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

No. 04-0044V

Filed: 10 January 2007

JULIANNE L. COLON, parent of SIERRA KENDALL COLON, a minor Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED Hepatitis B, Neonate, Sepsis, Serum Sickness

David R. Grant, Esq., Cleveland, Ohio, for Petitioner.
Alexis B. Babcock, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION[1]

On 15 January 2004, a petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)[2] was filed by Mrs. Julianne Colon alleging that her daughter, Sierra, died as the result of receiving a Hepatitis B vaccine administered 17 January 2002.

A hearing was held last year following which multiple supplemental evidentiary filings were made. While the Court does not generally countenance such abnormal procedure, in this instance and out of fundamental fairness to the Petitioner, the Court allowed such filings to be submitted and

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[1] Petitioner is 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 decision 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.A. §300aa.

allowed Respondent the opportunity to produce evidence per contra. After these filings were made, a full briefing schedule was had, and now the case is ripe for a decision.

The Vaccine Act authorizes the Office of Special Masters to make decisions on petitions which shall include findings of fact and conclusions of law. §12(d)(3)(A)(I).

I. FINDINGS OF FACT

The Vaccine Act indicates that the Court may not rule in favor of a petitioner based on her asseverations alone. Rather, a petitioner's claims must be substantiated at the very least by medical records or by medical opinion. § 13(a)(1). Therefore, the Court turns first to the recorded facts and then to the opinions offered thereon.

A. Hepatitis B Vaccine

According to evidence taken in this case, it is now standard procedure to administer the Hepatitis B vaccine to newborns. While such has occurred in certain areas around the world for some time, according to the experts in this case, it is a relatively recent phenomenon in these United States dating back only to 2002. Hearing Transcript ("Tr.") at 116.

The Hepatitis B vaccine is administered in a series of three shots. The effect of the first is to prime one's immune system such that the second and particularly the third administration will prompt one's system to create a protective barrier against Hepatitis B infection. Tr. at 195. One rationale for administering Hepatitis B vaccine to neonates is that such an administration has been shown to have the same effect if given to a newborn as it would if given several months out. Id. Ergo, a child can be protected sooner rather than later if immunized early. Yet, Petitioner's immunological expert disagrees as to the prudence of immunizing neonates with the Hepatitis B vaccine, particularly as a neonate's immune system does not come fully online until several months after birth. Tr. at 40-41. Until that time, the babe is primarily reliant on those attributes of immunity conferred by the mother. Id.

The Court draws no conclusion regarding the practice of immunizing neonates but would encourage further medical and scientific investigation in this "field bereft." Althen v. Secretary of HHS, 418 F.3d 1274, 1280 (Fed. Cir. 2005).

B. Factual Recitation

Sierra Colon was born 15 January 2002, the result of a pregnancy significant for maternal infection with group b streptococcus, premature rupture of the membranes 48 hours prior to birth, an antecedent urinary tract infection with hydronephrosis[3] and renal stones, and borderline premature

[3] Hydronephrosis is defined as "distention of the pelvis and calices of the kidney with urine, as a result of obstruction of the ureter." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 872.

birth. Petitioner's Exhibit ("Pet. Ex.") 3 at 6; 2 at 19. Therefore, during delivery the mother was treated with an antibiotic that transferred via the placenta to Sierra. Pet. Ex. 3 at 59; Hearing Transcript ("Tr.") at 153. The goal was to protect Sierra who was at risk for sepsis.[4] Sierra received no continuing antibiotic treatment post-delivery.

During Sierra's stay at the hospital, blood work demonstrated a normal platelet count. And on the morning of 17 January 2002, she received a Hepatitis B vaccination. Pet. Ex. 2 at 13. Overall, she seemed fine to all concerned, though a "scalp contusion" and "red reflex" in her eyes were noted, and she was listed as a "normal newborn" at discharge. Pet. Ex. 2 at 5.

However, during the afternoon of 17 January, concurrent with her discharge, the parents claim they noticed and consequently raised some concerns to the nurses regarding Sierra's color and apparent breathing difficulties. Those concerns are not noted in the medical records, but the Court has no reason to doubt the parental asseverations.

The mother recalls nursing Sierra at 7:30 p.m. and at frequent intervals thereafter. As a concerned, first-time mother, the Petitioner also took the child's temperature several times during the evening but noticed nothing unusual. She recalls waking in the middle of the night to feed Sierra. The child latched and the mother fell asleep sitting up while Sierra nursed. The mother recalls awaking after what appeared to have only been a few minutes to find Sierra unresponsive. Medical intervention was to no avail, and Sierra was pronounced dead the morning of 18 January 2002. Pet. Ex. 6 at 1; and Pet. Ex. 7.

The forensic pathologist who performed the autopsy that day, Dr. James Patrick, was very thorough.[5] Pet. Ex. 8. Jaundice, a yellowish discoloration of the skin, was clearly visible, but no rash was reported. On internal examination, Dr. Patrick noted nothing out of the ordinary with the brain, heart, thymus, adrenals or kidney. Regarding the spleen, he did note malpighian corpuscles, or white particles of the spleen, that were visible to the naked eye. Post-mortem cultures of the blood and of the cerebral spinal fluid ("CSF") grew no pertinent organisms. Some growth did occur in the CSF several days out but is agreed by all to have been caused by lab contamination. Pet. Ex. 8. The placenta was not tested.

The slides and samples taken by Dr. Patrick revealed prominent myelopoies occurring in the liver. In other words, the tissue that generates blood cells, found in the portal area of the liver, was producing leukocytes, or white blood cells. The liver also showed a presence of eosinophilic myelocites; however, as will be discussed, infra, there is a dispute between the pathologists involved in this case as to how these cells should be properly categorized as eosinophils or as metamyelocytes,

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[4] Sepsis was colorfully defined by Dr. Virginia Anderson as "Bugs in the blood." Tr. at 230. It refers to "the presence in the blood or other tissues of pathogenic microorganisms or their toxins." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1681.

[5] It was noted that Dr. Patrick produced not just a handful of evidence but a remarkable 70 slides and 79 sections. Tr. at 217.

and consequently whether their presence is normal or is indicative of an allergic or of an infectious process.

Some hematopoieis, the production of blood cells, is noted in the pancreas. Similarly, hematopoiesis is present in the bone marrow as well. Again there is some dispute as to the nature of that hematopoiesis – whether any erythropoiesis, the production of red blood cells, was occurring or whether the bone marrow was solely producing white blood cells – and the interpretations associated therewith. In addition, diffuse polymorphonuclear leukocytes ("diffuse polys") are noted in the lungs.[6] Again, there is a dispute as to what they represents and even whether they were present.

As for Dr. Patrick, he noted "extensive periportal inflammatory infiltrate in liver consistent with possible sepsis" and listed her death as such, "extensive periportal infiltrate consistent with possible sepsis (hours)." Pet. Ex. 8 at 1.

It later came to light that the Petitioner, prior to conceiving Sierra, had been immunized against Hepatitis B and, as shown by a test conducted in 2005, had protective levels against the malady. Hence, the Court can safely assume that the mother's immunization was effective and that she would have had protective levels when Sierra was conceived and born. Tr. at 182.

At trial, however, Petitioner testified that her health had been compromised by the aforementioned administrations of the Hepatitis B resulting in Crohn's disease.[7] Tr. at 9, 19-20. This fact had not previously been alleged or included with any of Petitioner's filings including her pre-hearing memorandum. Neither was any evidence or medical records filed in this respect. Hence, the Court informed the parties during the hearing that no conclusion would be drawn as to a connection between those vaccinations received by Petitioner and her subsequent medical course. Tr. at 239.

B. Medical Opinions

To reiterate, the Court may not find in favor of a petitioner based on his asseverations alone; rather, the claim must be substantiated either by medical records or by medical opinion. §13(a)(1). In the present instance, the medical records by themselves do not substantiate Petitioner's claim. Therefore, she must rely on the medical opinions proffered.

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[6] A polymorphonuclear leukocytes ("poly") is "any fully developed granular leukocye whose nucleus conains multiple lobes joined by filamentous connections, especially a neutrophil." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1021.

[7] Chron's disease is a "chronic granulomatus inflammatory disease of unknown etiology, involving any part of the gastrointestinal tract from mouth to anus, but commonly involving the terminal ileum with scarring and thickening of the bowel wall; it frequently leads to intestinal obstruction and fistula and abscess formation and has a high rate of recurrence after treatment." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at531.

In addition to the records summarized supra, the Petitioner offered live testimony as well as an initial and several supplemental reports from Dr. Alan Levin and from Dr. Kevin Bove.

Dr. Levin holds board certifications in allergy and immunology, pathology, clinical pathology and is board-eligible for anatomic pathology. While his medical training and practice go back some decades and while he remains an adjunct on the faculty of the University of California in the Department of Pediatrics as a pediatric immunologist, since 1993 Dr. Levin has concentrated on his legal practice. When he was actively practicing immunology, his patients primarily were adults. And he continues to follow a handful of patients. He has not practiced clinical pathology since the 1980s.

Dr. Kevin Emil Bove is a pediatric pathologist at Cincinnati Children's Hospital Medical Center and is on faculty with the University of Cincinnati College of Medicine. Dr. Bove was board certified in anatomic and clinical pathology in 1966 and, along with Respondent's expert, became board certified in pediatric pathology when such first came available in 1990. Tr. at 124.

The Respondent meanwhile offered written medical opinions as well as live testimony from Dr. Brian Ward and Dr. Virginia Anderson.

Dr. Ward is Chief of Infectious Diseases at McGill University and Montreal General Hospital and holds board certifications in these United States in internal medicine and infectious diseases. In Quebec he holds board certifications in internal medicine and infectiology, a mix of infectious diseases and microbiology. Tr. at 159-60.

Dr. Virginia Anderson is on the faculty of SUNY in Brooklyn, New York, and also the King's County Hospital, in Brooklyn, New York. She is board certified in anatomic pathology, clinical pediatrics, and pediatric pathology. She performs an estimated 100 autopsies per year, two thirds of which are infants, and has been doing so throughout her 38 years of practice. She has also published extensively in her field. Tr. at 206-08.

As will soon become apparent, though the histological evidence itself is not much in dispute, the interpretation of that data by the learned experts on both sides is most definitely at odds.

1. Dr. Levin

Dr. Levin avers that Sierra died as a result of a fatal, neo-natal serum sickness. That is to say, the Hepatitis B vaccine administered the morning of 17 January 2002 caused an immune-complex reaction that resulted in the child's death. Further, Dr. Levin maintains that, while some evidence could be interpreted as being related to sepsis, more likely than not it was serum sickness that caused Sierra's death. Tr. 101.

Prior to Sierra's birth, the mother had been immunized against Hepatitis B infection and had, as tests later revealed, protective levels against the virus. Hence, Sierra would have received antibodies transplacentally from her mother that would recognize and perhaps protect her from

Hepatitis B infection. Tr. at 42. According to Dr. Levin's theory, when the Hepatitis B antigen was introduced into Sierra via the vaccination, those existing antibodies recognized and reacted to that antigen resulting in an immune-complex disorder which then caused a "cytokine cascade" also known as serum sickness. In an adult such a condition is rarely, if ever, fatal, but in a fragile neonate such as Sierra, the shock to her system resulted in her untimely demise.

As Dr. Levin states:

> Well, when you have what we call a cytokine cascade, you're going to have – you can get shock, you get hypotensive, you get edema in your brain and that will kill you. You also get liver involvement, lung involvement, so it – the entire body is involved in this terrible reaction because these immune complexes are circulating with the blood all over the place and they're turning on inflammatory reactions in all tissues, so eventually, if the serum sickness goes on long enough, you're going to see all – virtually, all of the internal organs involved.
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> . . .
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> [F]or a two day old infant, it's fatal.

Tr. at 47.

According to Dr. Levin, the autopsy was as significant for what was not seen as for what was. For instance, had Sierra's death been related to sepsis, one would expect to find the organism itself that did the damage and one would also expect to see systemic evidence of an inflammatory reaction as well as stress induced changes. Instead, the thymus was normal as were the kidneys, the heart and the adrenals. Prior to death, blood work done at the hospital showed no elevated platelet count, which militates against an infection. Tr. at 84. Moreover, no organism was ever identified via the post-mortem cultures including blood and CSF cultures. And there is no indication in the autopsy slides or samples of an organism including no colonization of the lungs. Rather the diffuse polys in the lungs are indicative of a blood borne immune reaction rather than an infection. Tr. at 53-54. In addition, Sierra showed no signs of a seventy-two hour struggle – the time frame at issue if she was infected during labor as Respondent suggests. Likewise, there is no indication that she was irritable or cranky, and she was willing and able to nurse.

To Dr. Levin, the key finding revolves around the eosinophils in the liver, "which is classic of an allergic reaction, of a reaction against vaccine. The eosinophils give it away, so that's what – that's the autopsy evidence." Tr. at 54.

According to Dr. Levin, "both sepsis and immune complex disease can cause the kind of reaction that we see [in the liver], the periportal inflammatory response, but the presence of eosinophils indicates that it's an immune reaction, not a septic reaction." Tr. at 62.

As pointed out on cross examination, Sierra clearly did not evince the symptomatology one would expect to see with serum sickness including "chills, fever, rash, and arthritis." Tr. at 103. She exhibited no rash, nor hypothermia, nor artrhragias, and showed no sign of "complement activation

and vasculitis with tissue necrosis secondary to immune complex, which would cause pathological alterations in the tissue." Tr. at 78.

But Dr. Levin explains first, Sierra died so quickly that many of those elements had no time to develop and, second, a newborn would not show the same indicia as an adult. For instance, the immune response in a neonate's skin is immature, and so rashes often do not show. Tr. at 75. Neither would a newborn evince hypothermia (or fever for that matter) as its temperature is not well regulated. Id. at 75-76.

In support of his medical theory, Dr. Levin proffered numerous pieces of medical literature but none directly on point. According to the doctor, as the immunization of neonates with Hepatitis B vaccine is a relatively new phenomenon in these United States, not much exists by way of direct proof regarding his theory. Yet, enough has been written on the various topics such that certain inferences can be made.

> Dr. Levin concludes:
> The histopathology shows an antigen antibody reaction, there are no positive cultures, there's no evidence of that – of infection, so there's no other logical explanation for the child's death than the reaction to the Hepatitis-b.
> . . .
> It's the only logical explanation for the symptomatology that this child had. Every other explanation is simply speculation.

Tr. at 71.

2. Dr. Bove

Dr. Bove, a pediatric pathologist testifying on behalf of Petitioner, opines that the histolological picture does not support a diagnosis of sepsis. However, he also found no indication that her death was related to serum sickness.

Dr. Bove finds a lack of evidence telling. Namely, he saw no evidence of a "tissue response to a bacterial or a viral infection, such as pneumonia or meningitis, or myocarditis, or viral-induced tissue necrosis in vital organs." Tr. at 127.

Neither did he find evidence of an inflammatory process in the autopsy slides of the brain or spinal cord. Tr. at 141.

Neither was there a "positive postmortem blood culture for a likely pathogen, such as e-coli or group-b streptococcus, and that would be particularly useful in a baby who has not been treated with antibiotics, which is my understanding in this case." Tr. at 127.

Neither was there evidence of an inflammatory reaction identified in the placenta. Tr. at 127.

Neither was there "evidence of a pattern of ischemic damage in vital organs such as the heart, liver, or kidneys, that would occur during an episode of poor profusion and shock, something that is liable to happen in fatal sepsis, and I don't see such changes." Tr. at 127. For instance, with the heart, "[y]ou may not see anything," but one would expect to see certain indicia of stress. Tr. at 137.

And finally, Dr. Bove saw no "evidence of microthrombi in the small vascular organs such as the kidneys, liver, spleen, and lung, which would suggest that the child had developed a complication of sepsis known as disseminated intravascular coagulation.[8]" Tr. at 127-28. In particular, the spleen shows "normal lymphoid tissue" and no indication of a bacterial infection; hence, the spleen does not "show any positive evidence for sepsis." Tr. at 137.

Going into greater specificity, Dr. Bove considered the activity in the liver "a variant of the normal – that one would find in a newborn baby and in and of itself, the fact that it's present or actively producing leukocytes in the liver, which is a place where this normally takes place, is not a sign of sepsis." Tr. at 138. And yet, when asked by Petitioner's counsel if the eosinophils seen on autopsy are indicative of an allergic process, Dr. Bove responded quite certainly:

> No. These eosinophilic myelocytes are a normal component of active myelopoietic tissue. They are normally present in the bone marrow and they are normally present in the – among the myelopoesis that you find in the liver of a newborn baby.

Tr. at 139.

Dr. Bove likewise indicates that the presence of hematopoiesis in the bone marrow is not a sign of infection because: "in newborn babies, a transition is going on from the hematopoiesis in the liver to hematopoiesis in the bone marrow. The fact that there is hematopoiesis in the bone marrow, in this case, merely means to me that the normal transition is taking place." Tr. at 139.

Similarly, Dr. Bove interprets the pancreas as being normal and does not find the "little bit of hematopoiesis in the pancreas" indicative of sepsis although he admits the possibility that with sepsis, hematopoiesis may be more active in the pancreas and kidney. Tr. at 140.

Dr. Bove says that, with sepsis, you "might" expect to see "poor profusion related to poor blood flow, related to septic shock" in the esophagus, stomach, small intestine and colon, but none such was found. Tr. at 140-41.

Given these lack of findings, Dr. Bove believes a diagnosis of sepsis "possible, but it's not likely" and, in the end, is "more of a speculation." Tr. at 128.

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[8] Disseminated intravascular coagulation is "a bleeding disorder characterized by abnormal reduction in the elements involved in blood clotting due to their use in widespread intravascular clotting." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at531.

Dr. Bove admits that jaundice and respiratory difficulties can be indicative of sepsis. And yet, he insists on having hard evidence like infection of organs at autopsy or a positive blood culture before a such a diagnosis could be made. Tr. at 132.

Moreover, "Sepsis implies that there is bloodstream invasion and there is a generalized infection, so in the blood culture, properly obtained, is a pretty sensitive way of identifying whether sepsis was incurred, at autopsy, provided that there have been no antibiotics and that the culture was properly handled from the microbiological standpoint." Tr. at 133.

However, it became readily apparent at trial that Dr. Bove was not altogether familiar with the case. He was unaware, for instance, that several risk factors for sepsis were indicated in the medical records including a preceding urinary tract infection, prolonged rupture of the membranes, and maternal infection with group b streptococcus. He was similarly unaware that the mother and thereby the child had received antibiotics prior to and during delivery. Tr. at 129-31. Also, while there is no evidence of inflamation in the placenta, there is no indication in the records that it was ever examined. Tr. at 147.

On being appraised of these facts on cross examination, including the risk factors and antibiotic treatment, even so Dr. Bove maintains:

> [L]ike I say, it's possible the baby had sepsis. If you go down the list of criteria that I enumerated, blood culture is one of them.
>
> . . .
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> The interpretation of the negative blood culture, if the mother had received antibiotics, there's – obviously going to be different than if she didn't have antibiotics, but I would then – it's – the diagnosis of neonatal sepsis depends on the totality of all of these findings. One – no one is sufficient, one way or the other.

Tr. at 134.

As to the Dr. Levin's theory concerning serum sickness, when asked on cross examination "In your review of the slides, did you see any evidence of serum sickness," Dr. Bove responded with a resounding "No." Tr. at 147.

On redirect, Petitioner made some effort to discredit her expert's testimony regarding serum sickness. The exchange occurred as follows.

> Q Doctor, you're not a trained immunologist, is that correct?
>
> A No, I am not.
>
> Q Okay, so not talking about what you would see from autopsy for serum sickness, but in the sense of what serum sickness is, you would defer to an immunologist?
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> A Yes, but that doesn't mean I wouldn't engage in a discussion with him or her.
>
> Q Sure. Are you trained in, and actively practicing in, the field of Immunology?

A Well, in the field of immunopathology, yes. I routinely use immunological methods to analyze muscle biopsies, which is one of my areas of specialization.

Q Okay, thank you.

Tr. at 148-49.

According to Dr. Bove, while he cannot rule out a diagnosis of sepsis, "my ultimate conclusion is that the cause of death is not apparent from the autopsy." Tr. at 147.

3. Dr. Ward

According to Dr. Ward, while the serum sickness theory is not entirely implausible, given the near complete dearth of evidence in the medical literature including papers, case studies, and even anecdotal reports, it is quite unlikely to have occurred in the present instance.

Dr. Ward explains that serum sickness is categorized as a type III hypersensitivity (allergic) reaction and "is the result of antigen combining with antibody" thereby creating antigen-antibody complexes that can deposit in one's tissues causing "a number of pathologic consequences" including "the induction of fever, presumably through the production of the proinflammatory cytokines" as well as joint pain and swelling, skin rashes, an so forth. Tr. at 166. The typical time-frame for serum sickness to develop depends on whether antibodies are already circulating in one's system or whether one must manufacture those antibodies. "In the presence of preformed antibodies, [onset] can be more rapid, but very, very rarely, in the literature, is it under a day." Tr. at 167-68. The median is 36-48 hours. Whereas the complications associated with serum sickness can result in death, it is not considered fatal. Hence, "There are very, very few case reports, if any, of well-documented serum sickness leading to death, acutely." Tr. at 168.

However, Dr. Ward notes and provides ample documentation via medical literature that the neonatal immune system itself is "slow, sluggish, deficient in just about every aspect of it's (sic) capacity to respond." Tr. at 161. It relies on the anitbodies communicated transplacentally by the mother. And yet, the neonatal immune system can respond and, in fact, "clearly, to some organisms, the infant – even neonatal immune response can be adequate, even excellent." Tr. at 163. For instance, according to Dr. Ward, utilizing a combined approach of passive and active immunization[9] with the Hepatitis B vaccine perinatally, the time frame involving the last five months of gestation and shortly after birth, has worked quite well in protecting children at risk of contracting Hepatitis B. Tr. at 163.

According to Dr. Ward, there is no question that Sierra inherited a complement of Hepatitis B antibodies from her mother. Tr. at 182.

[9] Passive immunization involves direct delivery of antibodies for protection whereas active immunization involves triggering the immune system to protect against a specific threat. Tr. at 163-65.

But as for Dr. Levin's theory regarding a serum sickness reaction occurring in Sierra's case, Dr. Ward offered the following observation:

> [I]s it plausible that preformed antibodies would bind with antigen that was administered? Yes, I expect that I – that if that – if the question is, can – are there immune complexes circulating in children who have preformed antibodies and who receive hepatitis-b vaccine, I think that's a very interesting study to do, and my a priori hypothesis would be that we could identify them in a small number of kids.
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> . . .
>
> So, yes, I think it's plausible.

Tr. at 175.

And, in fact, if events did occur as theorized by Petitioner, Dr. Ward admits that the end result may look very similar to what is seen with sepsis:

> [I]f Dr. Levin's theory is, you know, in any circumstances, ever true, the final immunopathologic processes may be very similar between septic shock and serum sickness-induced pathology. It's just that we don't see people who die from immune complex. It doesn't happen that I'm aware of.

Tr. at 174.

Dr. Ward finds the possibility that Sierra's death was related to serum sickness quite unlikely given the totality of the circumstances and particularly the evidence weighing in favor of a diagnosis of sepsis.

> The clinical picture, unfortunately, is one of sepsis and/or sudden infant death syndrome, simply because the child, Sierra, was unfortunately more susceptible. She had several risk factors, borderline immaturity, premature rupture of membranes, the possibility of a maternal infection with the hydronephrosis, perinatally, and then, the fact that Sierra did not receive antibiotics postnatally, which is, in some hospitals, a standard protocol until the cultures have come back negative.

Tr. at 172.

Dr. Ward opines that Petitioner has not and cannot rule out sepsis as the cause of death given the risk factors and other indicia identified in the case. Moreover, the lack of a positive culture is not conclusive since, in as many as 30% of cases, the organism is never identified.

> We have many adults, infants, and neonates, particularly neonates, who die with sepsis syndrome, because we can't call it sepsis in the absence of a definitive bacterial cause, but they have sepsis syndrome and they die in the absence of any anti – any bacterial cultures coming up positive. And, in some cases, we really try. In many cases, we really try multiple cultures from multiple sites and we come up empty handed. It's frustrating as hell, but it happens all the time.

Tr. at 202.

In a colloquial take on Occam's Razor,[10] Dr. Ward remarked, "The saying on the rounds is, if you hear hoof beats, look for horses, not zebras.'" Tr. at 205.

4. Dr. Anderson

Dr. Anderson opines that the histologic evidence indicates sepsis is to blame for Sierra's death.

As two thirds of her autopsies involve sepsis, Dr. Anderson acknowledges that the diagnosis often can be difficult to reach "recognizing the enormous list of things that can occur in sepsis, but they never all occur, so we have to look toward the preponderance of evidence and answer, 'is it more likely than not?'" Tr. at 209.

Here, Dr. Anderson first examines the risk factors associated with Sierra's case including the preceding UTI and the presence of group b streptococcus and notes "risk factors are real. I mean, that's why they're risk factors. That means, if you have one of these heavy risk factors, you're more likely than not going to have the consequences of the risk factor." Tr. at 231. Dr. Anderson also posits that the partial-treatment with antibiotics, their administration via the mother, but not continuing that course after Sierra was born, made it all but impossible to identify the organism via a culture. Tr. at 226.

Histologically, Dr. Anderson points to evidence on autopsy that shows "footprints" indicating that Sierra's immature, underdeveloped immune system was trying to ramp up to combat an infection. Tr. at 210.

Of primary import to Dr. Anderson is the leukemoid reaction seen systemically in the liver, bone marrow and spleen.

As to the liver, Dr. Anderson argues that its generation of blood cells was more excessive than one would expect with a newborn and represented a leukemoid reaction or the creation of white blood cells designed to fight infection.

Dr. Anderson does not agree that the cells seen in the liver are eosinophils characteristic of an allergic reaction but are myelopoiesis cells indicative of an infectious process. Tr. at 215. According to Dr. Anderson, while there may be a few eosinophils in the liver, the predominant cell type is metamyelocyte which is the kind produced to combat bacterial infection; and, while "metamyelocytes have eosinophilic granules in the cytoplasm," these cells do not have the "morphology" of an eosinophil. Tr. at 227-28. As she further explains:

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[10] Named after the Franciscan friar William of Ockham, "This rule is interpreted to mean that the simplest of two or more competing theories is preferable and that an explanation for unknown phenomena should first be attempted in terms of what is already known." THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed.).

> Well, it's a very common problem I have with my residents. They call them eosinophils, but they're really metamyelocytes, which means they are immature polys.
>
> Immature polys, the metamyelocyte, has eosinophilic granules in them, but they're not of the eosinophilic series, okay? So, it's very easy to just call them that, so I don't really disagree with them, it's just the semantic – it's just that I'm a purist, okay? I agree with them, they are eosinophils there, but I'm being cautious because I don't want you to consider this an allergic reaction. It has nothing to do with allergic reactions, and I'm sure Dr. Levin understands what I'm trying to say.

Tr. at 228-29.

She disagrees with Dr. Bove as regards the bone marrow noting that, while it is normal for the liver to produce blood cells at first and then transfer that job to the bone marrow, Sierra's case was abnormal because the bone marrow was exclusively producing white blood cells, the sort meant to fight infection. Tr. at 224. In a normal newborn, when the job of producing blood cells shifts between the liver and the bone marrow "usually, it's mixed cellularity, and when you have an exclusive sheets of myelopoiesis cells in the bone marrow and also in the liver, as was noticed by Dr. Patrick, that kind-of tells you that there was something around, instigating that. That wouldn't just happen by itself." Tr. at 211-12. Instead of creating both red and white blood cells, Sierra's bone marrow was evincing "pure white cell hyperplasia" in response to some microorganism. Tr. at 224. This "brisk up-regulation of metamyelocytes and immature neutrophil cells" created to fight infection, seen in the bone marrow "even to the exclusion of the production of red cells," is an indication that the bone marrow was stimulated by a pathogen of some sort. Tr. at 211, 221.

According to Dr. Anderson:

> I rest a lot of my support for calling this sepsis on the basis of this finding in the bone marrow and the liver, and also, the malpighian corpuscles, the white particles of the spleen, were visible, grossly, to Dr. Patrick. He described this in his very well-done autopsy, and you would only really see that if there were increased expression of white blood cells in the spleen, as well.

Tr. at 215; see also Tr. at 223-24.

Continuing, Dr. Anderson opines:

> I know for a fact there's only one way that what I showed you in the bone marrow and in this liver, there's only one way that that can happen, and that means that that baby saw bugs, and if that baby saw bugs, those bugs were running around in the bloodstream and causing a response, an immunologic response, a myelopoiesis response, in these organs, so it can only be due to the presence of bugs. It didn't just happen just to happen.

Tr. at 232-33.

In addition to the "footprints" seen in the liver, bone marrow and spleen, Dr. Anderson argues that "petechiae[11] in the thymus, and I think petechiae often means that there is some, you know, some coagulopathy, which frequently follows sepsis. The fact that this baby had some petechiae in some organs may be related to that." Tr. at 220.

Dr. Anderson concludes that all of Sierra's organs save the liver, bone marrow and spleen were normal histologically. As for the lungs, she did not see the diffuse polys noted by the other pathologists. She concludes:

> I felt that the lung was not the source of the problems. The kidney was not the source of the problems. These are two major target organs and if you have serum sickness, you would affect small blood vessels, and if you had small blood vessel involvement, you would have necrosis of tissue, we didn't see that. Dr. Bove did not see that. No one has seen that, so, in terms of, you know, which hypothesis is more likely than not, I have to go with the horses and not the zebras and say that, you know, in my whole life experience as a perinatal pathologist, that I believe sepsis played a major role in the sad death of the Colon baby.

Tr. at 217.

5. Group Discussion

In the course of the evidentiary hearing, the Court allowed the pediatric pathologists, who are both eminently learned in the field, to discuss their particular disagreements concerning the histologic evidence in this case. That discussion was so instructive as to merit reprinting in full. At the Court's request, Respondent's expert, Dr. Anderson, initiated a dialogue with Dr. Bove who was on the witness stand:

> DR. ANDERSON: . . . when I looked at the bone marrow and the liver, I felt there was exaggerated myelopoesis, which can occur in sepsis in girl – in three day old babies. So, I just – it's my interpretation that that's what that means, and if you want to comment on that, you know, that's my interpretation of that.
>
> THE COURT: The court will permit that. That is, if you wish to comment, Dr. Bove.
>
> THE WITNESS: Well, I think I would agree that the hematopoiesis of the liver is a little bit exaggerated, but I don't think that's necessarily an indicator of sepsis, and – actually, if hematopoiesis is very prominent at many sites in a newborn baby, I think it makes – it carries a little more weight as you attempt to discern what actually happened, but in this case, I wasn't impressed that the extramedullary hematopoiesis was impressive anywhere else except in the liver, and I have seen the extramedullary hematopoiesis as inexplicably prominent in the liver and liver biopsies in the first few weeks of life in babies who are not septic and are not even suspected of being septic, so I've always thought that that's something I don't

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[11] Petechia are described as "a pinpiont, nonraised, perfectly round, purplish red spot caused by intredermal or submucous hemorrhage." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at1411.

understand very well, which is why I'm tending to minimize it in this particular case, in the absence of other prominent features, that this baby was severely stressed at the time of his death, in terms of tissue reactions, and in the absence of a clear-cut focus of infection anywhere in the tissues.

But, I understand, I appreciate where Dr. Anderson's being impressed by the myelopoiesis in the liver, because it's fairly prominent, it's just that I don't know of any – it doesn't get me to the point where I'll go from possible in the sense that anything's possible to probable with respect to sepsis.

DR. ANDERSON: Well, my – actually, Kevin, my impression of the bone marrow is even more developed because, as you know, a fetus is – a normal, healthy fetus is germ-free and in a normal autopsy of a perinatal death, and I would include up to three or four days, or a week, even, usually, the bone marrow is quite slow to react. There is not a lot of myelopoesis going on, and I might say that this is a leukemoid reaction. It is pure myelopoesis. There's very little erythropoiesis going on in the marrow, so I don't think it's just a switch from liver to marrow, I think that because of this exposure to pathogens in utero, which were treated as such, clinically, and which the mother experienced as a UTI and as a GBS-positive infection, that the marrow in this fetus responded and this baby was not born immunologically naïve and was up, regulating the myelopoiesis series more intensely in the marrow than even in the liver. And, also, there's a little bit in the spleen, and I noticed that Jim Patrick could visualize the malpighian corpuscles, which, for a late preemie, is a pretty impressive exuberance of lymphoid proliferation for the age of the patient. At least, this is, in my experience as a perinatal pathologist. And, I just present this as my best interpretation. I cannot – I agree with everything you've said other than these facts.

THE COURT: And, of course, the two of you can have honest disagreements. The court's not inquiring as to that, but you heard Dr. Anderson's perspective, Dr. Bove. Is there anything you wish to comment on, or not? That's up to you.

THE WITNESS: Well, I think it's interesting and attractive from a theoretical standpoint, but I don't think it explains the death of this child.

THE COURT: Okay, now, let me ask, Dr. Bove. Have you read the reports of Drs. Ward and Anderson in this case?

THE WITNESS: Yes.

THE COURT: Okay, if you had the opportunity to ask any questions of Dr. Anderson, even though she hasn't been sworn yet, what would you ask her, or would you not care to? Is there anything, on a professional level, that you would, if you had the opportunity?

THE WITNESS: Well, Virginia has basically covered the areas where disagreement mainly lays, what I regard as a slightly optimistic, or enthusiastic, overinterpretation of some of the findings in these slides. I don't think newborn babies are so fragile that they would die suddenly and inexplicably this way without there having been more evidence of illness in the baby, –

THE COURT: Okay, but –

THE WITNESS: – so, that's why I've leaned toward interpreting the death as unexplained. It's almost like sudden infant death syndrome, except the age range, by convention, that this baby is in, is excluded from consideration from sudden infant death syndrome, which – so, I can't – but, otherwise, you know, I would say this is an unexplained death to me, and I don't find the autopsy really guides me to a clear understand of what suddenly seems to have happened.

DR. ANDERSON: I agree with everything you're saying, Kevin. I do believe, though, that this is a partially-treated case because of the mother's reception of Ancef, which, as you know, crosses the placenta, and therefore, made the culture of blood, which would be ideal, impossible, and, you know, there are other things, the petechiae of the thymus, the icterus, that goes along with sepsis. The respiratory distress goes along with sepsis. You know, the myelopoesis which we mentioned. So, I believe – the clinical findings as well, you know, the preterm rupture of the membranes, the –

THE WITNESS: Why do you think the baby died at the moment of death?

DR. ANDERSON: Well, we don't know why anybody dies at this moment or any other moment, but infants with sepsis can die quite suddenly and the only finding that we have is, you know, some – well, often, we would have pneumonia or some other hard finding, but because this is a partially-treated situation and may not even be a classic ascending infection, it may even be hematogenous from the UTI which the mother had with hydronephrosis and renal stones a few days before delivery, there could have been some exposure to infectious agents in utero, which could have precipitated some reactions in the baby that could actually lead to the death of the baby.

THE WITNESS: It could have been. I mean, that's my reaction to all of that. It could have been. I don't – but, when this baby's heart stopped and she stopped respiring, and it's not clear to me at all why, in the absence of organ damage – or, absence of signs of stress, I mean, the thymus gland and the adrenal gland in this baby are pristine, in my opinion, and I would certainly – if there were signs of stress in those two organs, that would add consider – some more weight, I think, to what the – to the scenario that you're painting, but there are no signs of stress in those two organs, so I'm left not understanding what happened in the brief moments when the mother was breastfeeding and dozed off. It's the – inexplicable to me why this baby would have died this way, of sepsis.

Tr. at 150-55.

The Court then afforded Dr. Levin the opportunity to interact with Dr. Bove concerning their differences as to the histologic evidence:

DR. LEVIN: Your testimony is that the – you found that the child's tissues, to your analysis, were not consistent with a child who was fighting for his or her life from an infection, correct?

THE WITNESS: Correct.

DR. LEVIN: Now, what if the child was exposed to some massive cytokine response caused by his – her mother's antibodies reacting against an injected antigen?

THE WITNESS: What if?

DR. LEVIN: What would happen if the child was resting but a massive inflammatory response was going on between her mother's antibodies and the vaccine injected?

THE WITNESS: Oh, all right. I don't – I have no idea to what extent the tissue reactions referred to, such as the ones in the thymus and the ones in the adrenal gland, which are sort-of standard signs of stress in the – in, particularly, newborn babies, are caused by cytokines. It's possible they are, but I don't – do we – I don't think we fully understand the pathobiology of the reaction, at least, as something we can see under the microscope in the fetal adrenal and the thymus. That's one thing I would say.

The other thing I would say is, there – you're – the cytokine storm that you're proposing would, presumably, cause a death without causing any visible signs of an antigen antibody complex reaction. May be, I don't know.

DR. LEVIN: Okay.

THE WITNESS: I've – would have expected to see something, but I didn't see anything that I would say specifically indicates that – where the antigen came into contact with preformed antibodies, there was a tissue reaction. Can't say that.

DR. LEVIN: There were – I'm talking about tin the bloodstream. If the antibodies were in the bloodstream, the antigen is in the bloodstream, the reaction's in the bloodstream, could there be a cytokine storm created?

THE WITNESS: Yes, but there would also be complexes created, which might be – that might make their presence known in the histology and micronoscopy.

DR. LEVIN: IF the patient lived long enough.

THE WITNESS: Yes.

DR. LEVIN: Thank you.

Tr. 156-57.

C. Factual Findings

Concerning factual findings, it is axiomatic to say that the Petitioner bears the burden of proving, by a preponderance of the evidence, that a particular fact occurred. 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).

Regarding the medical records and medical opinions proffered in the above captioned case, the Court reaches the following conclusions.

First, the Court notes that there appears to be no disagreement as to whether Dr. Levin's theory of a serum-sickness reaction is plausible. Respondent's expert, Dr. Ward, admits as much. Granted, Dr. Ward does not think it likely to have occurred in this instance, as such a reaction has never been reported to the best of anyone's knowledge in the history of the world. Yet, as Petitioner convincingly argues, the immunization of neonates with the Hepatitis B vaccine is in its infancy. Further, Dr. Ward is not, nor did he hold himself out to be, an epidemiologist. Thus, his opinion as regards the statistical probabilities is taken cum grano salis by the Court. Almost by definition, cases that come under the purview of the Vaccine Act involve the rarest of occurrences. If Petitioner had epidemiology on her side, that sort of direct evidence would preclude the need to build a case circumstantially.

That being said, the Court notes some patent concerns regarding Petitioner's theory. For instance, it is not entirely clear whether the approximate 17 hours between vaccination and the child's death is a medically appropriate time frame. Petitioner could produce no evidence confirming such. The medical literature filed in this respect was less than convincing as the articles are easily distinguished from the present petition and, meanwhile, none of the case studies described therein approach a 17 hour onset. According to Dr. Ward, whose testimony on this point the Court finds most credible, even where preexisting antibodies are in circulation, there is little indication that a type III hypersensitivity reaction, or serum sickness, would occur sooner than 24 hours. Yet, his exact words were, "In the presence of preformed antibodies, [onset] can be more rapid, but very, very rarely, in the literature, is it under a day." Tr. at 167-68. Hence, the Court must presume that it can take place, though rarely, in less than 24 hours. And therefore, the Court is unwilling to hold that the timing of the alleged reaction is beyond the realm of medical plausibility.

Yet, even if the timing is medically appropriate, Petitioner provided little evidence beyond Dr. Levin's testimony that a serum sickness reaction can prove fatal. The only mitigating factor for Petitioner is that the present case involves a neonate; and, therefore, one might argue insufficient data exists to say how a neonate would respond to a serum-sickness reaction because such has never been described in any reliable medical publication. Yet, Dr. Ward does agree that, in extreme cases, serum sickness can be fatal. And, hence, the Court is loathe to say that a serum sickness reaction might not be fatal to a three-day-old baby.

Of greater concern to the Court, however, is that neither the forensic pathologist who conducted the autopsy nor the learned pediatric pathologists who opined in this case found any evidence of a serum sickness (allergic or immune-complex) reaction in Sierra's histologic picture. On this point, Dr. Levin is the lone voice in the wilderness. He finds the eosinophils in the liver particularly telling; and, were he to convince the Court on this point, it might be the end of the matter as the presence of eosinophils certainly can indicate that an allergic reaction occurred. Yet, Dr. Bove and Dr. Anderson interpret those same slides in quite a different manner than Dr. Levin. In fact, Dr. Anderson argues that the activity in the liver, far from evincing an allergic reaction, actually is evidence that Sierra's immune system was struggling against an infection. Dr. Bove admits the liver showed evidence of "exaggerated" or "prominent" activity but disagreed with Dr. Anderson, characterizing her analysis as an "enthusiastic" or "overinterpretation" of the evidence presented. Yet,

neither Dr. Bove nor Dr. Anderson felt that the eosinophilic cells seen in the liver were indicative of an allergic or immune-mediated reaction. At this time, the Court reaches no definite conclusion as to whether Dr. Bove or Dr. Anderson is correct in interpreting the activity in the liver. However, the Court does find their testimony concerning this anatomic pathological evidence more credible than that of Dr. Levin who is not board certified in anatomic pathology and has not practiced clinical pathology for a score of years. Hence, the Court finds, as per the testimony of Dr. Bove and Dr. Anderson, there is no evidence on autopsy of an allergic or immune-complex reaction. Put another way, there is no histologic evidence that Sierra suffered a serum sickness reaction.

That is not to say the Court finds it more likely than not by a preponderance of the evidence that Sierra's death was related to sepsis. Certainly several prominent risk factors are identified in her medical records. Her mother's membranes ruptured 48 hours prior to birth, and the mother was positive for group b streptococcus, a bacteria that is particularly devastating to babies. Antibiotics were administered during labor as a prophylactic measure to protect Sierra, but these were not continued after her birth. The Court also notes that Sierra exhibited symptoms of sepsis including jaundice and respiratory difficulties. However, on autopsy, the forensic pathologist diagnosed "possible sepsis." Similarly, Dr. Bove was unwilling to diagnose sepsis preferring to label the cause of Sierra's death as undetermined. But the credibility of Dr. Bove's testimony was undermined by his lack of familiarity with the case and, in particular, with the risk factors identified in the medical records. As well, the Court is somewhat swayed by Dr. Anderson's interpretation of the evidence on autopsy concerning the footprints identified in the liver, bone marrow and spleen regarding the alleged leukemoid reaction occurring therein. Yet the Court is not decided as to whether that evidence meets the preponderance standard. Regardless, the Petitioner certainly has not ruled out sepsis as a possible and perhaps even a probable cause of Sierra's demise.

All else aside, with the exception of Dr. Levin's testimony, the Court finds no evidence in the record in support of the proposition that Sierra's death was related to a serum sickness reaction.

As to Dr. Levin's testimony, the Court has some concern as to his reliance on "a growing body of literature" that includes certain articles and "reliable" internet sources the credibility of which the Court might consider de minimis at best. Tr. at 48; Pet. Ex. 20. The Court is similarly concerned about the dearth of any evidence in the medical literature filed of a serum sickness reaction occurring within 17 hours. Likewise, the Court is troubled that Petitioner could present not even a single case report of a neonate presenting with serum sickness, much less fatal serum sickness, and that the preeminent experts offered in this regard, Dr. Bove and Dr. Anderson, had never heard of such an affliction nor did they see evidence of such on autopsy. Further, if this is indeed the one case out of a million, still the Court has been given no indication that any of the medical personnel familiar with Sierra's case are undertaking any effort to enter it in a peer reviewed publication. Finally, the Court has encountered Dr. Levin's "cytokine storm" theory in previous unrelated cases and is a bit concerned as to his Procrustean approach to causation. Yet, as Dr. Ward and the Respondent take limited umbrage with Dr. Levin, the Court declines to progress down that road sua sponte.

II. CONCLUSIONS OF LAW

That is not the end of the matter, however, as the Court must assess the foregoing factual findings under the rubric of the law as it presently stands in order to determine whether the Petitioner has proved entitlement to compensation. Under the Vaccine Act, a petitioner is not required to prove his case by medical certainty but only by a preponderance of the evidence, which this Court has described as 50% and a feather. Neither is a petitioner required to submit direct proof in order to prevail. Nor is he required to submit certain types of evidence. Such a bright line test "prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." Althen v. Secretary of HHS, 418 F.3d 1274, 1280 (Fed. Cir. 2005); but see, Knudsen, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof failed to meet that burden) and Hines v. Secretary of HHS, 21 Cl. Ct. 634, 646 (1990), aff'd, 940 F.2d 1518 (Fed. Cir. 1991). Instead, as has been noted by the Court of Federal Claims, ultimately there is "no hard and fast rule for what specific, individual elements of proof a petitioner must present in order to establish a prima facie case of causation-in-fact; the rule is really one of reason, in which the Special Master gives greater weight to certain factors in certain cases depending on the facts of that particular case and the medical developments existing at that time." Pafford v. Secretary of HHS, 64 Fed. Cl. 19, *31 (2005), aff'd, Pafford v. Secretary of HHS, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (emphasis in original) (citing Knudsen, 35 F.3d at 548 ("Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules.")).

Hence, in addition to findings of fact, decisions issued by this Court must also include conclusions of law. §12(d)(3)(A)(I).

According to the plain language of the Vaccine Act, "Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole–

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

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." §13(a)(1).

Concerning §11(c)(1) and certain other preliminary requirements, it is undisputed that (1) Petitioner is a valid legal representative; (2) the vaccine at issue is set forth in the Vaccine Injury Table; (3) the vaccine was administered in the United States; (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. §§ 300aa-11(b) and (c). Additionally, the § 300aa-16(a) requirement that the petition be timely filed has been met.

A. Legal Standards

The Petitioner may prove entitlement to compensation under the Program in one of two ways. She can prove entitlement via a statutorily prescribed presumption of causation or by proving that a vaccine caused in fact the injury alleged.

First, the Petitioner may prove that Sierra's death resulted from an injury or condition listed in the Vaccine Injury Table. 42 C.F.R. § 100.3. If she establishes by a preponderance of the evidence that Sierra suffered such an injury within the statutorily prescribed time period, she is entitled to a presumption of causation. The burden would then shift to the Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B).

If the Petitioner does not qualify for the statutorily prescribed presumption, she may yet succeed if she can demonstrate by preponderant evidence that the vaccination in question, more likely than not, caused Sierra's death. § 11(c)(1)(C)(I) & (ii)(I). Once again, if a petitioner is successful in that showing, the burden shifts to Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B); Whitecotton v. Secretary of HHS, 17 F.3d 374, 376 (Fed Cir. 1994).

1. Table Injury

Injuries listed on the Vaccine Injury Table in conjunction with Hepatitis B include:

A. Anaphylaxis or anaphylactic shock 0-4 hours

B. Any acute complication or sequela (including death) of above event

42 C.F.R. § 100.3 (VIII).

Anaphylaxis and anaphylactic shock are defined by the Qualifications and Aids to Interpretation ("QAI") that accompany the Vaccine Table as follows:

> Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. 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 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. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

42 C.F.R. § 100.3(6) (emphasis added).

As mentioned, infra, the Court acknowledges that eosinophils in the liver can be a sign of an allergic reaction as evidenced in the QAI. Yet, the Court found Dr. Bove and Dr. Anderson more credible in their testimony that the eosinophilic cells seen in the present instance were not evidence of an allergic reaction.

Moreover, Petitioner is not arguing that Sierra's death fits the Table definition of anaphylactic shock, but is instead alleging that she died as the result of a fatal, neo-natal serum sickness caused-in-fact by a Hepatitis B vaccine.

2. Causation-in-fact

While the Petitioner is not entitled to a presumption of causation afforded by the Vaccine Injury Table, she may yet prevail if she can demonstrate by a preponderance of the evidence that the vaccination in question, more likely than not, caused Sierra's death. See 11(c)(1)(C)(ii)(I) & (II); Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992); Strother v. Secretary of HHS, 21 Cl. Ct. 365, 369-70 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that every petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); see also Strother, 21 Cl. Ct. at 370. Merely showing an absence of an alternative cause of injury does not meet petitioner's burden of proof. Grant, 956 F.2d at 1149. In addition, the Court cannot infer causation from temporal proximity alone. In fact, it has been held, that where a petitioner's expert views the temporal relationship as the "key" indicator of causation, the claim must fail. Thibaudeau v. Secretary of HHS, 24 Cl. Ct. 400, 403 (1991). Rather, a petitioner must explain how and why the injury occurred. Strother, 21 Cl. Ct. at 370. After all, inoculation is not the cause of every event that follows. Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1993), cert. denied, 469 U.S. 817 (1984). That being said, where several potential causes present themselves, a petitioner need not show that the vaccination was the sole cause of the injury but may demonstrate that it was a "substantial factor" in causing the alleged injury which would not have occurred "but for" the vaccine. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir.1999).

All that aside, the Federal Circuit recently articulated an alternative three-part causation-in-fact analysis as follows:

> [Petitioners'] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Furthermore, "[R]equiring that the claimant provide proof of medical plausibility, a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes-is merely a recitation of this court's well-established precedent." Id. at 1281.

While the Petitioner is not required to propose or prove that a specific biological mechanism can and did cause Sierra's death, she must still proffer a plausible medical theory that causally connects the vaccine with the injury alleged. See Knudsen v. Secretary of HHS, 35 F.3d 543, 549 (1994). But even where a medical theory involves "a sequence hitherto unproven in medicine, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." Althen, 418 F.3d at 1280.

Not just any plausible medical theory will suffice. In order to prevail under the causation in fact standard provided in Althen, a petitioner must demonstrate by preponderant evidence a reliable medical theory that links, via "a logical sequence of cause and effect," the vaccination and the injury alleged, thereby "showing that the vaccination was the reason for the injury." Hence, though this Petitioner need not identify or prove that a specific biological mechanism occurred, Knudsen, 35 F.3d at 549, she cannot prevail simply by bootstrapping a plausible medical theory to her petition based solely on a proximate temporal relationship and lack of alternative causation. Moreover, this Court has the obligation, in light of the "gatekeeping" function required by Daubert v. Merrow Dow Pharm. Inc., 509 U.S. 579, 597 (1993), to assess the reliability of medical or scientific opinion or testimony and the logical sequence of cause and effect attendant thereto. See, Terran v. Secretary of HHS, 195 F.3d 1302, 1316 (Fed. Cir. 1999); see also Ryman v. Secretary of HHS, 65 Fed. Cl. 35, 40 (2005) (a special master acts properly as a gatekeeper when he "determines whether expert testimony may be admitted, credited, or otherwise relied upon.").

Petitioner argues that the Daubert line of cases has no bearing whatsoever in proceedings under the Vaccine Act. Not so. Daubert is instructive as Vaccine cases often involve the evaluation and weighing of the reliability and credibility of medical expert opinion. True enough, this Court does not utilize the stringencies of Daubert to exclude medical expert opinion from reaching the finder of fact. Given the nature of the Vaccine Court, which was envisioned by Congress as an adjudicatory body of subject matter experts, it makes little sense to screen on the front end that corpus malus often referred to in the vernacular as "junk science." Instead, this Court is rather friendly toward petitioners, allowing them to submit medical opinion at their discretion and provides reasonable compensation to their experts, such that petitioners typically bear no out of pocket expense. Of course, even a forum as open as this one must have some limits. Hence, a special master may decline to hear, for instance, from a dentist who is offered to opine on an immunological insult.

That being said, the Vaccine Act adjures the Court to consider, "in addition to all other relevant medical and scientific evidence contained in the record -

> (A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of

> the petitioner's illness, disability, injury, condition, or death, and (B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Even so, the Act explicitly states that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master" but must be accorded proper weight in light of the "entire record and the course of the injury, disability, illness, or condition." § 13(b)(1) (emphasis added).

Hence, the Court allows petitioners the opportunity to present their case in whatever manner seems meet. However, the weight or credibility to be applied to medical expert testimony is very much the demesne of this Court.

Petitioner likewise argues that the production of medical literature is not a required element of proving causation. Quite so. This Court has long recognized that, while petitioners are not required to submit peer reviewed literature in support of their theory as a prerequisite for proving causation, yet the plausibility of a medical theory or credibility of a medical expert can be bolstered in any number of ways including, but not limited to (1) evidence that at least a sufficient minority in the medical community has accepted the theory as to render it credible; (2) epidemiological studies and an expert's experience, while not dispositive, lend significant credence to the claim of plausibility; (3) articles published in respected medical journals, which have been subjected to peer review, are also persuasive; however, publication "does not necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." Daubert, 509 U.S. 579, 593-94. Even so, petitioners are often encouraged to submit such literature where available in order to meet their burden of proof – that the vaccine in question more likely than not caused the injury alleged.

When and if a petitioner demonstrates by a preponderance of the evidence that a vaccination caused in fact a particular injury or death, the burden of proof then shifts to Respondent to show that the claimant's injuries are "due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B); Whitecotton v. Secretary of HHS, 17 F.3d 374, 376 (Fed. Cir. 1994).

B. Discussion

Under the standard elucidated in Althen and in line with the factual discussion supra, the Court makes the following conclusions of law. First, the Petitioner has demonstrated that the medical theory offered by Dr. Levin is not entirely implausible. Second, the Petitioner has demonstrated that the time frame between Sierra's death and the administration of the Hepatitis B vaccine, while bordering on the edge of plausibility, is not outside the realm of medical reliability.

However, the Court finds that Petitioner has not causally connected the vaccine with the injury alleged. As stated by the Federal Circuit in Grant and then reiterated in Althen, "Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Grant, 956 F.2d at 1148; Althen, 418 F.3d 1274, 1278. The Petitioner has

presented no objective evidence that Sierra suffered a serum sickness reaction and is relying almost exclusively on her medical expert, Dr. Levin, to connect the vaccine with Sierra's death. Although there is a striking temporal relationship, the sort of post hoc ergo propter hoc[12] reasoning offered by Dr. Levin has been consistently rejected by the Court and "is regarded as neither good logic nor good law." Fricano v. U.S., 22 Cl. Ct. 796, 800 (1991). While perhaps not impossible, Petitioner's alleged sequence of cause and effect, based largely on speculation and conjecture, does not satisfy the preponderance of the evidence standard.

Neither has the Petitioner eliminated an alternative cause identified in the medical records on autopsy, which is an aspect of her burden and, according to the Court in Althen, is recognized as "well-established precedent." Althen, 418 F.3d 1274, 1278. Of course, a petitioner need not exclude any and every possible cause, but where the records identify a cause, a petitioner must needs eliminate that potentiality. Petitioner argues, per contra, that Respondent bears the burden of proving that Sierra's death was "due to factors unrelated to the administration of the vaccine." §13(a)(1)(B). But Petitioner misapprehends her burden of proof, which is to show that the vaccine more likely than not caused the injury alleged and which may be shown by affirmatively meeting the three prongs articulated in Althen. This Petitioner has not done. And therefore the burden of proof has not shifted to Respondent. Regardless, after hearing multiple experts and examining the entirety of the records and opinions proffered in this case, the listing on autopsy as "possible sepsis" is perhaps as accurate a description as can be offered for Sierra's death.[13]

III. CONCLUSION

The Petitioner has not connected a plausible medical theory with "a logical sequence of cause and effect showing that the vaccination was the reason for the injury"; therefore, the she has not proved by a preponderance of the evidence those matters required by §11(c)(1) of the Vaccine Act. Hence, the petition is **denied**. §13(a)(1)(A).

In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

Richard B. Abell
Special Master

[12] Latin for "after this, therefore because of this."

[13] In the alternative, were the Court to plug these factors into an equation tallying the quantum of proof required to reach a preponderance, it is likely that Respondent's argument would succeed as it has demonstrated a plausible medical theory (sepsis syndrome) logically connected via the risk factors, symptomatology and limited histologic evidence, to the injury in question and within a medically appropriate time-frame.