causal factor. SIDS as a nonspecific, cryptogenic description of exclusion is insufficient as a matter of law to explain the cause of Jordon's death. Positional asphyxia is not found as a causal factor of Jordon's death in this case because Jordon was alone in the bed and he was physically capable of protecting his airway against one -- even a few -- blankets away or the blanket that was partially over him, given his age and noted ability to roll over and even to raise himself up on his hands and knees.

The blanket's position as described by the only eye witness did not cover his mouth, only laid partially across part of his face, not enough to obstruct the airway. The blanket was not wrapped around the face, was only a light end-portion -- edge or corner -- that laid across.

Therefore, Petitioner prevails and the Court awards the standard death benefit as indicated and permitted by the Vaccine Act.

All right. I read that rather fast if anyone paid attention, but let me ask both parties ad seriatim whether there's anything that the Court did not explain that the Court needs to explain. Mr. Webb?

MR. WEBB: No.

THE COURT: Mr. Milmoe?

MR. MILMOE: No, sir. Thank you.

CONCLUSION

Therefore, in light of the foregoing, the Court **RULES** in favor of entitlement in this matter. **Petitioner is awarded the statutorily-determined sum of $250,000.00.**[3] § 15(a)(2). In the absence of the filing within 30 days of this date of a motion for review, filed pursuant to Vaccine Rule 23, **the clerk shall forthwith enter judgment in accordance herewith.**

IT IS SO ORDERED.

Richard B. Abell
Special Master

[3] If Petitioner believes that she is entitled to lifetime economic losses, she may move the Court for Reconsideration on the limited question of any additional, legally cognizable damages.