# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

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| CHEYENNE WHITESELL, on behalf of her deceased minor child, M.W., | * | No. 17-1557V |
| Petitioner, | * | Special Master Christian J. Moran |
| v. | * | Filed: July 12, 2022 |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | Entitlement; hepatitis A vaccine; influenza ("flu") vaccine; measles, mumps, and rubella ("MMR") vaccine; varicella vaccine; SUID; SUDC; cytokine storm. |
| Respondent. | * | |

Patricia A. Finn, Patricia Finn, P.C., Nanuet, NY, for petitioner;
Benjamin P. Warder, United States Dep't of Justice, Washington, DC, for respondent.

**PUBLISHED DECISION DENYING COMPENSATION**[1]

Cheyenne Whitesell claims that the hepatitis A, influenza ("flu"), measles, mumps, and rubella ("MMR"), and varicella vaccines her son, M.W., received on October 19, 2015, caused his death on October 22, 2015. The parties have submitted reports from experts and argued their positions through legal briefs. Ms. Whitesell has not shown that the hepatitis A, flu, MMR, or varicella vaccines can cause an infant or child's death. Further, Ms. Whitesell has not demonstrated a logical sequence of cause and effect connecting the vaccines to M.W.'s death.

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. This posting will make the decision available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

Finally, Ms. Whitesell has not put forth a medically acceptable timeframe from which to infer vaccine-causation. Accordingly, Ms. Whitesell has not met her burden of establishing that the hepatitis A, flu, MMR, and varicella vaccines caused M.W.'s death. Thus, her case is dismissed.

## I. Facts

M.W. was born on September 30, 2014. His newborn screening was normal, and he was discharged home on October 2, 2014. Exhibit 2 at 4-6. M.W. saw his pediatrician for well-baby visits on October 8, 2014, October 28, 2014, and November 25, 2014. Id. at 27-28, 35-37, 40-42.

On January 29, 2015, M.W. saw pediatrician Julie Utendorf, M.D., for his three-month well-baby visit. His family reported that M.W. was not pushing himself up on his arms. His physical examination was normal, and Dr. Utendorf had no concerns about his development. Id. at 45-47.

M.W. visited to Dr. Utendorf for his six-month well-baby visit on April 10, 2015. M.W. was diagnosed with serous otitis media (an ear infection) and prescribed amoxicillin. Id. at 50-53. M.W. returned for a well-baby visit on August 20, 2015, and his examination was normal. Id. at 55-58.

M.W. returned to Dr. Utendorf for a well-baby visit on October 19, 2015. This appointment was about three weeks after M.W. turned one-year old. Dr. Utendorf noted mild delays in some of M.W.'s developmental milestones. Id. at 61-62. During this visit, M.W. received the hepatitis A, flu, MMR, and varicella vaccinations. Id. at 60; see also exhibit 5.

On October 22, 2015, Brittney Whitesell, M.W.'s aunt and caretaker, observed that M.W. was cranky and had a temperature of 101.1 degrees Fahrenheit. Exhibit 4 (Brittney Whitesell's affidavit) at 1. She gave M.W. Tylenol and put him down for a nap. Id. Brittney observed that after his nap, M.W.'s fever had gone down, and he was no longer cranky. Id. at 2. A history taken by the coroner noted that M.W. was placed in bed on his back at 7:30 P.M. on October 22, 2015, at which time he had a temperature of 100.2 degrees Fahrenheit. Exhibit 7 at 1.

About 12 hours later, at 7:28 A.M. on October 23, 2015, emergency medical services ("EMS") were called because M.W. was unresponsive. Exhibit 6 at 1. When EMS arrived, M.W. was on the floor of his room while fire department

personnel were performing CPR. Id. at 1, 3. Fire department personnel were unable to resuscitate M.W., and he was pronounced dead. Id. at 4.

Shruti Shukla, M.D., performed an autopsy on M.W. on October 24, 2015. Dr. Shukla noted that M.W. was found on his stomach in a pack and play. Exhibit 8 at 2. She also noted that M.W. received vaccinations on October 19, 2022, and that he was treated with Tylenol for a fever on October 22, 2022. Id. The autopsy revealed petechiae of the thymus and lungs and pulmonary and visceral congestion. Id. at 1. Dr. Shukla observed that M.W.'s lungs had "mild passive congestion," his liver was "mildly passively congested," and his "kidneys were congested. Id. at 4. Under a section for "significant findings," Dr. Shukla listed vascular congestion for all of M.W.'s organs, including the heart, lungs, brain, liver, and kidney. Id. at 5. She did not observe any hemorrhages or vascular leakage in the central nervous system. Id. at 4-5. The coroner listed M.W.'s cause of death as Sudden Unexplained Infant Death ("SUID"). Exhibit 7.[2]

On March 14, 2016, M.W.'s pediatrician, Dr. Utendorf, submitted a Vaccine Adverse Reporting System ("VAERS") report. Exhibit 11.

## II. Procedural History

Ms. Whitesell filed a petition for compensation on behalf of M.W. on October 18, 2017. Pet., filed Oct. 18, 2017. She filed medical records on December 20, 2017. The Secretary reviewed this material and recommended that compensation be denied. Resp't's Rep., filed Apr. 17, 2018. The Secretary argued that Ms. Whitesell failed to offer a theory connecting the vaccines to M.W.'s death, and that there was no evidence to support a medically appropriate temporal association between the vaccinations and M.W.'s death. Id. at 4.

The parties then proceeded to the expert report stage. To support her case, Ms. Whitesell presented an initial report from Alan Levin, M.D., J.D., on January 2, 2019. Exhibit 16. Due to deficiencies in Dr. Levin's first report, he was ordered to submit a supplemental report. Order, issued Feb. 13, 2019. Dr. Levin submitted a supplemental report on April 4, 2019. Exhibit 18. The Secretary then submitted reports from Christine McCusker, M.Sc., M.D., and Brent Harris, M.D., Ph.D., on

[2] The Secretary's experts indicated that M.W.'s cause of death is more appropriately classified as Sudden Unexplained Death in Childhood ("SUDC") because M.W. was over twelve months of age at the time of his death. See exhibit A (Dr. McCusker's report) at 3; exhibit C (Dr. Harris's report) at 5.

August 29, 2019. Exhibits A and C. Ms. Whitesell submitted a rebuttal report from Dr. Levin on January 20, 2020, and a supplemental report from Dr. Levin addressing the autopsy slides on May 18, 2020. Exhibits 45 and 51. The Secretary then provided a responsive report from Dr. McCusker on June 15, 2020. Exhibit E Ms. Whitesell then offered supplemental reports from Dr. Levin on October 13, 2020, and April 28, 2021. Exhibits 52 and 55. The parties also filed several medical articles their experts cited.

Following the completion of the expert report stage, the parties were instructed to file briefs advocating for their positions. Order, issued Dec. 20, 2020. After multiple motions for extensions of time, Ms. Whitesell filed a brief in support of entitlement on May 10, 2021. Due to weaknesses in the content and presentation of the brief, Ms. Whitesell was ordered to file a revised brief, which she submitted on July 1, 2021. The revised brief was deficient in several respects, including Ms. Whitesell's failure to clearly distinguish the separate Althen prongs. See order, issued July 7, 2021. Thus, Ms. Whitesell was again ordered to address these deficiencies and submit an amended brief. Id. Ms. Whitesell filed her final revised brief on August 25, 2021. The Secretary submitted a well-organized brief on December 9, 2021, which comprehensively addressed the articles the experts cited. Ms. Whitesell did not file a reply. The case is now ready for adjudication.

## III. Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a "trier of fact to 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 judge of the fact's existence." Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Hum. Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

When pursuing an off-Table injury, a petitioner bears a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] 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. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

## IV. Analysis

This section will first analyze the relative qualifications of the experts, as their expertise is relevant to their diverging opinions regarding the cause of M.W.'s death. Next, this section will consider whether Ms. Whitesell has met her burden to prove each Althen prong.

### A. Qualifications of Experts

Because a determination regarding whether Ms. Whitesell has met her burden to prove that M.W.'s vaccinations were the cause-in-fact of his death hinges largely on the opinions of Dr. Levin, Dr. McCusker, and Dr. Harris, it is helpful to compare their qualifications as a preliminary matter. Special masters may consider the relative expertise of testifying experts when weighing the value of their opinion. See Depena v. Sec'y of Health & Hum. Servs., No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 Fed. App'x 938 (Fed. Cir. 2018); Copenhaver v. Sec'y of Health & Hum. Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016).

Dr. Levin is board-certified in immunology. Exhibit 17 (Dr. Levin's CV) at 1; see also exhibit 18 at 1. He received his medical degree from the University of Illinois in 1964 and later received his juris doctor from Golden Gate University in 1995. Exhibit 17 at 1. He has prepared 65 peer-reviewed research articles focusing on immunology, immunopathology, cancer biology, and treatments. Exhibit 18 at 4. The most recent article for which Dr. Levin provided a date is from 1994. This date is not surprising as Dr. Levin has not practiced clinical medicine since 1993. Id.

Instead of practicing immunology, Dr. Levin primarily practices law. Id. This lack of a current medical practice has contributed to special masters' criticism

of Dr. Levin's work in previous Vaccine Program cases. See, e.g., Martin v. Sec'y of Health & Hum. Servs., No. 15-789V, 2020 WL 4197748, at *31 (Fed. Cl. Spec. Mstr. May 8, 2020) (describing Dr. Levin as "an expert out of his depth"); Bigbee v. Sec'y of Health & Hum. Servs., No. 06-663V, 2012 WL 1237759, at *30, 36 (Fed. Cl. Spec. Mstr. Mar. 22, 2012) (discrediting Dr. Levin's "cytokine storm" theory and noting that Dr. Levin "ha[s] not see[n] a patient since 1993" and "has not performed an autopsy on a child since the 1980's"); Doe/11 v. Sec'y of Health & Hum. Servs., No. 99-212V, 2008 WL 4899356, at *8-9 (Fed. Cl. Spec. Mstr. Oct. 29, 2008) (rejecting Dr. Levin's theory that a vaccine-induced cytokine response led to brain inflammation and caused a child's death), mot. for rev. denied, 87 Fed. Cl. 1 (2009), aff'd, 601 F.3d 1349 (Fed. Cir. 2011).

Dr. McCusker holds a Bachelor of Science in microbiology and immunology from the University of Toronto and a Master of Science in molecular biology from McMaster University, where she also attended three years of a Ph.D. program in immunology. Exhibit B (Dr. McCusker's CV) at 1-2; see also exhibit A at 1. She attended medical school at McMaster University. Exhibit B at 1. After completing medical school, she trained in pediatrics and allergy and clinical immunology at McGill University's Montreal Children's Hospital. Id. She is board-certified by the American Board of Pediatrics and holds certifications in pediatrics and allergy and clinical immunology from the Royal College of Physicians and Surgeons of Canada and the College des Medecins du Quebec. Id. at 2. Dr. McCusker currently works as an associate professor of pediatrics at McGill University. Id. at 3. She also practices as the Division Director of Pediatric Allergy, Immunology and Dermatology at the Montreal Children's Hospital. Id. Additionally, she conducts research focused on the regulation of immune responses at the Meakins-Christie Labs of McGill University. Id. at 20-21.

Furthermore, Dr. McCusker's medical opinions have been credited in several Vaccine Program cases involving a death in infancy or childhood. See, e.g., Martin, 2020 WL 4197748, at *31 (stating that Dr. Levin's "credentials as an immunologist were far outweighed by Dr. McCusker's"); Cozart v. Sec'y of Health & Hum. Servs., No. 00-590V, 2015 WL 6746616, at *13, 18 (Fed. Cl. Spec. Mstr. Oct. 15, 2015) (crediting Dr. McCusker's testimony that there was no evidence that vaccines cause cytokines to act in a way that contributes to sudden infant death syndrome ("SIDS") or that the deceased child experienced cytokine dysregulation), mot. for rev. denied, 126 Fed. Cl. 488 (2016); Bigbee, 2012 WL 1237759, at *35 (describing Dr. McCusker's testimony regarding the role of cytokines during vaccination as "highly persuasive").

Dr. Harris has practiced as an anatomic pathologist/neuropathologist for over twenty years. Exhibit D (Dr. Harris's CV) at 1-2. He is board-certified in anatomic pathology and neuropathology. Id. at 3. He has worked at various academic medical centers, including Stanford University Medical Center, Dartmouth Medical School, and Georgetown University Medical Center. Id. at 1-2. He currently works as an attending pathologist, associate professor in neurology and pathology, and the Director of Neuropathology at Georgetown University Medical Center. Id. at 1. Additionally, he serves as a neuropathology consultant at the following institutions: the Chief Medical Examiner's office in Washington, DC; Howard University Hospital; the National Institutes of Health, the Veteran's Administration Hospital in Washington, DC; and the MedStar Hospital System. Exhibit C at 1. Throughout his career, Dr. Harris has reviewed over 10,000 surgical pathology and autopsy cases. Id. He conducts research focused on neurodegenerative diseases, adult and pediatric central nervous system tumors, pediatric head trauma, and neuroinflammation. Id. Dr. Harris's opinions have also been accepted in previous Vaccine Program cases. See, e.g., Martin, 2020 WL 4197748, at *10 (noting that Dr. Harris was board-certified in neuropathology, while Dr. Levin was not).

The experts' backgrounds show that the Secretary's experts are much more qualified than the expert Ms. Whitesell retained. Dr. McCusker's extensive clinical work in the field of immunology vastly outweighs Dr. Levin's immunological expertise. Additionally, special masters have frequently credited Dr. McCusker's opinions in Vaccine Program cases, while Dr. Levin has often been criticized. Furthermore, while Dr. Levin has limited expertise in pathology and has not performed an autopsy on a child since the 1980s, Dr. Harris specializes in pathology and neuropathology and has reviewed over 10,000 surgical pathology and autopsy cases. Though Dr. Levin's certifications and focus areas of research are relevant to this case, Dr. McCusker's vast clinical experience and specialty in pediatric immunology make her particularly qualified to opine on this case. Similarly, Dr. Harris's expertise in pathology and neuropathology make him more qualified to opine on the significance of M.W.'s autopsy findings. This disparity in qualifications contributes to the evaluation of the evidence under the three Althen prongs.

### B. Althen Prong 1: A Causal Theory Connecting the Vaccine to M.W.'s Death

The first Althen prong requires the petitioner to provide a "sound and reliable" medical theory demonstrating that the vaccine can cause the alleged

injury. Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 548 (Fed. Cir. 1994)). The petitioner must also offer "a reputable or scientific explanation that pertains specifically to [his] case." Moberly, 592 F.3d at 1322.

Through Dr. Levin, Ms. Whitesell has attempted to present a mechanism by which the hepatitis A, flu, MMR, and varicella vaccines can cause an infant or child's death. First, Ms. Whitesell argued that the vaccines M.W. received can create a "cytokine storm," which can produce vascular congestion and leakage, resulting in death. Next, to explain why M.W. previously received vaccines without issue, Dr. Levin offered the theory that M.W. was "primed" for an enhanced immune response. These theories are discussed individually below.

1. Cytokine Storm

Ms. Whitesell argued that M.W. died due to vascular congestion and leakage, which was caused by a vaccine-induced "cytokine storm." Pet'r's Br., filed Aug. 25, 2021, at 3. With respect to his cytokine storm theory, Dr. Levin explained that dysregulated cytokines can "cause disruption of vascular endothelial intercellular adherence," which leads to vascular leakage and congestion. Exhibit 16 at 3; exhibit 18 at 2. He elaborated that this vaccine-induced disruption caused by dysregulated cytokines can lead to significant vascular congestion of the brain, lung, and heart. Exhibit 16 at 3; exhibit 18 at 2.

To support the proposition that cytokines can cause dysregulation of vascular endothelial intercellular adherence, resulting in vascular leakage and congestion, Dr. Levin offered multiple articles. One article reviewed endothelium functions and explained that leukocyte transmigration is site-specific. Exhibit 41 (William C. Aird, Phenotypic Heterogeneity of the Endothelium, 100 Circulation Rsch. 158 (2007)) at 160. The article noted that central nervous system barriers are unique, and the release of cytokines affects normal endothelial cell function. Id. at 164. Another article examined the role of inflammation in vascular diseases and emphasized that chronic inflammation can cause atherosclerosis, aneurisms, and hypertension. Exhibit 43 (Alexander H. Sprague & Raouf A. Khalil, Inflammatory Cytokines in Vascular Dysfunction and Vascular Disease, 78 Biochemical Pharmacology 539 (2009)). The authors concluded that cytokines can be created by circulating cells and endothelial cells, and cytokine-endothelial cell interactions can increase vascular permeability. Id. at 542.

Although Dr. McCusker acknowledged that cytokines are released by the peripheral immune system during vaccination, she maintained that there is no evidence that the level of cytokines released during vaccination are sufficient to cause massive vascular congestion. Exhibit A at 4-5 (citing exhibit A, tab 9 (Yasuyo Kashiwagi et al., Production of Inflammatory Cytokines in Response to Diphtheria-Pertussis-Tetanus (DPT), Haemophilus Influenzae Type b (Hib), and 7-Valent Pneumococcal (PCV7) Vaccines, 10 Hum. Vaccines & Immunotherapeutics 677 (2014))). She added that while local cytokine production at the site of vaccination triggers cytokine release, "there is no evidence that these low concentrations of peripheral cytokines result in significant increases and over expression of these cytokines in the brain tissue." Id. at 9.

In response, Dr. Levin argued that the Kashiwagi article (exhibit A, tab 9) lacks relevance to M.W.'s case because the study explored only one vaccine, while M.W. received four vaccines. Exhibit 45 at 3. He added that the study's small sample size renders it of limited value. Id. at 2.

Dr. McCusker also relied on epidemiological studies to show that there is no evidence of increased risk of SUDC following vaccination. Exhibit A at 3-4 (citing exhibit A, tab 5 (Elaine R. Miller et al., Deaths Following Vaccination: What Does the Evidence Show?, 33 Vaccine 3288 (2015) at 3-4; exhibit A, tab 6 (Giuseppe Traversa et al., Sudden Unexpected Deaths and Vaccinations During the First Two Years of Life in Italy, 6 PLoS One 16363 (2011) at 5).

Dr. Levin responded that the Traversa study (exhibit A, tab 6) article is not reliable evidence of no increased risk of childhood death following vaccination. Exhibit 45 at 1-2. He explained that because the study was retrospective, it is of little value. Id. He did not raise criticisms of the Miller study (exhibit A, tab 5) Dr. McCusker relied on to support the proposition that there is no increased risk of SUDC following vaccination.

Dr. McCusker responded to Dr. Levin's critiques of the epidemiological studies she relied on in a responsive report. Exhibit E. She acknowledged, "While limitations exist in these studies, there are no studies showing increased frequency of sudden unexpected death in childhood following vaccination." Id. at 1 (emphasis removed). She reiterated her conclusion that M.W. did not die due to a vaccine-induced cytokine storm. Id.

Dr. McCusker identified several gaps in Dr. Levin's cytokine storm theory. She persuasively explained that the levels of cytokines released during vaccination

are insufficient to cause massive vascular congestion and death. Furthermore, special masters in previous cases have rejected the theory that a vaccine-induced cytokine storm or cytokine dysregulation can cause an infant or child's death. See, e.g., Bohn v. Sec'y of Health & Hum. Servs., No. 16-0265V, 2021 WL 4302367, at *16-21 (Fed. Cl. Spec. Mstr. Aug. 23, 2021); Martin, 2020 WL 4197748, at *27; Copenhaver, 2016 WL 3456436, at *17; Cozart, 2015 WL 6746616, at *7-13; Bigbee, 2012 WL 1237759, at *32-36; Doe/11, 2008 WL 4899356, at *8-9. Therefore, Ms. Whitesell's cytokine storm theory does not satisfy her burden under Althen prong one.

2. Priming Theories

To explain why M.W. previously received vaccines without issue, Dr. Levin offered two explanations. First, he asserted that the six-month vaccinations M.W. received while suffering from an ear infection acted as a further adjuvant and enhanced M.W.'s response to the vaccinations he received on October 19, 2015. Exhibit 16 at 3-4. Second, he opined that the amoxicillin M.W. received to treat his ear infection caused an adverse reaction that "primed" him for future injury during his next round of vaccinations on October 19, 2015. Exhibit 18 at 5. These two explanations are discussed individually below.

*a) M.W.'s Ear Infection*

Dr. Levin opined that at the time of his vaccinations on October 19, 2015, M.W. had dysregulated cytokine activity in his innate cells due to the ear infection he had when he received his six-month vaccinations. Exhibit 16 at 3. He explained that this primed M.W. for an augmented immune response to his later vaccinations. Id.

To support this theory, Dr. Levin offered multiple articles. One article examined the release of cytokines during vaccination and found that certain cytokines, specifically IFN-γ, could impact drug metabolism pathways. Exhibit 20 (Paolo Pellegrino et al., Vaccine-Drug Interactions: Cytokines, Cytochromes, and Molecular Mechanisms, 38 Drug Safety 781 (2015)) at 783. Dr. Levin also cited an epidemiological study that examined infant mortality following the diphtheria-tetanus-pertussis/oral polio ("DPT/OPV") vaccines. Exhibit 22 (Soren Wengel Mogensen et al., The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community, 17 EBioMedicine 192 (2017)).

Additionally, Dr. Levin relied on two articles that explored the effects of the Bacille Calmette-Guéin ("BCG") vaccine, which protects against tuberculosis. One article found that the BCG vaccine increases the production of activation markers and leads to a more robust release of cytokines. Exhibit 19 (Deeva Uthayakumar et al., Non-Specific Effects of Vaccines Illustrated Through the BCG Example: From Observations to Demonstrations, 9 Frontiers in Immunology 2869 (2018)) at 8. He also cited a study of peripheral blood mononuclear cells taken from low-birth weight infants who had received a BCG vaccination when they were younger than six weeks old. Exhibit 21 (Andreas Andersen et al., Both Very Low and Very High In Vitro Cytokine Responses Were Associated with Infant Death in Low-Birth-Weight Children from Guinea Bissau, 9 PLos One 93562 (2014)).

Dr. McCusker persuasively explained why most of the literature Dr. Levin relied on has little relevance to M.W.'s case. Dr. McCusker noted that the Pellegrino article (exhibit 20) is irrelevant to M.W.'s case because the authors do not discuss IL1β, TNFα, or IL6, "the cytokines implicated in the development of fever." Exhibit A at 5 (citing exhibit 20 at 3). With respect to the Mogensen article (exhibit 22), Dr. McCusker noted that M.W. did not receive the DPT/OPV vaccines, which are the focus of the study. Id. at 6.

Further, Dr. McCusker asserted that the Uthayakumar article (exhibit 19) did not discuss "harmful" effects of the BCG vaccine and asserted that the article was irrelevant to M.W.'s case as M.W. did not receive the BCG vaccine. Exhibit A at 5 (citing exhibit 19 at 4). Similarly, Dr. McCusker stated that the Andersen article (exhibit 21) was irrelevant because M.W. did not receive the BCG vaccine, and M.W. was not a low-birth weight infant. Id. at 6.

In response, Dr. Levin defended the literature he used to support his theory. Dr. Levin addressed Dr. McCusker's critique of the Pellegrino article (exhibit 20) and argued that although it did not explore the cytokines involved in fever development, it is still relevant because it found that some cytokines affect drug metabolism pathways. Exhibit 45 at 3. Regarding the Mogensen article (exhibit 22), Dr. Levin asserted that it is relevant because it demonstrates increased mortality following the DPT/OPV vaccine. Id. He did not address Dr. McCusker's criticism that M.W. did not receive the DPT/OPV vaccine. See id. Finally, with respect to the Uthayakumar article (exhibit 19), Dr. Levin stated, "While [M.W.] did not receive the BCG vaccination, the study is relevant to the current case because . . . it shows how early vaccination followed by additional vaccination can lead to cytokine reactions of unexpected magnitude." Id.

Dr. McCusker persuasively pointed out deficiencies in Dr. Levin's theory regarding the role of M.W.'s ear infection and earlier vaccinations in priming him for an enhanced immune response. Specifically, Dr. McCusker explained that the literature Dr. Levin relied on has little relevance to M.W.'s case. Although Dr. Levin attempted to address Dr. McCusker's concerns, he did not substantively address the issues Dr. McCusker identified. Without any credible and relevant literature to support this theory, it is untenable. Although literature is not required, Althen, 418 F.3d 1274, "a scientific theory that lacks any empirical support will have limited persuasive force." Caves v. Sec'y of Health & Hum. Servs., 100 Fed. Cl. 119, 134 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012).

*b) M.W.'s Course of Amoxicillin*

Dr. Levin also claimed that the amoxicillin M.W. received to treat his ear infection primed him for an augmented response to his vaccinations on October 19, 2015. Exhibit 18 at 5. Dr. Levin explained that "proinflammatory cytokines disrupt the functioning of endothelial cells, which leads to 'reactive gliosis.'" Exhibit 18 at 4 (citing exhibit 23; exhibit 24; exhibit 25).[3] He opined that "repeated instances of gliosis can lead to chronic reactive gliosis, where glial cells are 'primed' to respond more readily to less traumatic signals than they normally would." Exhibit 18 at 4 (citing exhibit 28 (Russell L. Blaylock & Joseph Maroon, Immunoexcitotoxicity as a Central Mechanism in Chronic Traumatic Encephalopathy—A Unifying Hypothesis, 2 Surgical Neurology Int'l 107 (2011)).

Dr. Levin also offered literature in support of his proposition that the amoxicillin M.W. received primed him for an enhanced response to the vaccinations he received on October 19, 2015. One article discussed the neurotoxic features of chemotherapies. Exhibit 24 (Wardill). Another study examined the effects of thimerosal in neonatal hamsters. Exhibit 26 (Jonny Laurente et al., Neurotoxic Effects of Thimerosal at Vaccines Doses on the Encephalon and Development in 7 Days-Old Hamsters, 68 Anales de la Facultad de Medicina 222 (2007)). Dr. Levin also referenced a study that concluded that

[3] Exhibit 23 (H.F. Galley & N.R. Webster, Physiology of the Endothelium, 93 British J. Anaesthesia 105 (2004)); exhibit 24 (Hannah R. Wardill, Cytokine-Mediated Blood Brain Barrier Disruption as a Conduit for Cancer/Chemotherapy-Associated Neurotoxicity and Cognitive Dysfunction, 139 Int'l J. Cancer 2635 (2016)); exhibit 25 (Wei Guo et al., Glial-Cytokine-Neuronal Interactions Underlying the Mechanisms of Persistent Pain, 27 J. Neurosci. 6006 (2016)).

cytokines released during vaccination could reach the brain and cause neuroinflammation. Exhibit 39 (G. Giannotta & N. Giannotta, Vaccines and Neuroinflammation, 3 Int'l J. Pub. Health & Safety 163 (2018)). Another study of mice prone to lupus-like disease found that the hepatitis B vaccine accelerated the onset of kidney disease. Exhibit 40 (Nancy Agmon-Levin et al., Immunization with Hepatitis B Vaccine Accelerates SLE-Like Disease in a Murine Model, 54 J. Autoimmunity 21 (2014)). Dr. Levin also cited an article discussing the benefits and risks of using cytokines as adjuvants for vaccination. Exhibit 42 (Christopher E. Taylor, Cytokines as Adjuvants for Vaccines: Antigen-Specific Responses Differ from Polyclonal Responses, 63 Infection & Immunity 3241 (1995)).

The relevance of the articles Dr. Levin offered to support his theory regarding the priming effect of amoxicillin is not readily apparent. Dr. McCusker noted that the Wardill article (exhibit 24) provided no evidence that the effect of chemotherapy and increased peripheral cytokines resulted in increased vascular congestion. Exhibit A at 6. She pointed out that the Laurente article (exhibit 26) has no connection to this case as M.W. did not receive any vaccinations containing thimerosal, and he was not neonate when he received his vaccinations on October 19, 2015. Id. Regarding the Giannotta article (exhibit 39), Dr. McCusker observed that the study examined the effects of cytokines released during vaccinations on learning and memory, and M.W. had no issues with learning or memory. Id. at 7. Concerning the Agmon-Levin article (exhibit 40), Dr. McCusker stated that it was irrelevant because M.W. did not have kidney disease. In response to the Taylor article (exhibit 42), Dr. McCusker asserted that M.W. received routine vaccinations without added exogenous cytokines. Id. She added that M.W.'s fever resolved after taking Tylenol, which indicates that there was no excessive cytokine activity prior to his death. Id.

In response, Dr. Levin attempted to address the issues with the literature he relied on to support his proposition. With respect to the Wardill study (exhibit 24), Dr. Levin responded that while there is no evidence that the effects of chemotherapy and increase in peripheral cytokines lead to increased vascular congestion, "there is no evidence that these effects do NOT lead to increased vascular congestion." Exhibit 45 at 3. He added that the study is relevant because it shows that "exogenous cytokines can cross the blood brain barrier and enter the brain." Id. Regarding the Laurente article (exhibit 26), Dr. Levin claimed that M.W. received the flu vaccine, which would have contained thimerosal if administered from a multi-dose vial. Id. There is no information regarding whether M.W. received his flu vaccine from a multi-dose vial. Dr. Levin also defended the Giannotta article (exhibit 39), arguing that it supports the theory that

exogenous/peripheral/exocranial cytokines can enter the brain. Id. at 3-4. Finally, he addressed the Agmon-Levin article (exhibit 40) by stating that it has "no obvious relevance to [M.W.'s] systemic and widespread congestion," but is relevant because M.W.'s autopsy showed congestion in the kidney. Id. at 4 (citing exhibit 8 at 3).

Overall, Dr. Levin failed to substantively engage with Dr. McCusker's criticisms. His brief responses defending the articles he relied on do not cure the deficiencies Dr. McCusker raised. Therefore, Dr. Levin's opinion that M.W.'s course of amoxicillin primed him for an augmented response following his October 19, 2015 vaccinations is not persuasive.

In sum, Dr. McCusker identified several flaws and gaps in Dr. Levin's cytokine storm and priming theories. Therefore, Ms. Whitesell has not met her burden of proof on Althen prong one.[4]

### C. Althen Prong 2: A Logical Sequence of Cause and Effect

The second Althen prong requires a petitioner to show a logical sequence of cause and effect usually supported by the medical records. Althen, 418 F.3d at 1278; Capizzano, 440 F.3d at 1326. With respect to the second prong, the Federal Circuit has instructed special masters to carefully consider the views of treating doctors. Capizzano, 440 F.3d at 1326.

Dr. Levin opined that based on his review of M.W.'s tissue slides examined at autopsy, M.W. had "significant" vascular congestion in his brain, lungs, and heart. Exhibit 18 at 3; exhibit 51 at 1; see also exhibit 52 at 1 (Dr. Levin describing M.W.'s vascular congestion as "massive"). He argued that the congestion shows that M.W. suffered a massive vaccine-induced lymphocytic infiltrate, which caused a cytokine storm that resulted in his death. Exhibit 51 at 1. He added that there was no other intervening factor to explain his death. Exhibit 18 at 2.

[4] While the outcome depends on the evidence presented in this case, special masters have found a lack of persuasive evidence for claims that vaccines can cause an infant or child's unexpected death. See, e.g., Martin, 2020 WL 4197748, at *27; Copenhaver, 2016 WL 3456436, at *17; Cozart, 2015 WL 6746616, at *7-13; Bigbee, 2012 WL 1237759, at *32-36; Doe/11, 2008 WL 4899356, at *8-9.

In response to Dr. Levin's opinion that the vaccines caused M.W.'s death, the Secretary raises three points of disagreement. First, the evidence from the autopsy does match what Dr. Levin's description of it. Resp't's Br. at 47-49. Second, M.W.'s health in the evening before he died does not correspond with a person who is suffering a cytokine storm. Id. at 41-42. Finally, the VAERS report submitted by M.W.'s pediatrician is of limited value. Id. at 46 n.6.

1. Autopsy

Here, the parties dispute the autopsy findings. Ms. Whitesell puts forward Dr. Shukla's statement that vascular congestion in many organs was a significant finding. In contrast, Dr. Harris opines that the congestion was not as extensive as Dr. Levin suggests.

As the person who conducted the autopsy, Dr. Shukla's views are entitled to some deference. Nordwall v. Sec'y of Health & Hum. Servs., 83 Fed. Cl. 477, 488 (2008). However, findings of a treating doctor are not sacrosanct. Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 745 n.67 (2009).

Dr. Shukla made the following findings on M.W.'s autopsy. She found petechiae of the thymus and lungs and pulmonary and visceral congestion. Exhibit 8 at 1. Dr. Shukla noted that vascular congestion was a "significant finding" in all of M.W.'s organs. Id. at 5. When discussing the findings for specific organs, Dr. Shukla noted that M.W.'s lungs had "mild passive congestion," his liver was "mildly passively congested," and his "kidneys were congested." Id. at 4. However, Dr. Shukla did not specifically discuss the level of congestion found in several of M.W.'s organs, including the heart and brain. Id. at 4-5. She also observed that there were no hemorrhages or vascular aneurysms in the central nervous system. Id. at 4-5.

In the context of preparing an opinion for this case, Dr. Levin examined the autopsy slides. Dr. Levin reported that M.W. had "significant" or "massive" vascular congestion in his brain, lungs, and heart. Exhibit 18 at 3; exhibit 51 at 1; exhibit 52 at 1. He stated that he "agree[d] entirely" with Dr. Shukla's autopsy report "in that virtually all of the tissues examined show[ed] significant 'vascular congestion.'" Exhibit 51 at 1. He added that the congestion consisted mostly of lymphocytes, which further supports his theory that M.W. died of a cytokine storm. Id.

In response to Dr. Levin's assertion that M.W. suffered "significant" or "massive" vascular congestion, Dr. Harris noted that Dr. Shukla did not describe the vascular congestion as "massive." Exhibit C at 6. In contrast, Dr. Harris reviewed M.W.'s autopsy slides and found the vascular congestion to be minimal. Id. at 5. He added that Dr. Shukla's microscopic findings of vascular congestion in every part of M.W.'s body were inaccurate. Id. In his review of the autopsy slides, Dr. Harris observed only "minor congestion within the lungs, liver, kidneys, and some areas of the brain." Id. He explained that because M.W.'s organ weights were all close to the fiftieth percentile expected for a child his age, the congestion was minimal. Id. Dr. Harris also pointed out that neither he nor Dr. Shukla found any vascular leakage or hemorrhage. Id. at 6. Dr. Harris further asserted that the minimal amounts of vascular congestion found in M.W.'s organs were not "pathophysiologically significant" and insufficient to cause M.W.'s death. Id. at 6. He elaborated that in cases where there is massive congestion and edema in the brain, the brain swells and herniates, causing death. Id. Dr. Harris stated that this type of congestion was not observed in M.W.'s case. Id. With respect to Dr. Levin's assertion that the congestion found in M.W.'s autopsy was made up primarily of lymphocytes, Dr. Harris explained, "In the tissues sampled there was no significant evidence for an immune response to vaccination or infectious disease with the possible exception of mild lymphoid aggregates noted around some bronchioles in the lung sections." Id. at 5.

Dr. Harris also noted that several of M.W.'s organs were not sampled and that M.W.'s lungs, brain, and heart should have had more extensive sampling. Id. at 5. Specifically, he pointed out that the key area implicated in seizure disorders (the hippocampus) and the key area implicated in many SIDS cases (the medulla) were not sampled. Id. Due to the incomplete autopsy, Dr. Harris opined that a seizure-related incident, cardiac arrythmia, or suffocation from prone sleeping position cannot be ruled out as potential causes of death. Id. Therefore, Dr. Harris concluded that SUID or SUDC is the correct classification for M.W.'s cause of death. Id. Dr. Levin did not comment on the need for more sampling raised by Dr. Harris.

According to Dr. Harris, Dr. Shukla's autopsy was incomplete.[5] Given Dr. Harris's experience and training, his opinion on this point is credited. Therefore,

[5] Other mistakes in Dr. Shukla's report concerning the date of vaccination and a typographical error in presenting the weight of the heart (see Pet'r's Br. at 23) are relatively trivial and do not affect the value of Dr. Shukla's findings on microscopic examination.

due to some inaccuracies in Dr. Shukla's report and that it was incomplete, Dr. Harris persuasively explained why Dr. Shukla's findings of vascular congestion in *every* part of M.W.'s body were inaccurate.

As noted by Dr. Harris, M.W.'s autopsy showed only minimal vascular congestion the lungs, liver, kidneys, and some areas of the brain. Exhibit C at 6. Given Dr. Harris's expertise in pathology and that he has reviewed over 10,000 cases involving surgical pathology and autopsy, his opinion is persuasive on this point. See id. at 1; see also Martin, 2020 WL 4197748, at *13 (noting Dr. Harris's testimony that he "reviews about thirty pediatric autopsies a year—including autopsies for unexplained deaths in children and infants" and has reviewed "several hundred pediatric autopsies" in the last few years). Dr. Harris's opinion also aligns with Dr. Shukla's findings of "mild" and "passive" congestion in the lungs and liver. See exhibit 8 at 4.

Conversely, Dr. Levin's attempt to exaggerate Dr. Shukla's autopsy findings are not persuasive. Contrary to Dr. Levin's assertions, Dr. Shukla never described the vascular congestion as "massive," and noted that some organs showed only "mild" or "passive" congestion. See exhibit 8. Additionally, with respect to other organs such as the brain and heart, Dr. Shukla only noted that vascular congestion was a "significant finding" but did not mention the level of congestion in her individual discussion of those organs as she did with the lungs and liver. See id. at 3-5. Given Dr. Levin's limited experience reviewing autopsies, his attempt to overstate the level of congestion found in M.W.'s organs is not credited. See Bigbee, 2012 WL 1237759, at *4 (discussing Dr. Levin's testimony that "when he was practicing medicine, he performed fifty to sixty autopsies on children, half of which were 'probably' infants, with the last infant autopsy being performed in the '1980's'").

Overall, Dr. Harris's opinion that there was only minimal congestion in M.W.'s lungs, liver, kidneys, and some areas of the brain is persuasive. Further, Dr. Levin's assertions that M.W. had "massive" vascular congestion in his brain, lungs, and heart, do not match Dr. Shukla's autopsy findings. Thus, M.W.'s autopsy does not support a logical sequence of cause and effect.

2. M.W.'s Behavior and Health Before Dying

Brittney Whitesell noted that after a nap, M.W.'s fever went down with Tylenol, he was no longer cranky, and "[n]othing was out of the ordinary" the night before his death. Exhibit 4 (Brittney Whitesell's affidavit) at 2; see also

exhibit 7 (coroner's report) at 1 (reporting that M.W. had a temperature of 100.2 degrees when he was placed in bed at 7:30 P.M. the night before his death).

Dr. Levin opined that before M.W. died, he experienced cytokine dysregulation or a cytokine storm. Exhibit 16 at 3; exhibit 18 at 2; exhibit 51 at 1; Pet'r's Br. at 3.

In contrast, Dr. McCusker noted that there was "no evidence of progressive signs of excessive dysregulated cytokine activation." Exhibit A at 8. She added that if M.W. had suffered a cytokine storm as Dr. Levin suggested, "he would not have been described as acting normally." Id. She explained that M.W. would have been very ill and in addition to fever, showed signs of "increased irritability, inconsolable crying and respiratory distress." Id.; see also exhibit E at 4. To support her opinion, Dr. McCusker referenced a clinical trial that describes headache, myalgias, high fever, notable rash and rigors, respiratory distress, nausea, vomiting, diarrhea, and multi-organ failure in adults experiencing cytokine storm or systemic inflammatory response syndrome ("SIRS") induced by a T cell immunomodulatory agent (anti-CD28 monoclonal antibody). Exhibit A, tab 11 (Ganesh Suntharalingham et al., Cytokine Storm in a Phase 1 Trial of the Anti-CD28 Monoclonal Antibody TGN1412, 355 New England J. Med., 1018 (2006)).

Conversely, Dr. Levin claimed that Dr. McCusker made "unwarranted generalizations" about the symptoms one would experience during a cytokine storm. Exhibit 45 at 4. Dr. Levin also opined that the Suntharalingham study (exhibit A, tab 11) is unpersuasive because although M.W. did not experience similar symptoms as those in the clinical trial, he did not receive the anti-CD2 monoclonal antibody. Id. He added, "There is no evidence that the specific cytokine processes initiated by anti-CD2 monoclonal antibodies are the same as the suite of immunopathologies that can be induced by vaccines, which involve (in this case) aluminum adjuvants and viral proteins, not monoclonal antibodies." Id. He also noted that the clinical trial involved adults, and "infants the age of [M.W.] have very different immune systems." Id. Finally, to explain why M.W. would be acting normally while experiencing a cytokine storm, Dr. Levin opined that "the cytokine reaction clearly mounted and progressed in the middle of the night, and [M.W.] could very well have exhibited symptoms unseen." Id. at 4-5. He added that the congestion in M.W.'s lungs could be evidence for respiratory distress. Id. at 5.

In response to Dr. Levin's criticisms, Dr. McCusker defended the relevance of the Suntharalingham study (exhibit A, tab 11). She noted that cytokine storm

and SIRS occurs in both children and adults. Exhibit E at 4. She further explained that children experiencing cytokine storms exhibit "unremitting fevers," and often suffer splenomegaly, cytopenias, hepatitis, multi-organ dysfunction, and hypercytokinemia. Id. (citing exhibit E, tab 12; exhibit E, tab 14; exhibit E, tab 15; exhibit E, tab 16).[6] Dr. McCusker explained that because M.W. did not have an "unremitting fever," there was no report of splenomegaly on his autopsy, and "no description of significant infiltration of immune cells in the organs," M.W.'s health before his death was inconsistent with a child experiencing a cytokine storm. Id. at 4-5.

Ms. Whitesell argued that M.W.'s fever of 101.1 degrees cannot be said to have "resolved quickly" as Dr. McCusker suggested because he died within twelve hours. Pet'r's Br. at 21, 25-26. In making this argument, Ms. Whitesell did not address the coroner's report that M.W.'s temperature had gone down to 100.2 degrees. See id. Some healthcare providers consider a temperature of 100.4 degrees and above to be febrile. See Holmes v. Sec'y of Health & Hum Servs., 115 Fed. Cl. 469, 477 (2014) (quoting a medical expert's testimony that "the lower level for recognized fever would be 100.4 degrees for rectal temperature"). Even if a temperature of 100.2 degrees is considered a fever, M.W.'s temperature had gone down from 101.1 degrees with Tylenol. Therefore, M.W.'s fever cannot be said to have been "unremitting" or "sustained" as Dr. McCusker opined would be expected for a child experiencing a cytokine storm. See exhibit E at 4; see also exhibit E, tab 12 (Shimizu) at 32 (stating that the clinical features of cytokine storm include "sustained fever," which is "usually high-grade" (greater than 101.3 degrees Fahrenheit), "prolonged, and unresponsive to anti-infective treatment").

Here, M.W.'s behavior and health the night before his death do not support Dr. Levin's theory that he was experiencing a cytokine storm. Dr. Levin's attempt to dispute Dr. McCusker's opinion that M.W.'s signs and symptoms were

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[6] Exhibit E, tab 12 (Masaki Shimizu, Clinical Features of Cytokine Storm Syndrome, in Cytokine Storm Syndrome (Randy Q. Cron & Edward M. Behrens eds. 2019)); exhibit E, tab 14 (Lehn K. Weaver & Edward M. Behrens, Weathering the Storm: Improving Therapeutic Interventions for Cytokine Storm Syndromes by Targeting Disease Pathogenesis, 3 Current Treatment Options Rheumatology 33 (2017)); exhibit E, tab 15 (Xiao-Jun Xu et al., Diagnostic Accuracy of a Specific Cytokine Pattern in Hemophagocytic Lymphohistiocytosis in Children, 160 J. Pediatrics 984 (2012)); exhibit E, tab 16 (Silencing the Cytokine Storm: The Use of Intravenous Anakinra in Haemophagocytic Lymphohistiocytosis or Macrophage Activation Syndrome, 2 Lancet Rheumatology 358 (2020)).

incompatible with a child experiencing a cytokine storm are unpersuasive. Although Dr. Levin claimed that infants experiencing cytokine storm would present differently than adults, he did not provide any medical literature to show how an infant or child experiencing a cytokine storm would present. He merely claimed that M.W. may have exhibited additional symptoms in the middle of the night that were unknown to his caretakers. See exhibit 45 at 5. This point rests upon speculation. Although he claimed that there may have been evidence of respiratory distress in M.W.'s autopsy, Dr. McCusker aptly pointed out that M.W.'s autopsy showed no other signs of cytokine storm such as splenomegaly. Given Dr. McCusker's vast experience with pediatric immunology, her opinion regarding the signs and symptoms associated with cytokine storms in children is credited. Therefore, M.W.'s normal behavior and health the night before his death casts doubt on Ms. Whitesell's logical sequence of cause and effect.

3. VAERS Report

Dr. Utendorf's submission of a VAERS report could be viewed as some evidence that a treating doctor believed that a vaccine contributed to M.W.'s death. See Pet'r's Br. at 22. However, the VAERS report does not contain any affirmative opinion from Dr. Utendorf. Without more developed reasoning, the VAERS report presents a sequence of events in which the vaccination preceded M.W.'s death. A recitation of a chronological sequence of events is not the same as an opinion regarding causation. Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1347-48 (Fed. Cir. 2010); La Londe v. Sec'y of Health & Hum. Servs., 110 Fed. Cl. 184, 206 (2013), aff'd on other ground, 746 F.3d 1334 (Fed. Cir. 2014).

Therefore, Ms. Whitesell has not presented a logical sequence of cause and effect sufficient to satisfy her burden under Althen prong two.[7]

**D. Althen Prong 3: A Showing of a Proximate Temporal Relationship Between Vaccination and M.W.'s Death**

The third Althen prong requires the petitioner to show a "proximate temporal relationship" between the vaccination and the alleged injury. Althen, 418

[7] Finally, Ms. Whitesell emphasizes that the Secretary has not identified an alternative cause for M.W.'s death. See, e.g., Pet'r's Br. at 16, 21. However, the Secretary does not bear this burden until Ms. Whitesell presents a persuasive prima facie case, which she has not done. La Londe, 746 F.3d at 1340.

F.3d at 1281. The timing prong of Althen contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Hum. Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

The parties agreed that M.W. died within four days after receiving his vaccinations. However, the Secretary argued that Ms. Whitesell failed to put forth a medically acceptable timeframe to infer that the vaccinations caused M.W.'s death.

Dr. Levin did not offer a range of time for which it would be medically acceptable to infer that the vaccinations caused M.W.'s death. Instead, Dr. Levin suggested that an interval of four days between vaccination and death falls within an appropriate temporal relationship. Exhibit 18 at 6. He added that it was "difficult to set a definite end of time period within which a death could medically be considered causal from a vaccine, however, given the short duration of time[] (less than 4 days), [M.W.'s] death falls within any medically acceptable reasonable time limitation." Id. Dr. Levin did not provide further explanation for this proposed time interval.

In response, Dr. McCusker cited literature that found fever episodes occurred within seven to thirteen days following receipt of the MMR and MMR-V vaccinations. See exhibit A at 12 (citing exhibit A, tab 20 (J.A. Englund et al., Placebo-Controlled Trial of Varicella Vaccine Given with or After Measles-Mumps-Rubella Vaccine, 114 J. Pediatrics 37 (1989)) at 4). Thus, she opined, a M.W.'s fever four days after vaccination was unlikely to be related to the MMR vaccine. See id. She also relied on two studies that found no increased incidence of fever following the hepatitis A and flu vaccines. Exhibit A, tab 21 (Alan Werzberger et al., A Controlled Trial of a Formalin-Inactivated Hepatitis A Vaccine in Healthy Children, 327 New England J. Med. 453 (1992)) at 3; exhibit A, tab 22 (Eric Plennevaux et al., Influenza A (H1N1) 2009 Two-Dose Immunization of US Children: An Observer-Blinded, Randomized, Placebo-Controlled Trial, 29 Vaccine 1569 (2011)) at 4, 6. Therefore, Dr. McCusker concluded that it was unlikely that the fever M.W. developed on October 22, 2015, was related to the vaccinations he received four days earlier. Exhibit A at 12.

She also explained that while "[v]accines are designed to activate the immune system," "any effects of the adjuvant would be, at least initially, a local

effect, during the first few days." See id. (citing exhibit A, tab 23 (Mirjam Kool et al., Alum Adjuvant Boosts Adaptive Immunity by Inducing Uric Acid and Activating Inflammatory Dendritic Cells, 205 J. Experimental Med. 869 (2008)). In her second report, she added that antibodies would not have formed within four days after vaccination. See exhibit E at 5-6. Therefore, she opined that M.W.'s vaccinations would have had only a local effect during the first four days after vaccination and would not have caused his death.

The Secretary argued that Dr Levin provided "no support for [his] incredibly broad opinion regarding an appropriate time limitation." Resp't's Br., filed Dec. 9, 2021, at 50. He asserted that Dr. Levin's opinion regarding timing was "too vague to explain the particulars of this case, i.e., hepatitis A, flu, MMR, and varicella vaccinations and sudden, unexpected death of a child." Id. He added that "Dr. McCusker's discussion of timing in no way attempts to demonstrate that there is a medically acceptable timeframe during which the hepatitis A, flu, MMR, and varicella vaccinations can cause the sudden, unexpected death of a child." Id.

Dr. Levin failed to provide any medical literature to support his contention that an interval of four days between vaccination and death is medically appropriate to infer vaccine-causation. Conversely, Dr. McCusker offered credible articles to dispute Dr. Levin's opinion on timing. Without any literature to support the timing in this case, Ms. Whitesell is unable to meet her burden of proof under the third Althen prong.

## V. A Hearing Is Not Required

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

Ms. Whitesell has had a fair and full opportunity to present her case. After Dr. Levin presented his initial opinions, Dr. McCusker and Dr. Harris critiqued them, persuasively pointing out gaps and flaws in Dr. Levin's reports. Ms. Whitesell then presented a rebuttal opinion from Dr. Levin, which Dr. McCusker again critiqued. Dr. Levin had the opportunity to address any criticisms in his final supplemental reports; however, any efforts to do so were unsuccessful. During briefing, Ms. Whitesell failed to shore up any deficiencies in Dr. Levin's reports. After submitting two deficient briefs, Ms. Whitesell was permitted to submit a third brief in support of entitlement. Unfortunately, Ms. Whitesell's brief merely

repeated her earlier arguments in a disjointed manner. After the Secretary submitted his responsive brief pointing out flaws in Ms. Whitesell's arguments, Ms. Whitesell had the chance to submit a reply brief. However, Ms. Whitesell elected not to submit a reply brief to address the issues in her argument. Therefore, Ms. Whitesell's efforts to cure any deficiencies during the briefing process were unpersuasive.

Ms. Whitesell was unable to offer a reliable theory by which the hepatitis A, flu, MMR, or varicella vaccines can cause an infant or child's death. Additionally, Ms. Whitesell's logical sequence of cause and effect lacked persuasiveness. Finally, Ms. Whitesell offered no support for the four-day time interval between vaccination and death. Therefore, a hearing would not resolve the problems in Ms. Whitesell's case.

## VI. Conclusion

Ms. Whitesell has not met her burden of demonstrating that the hepatitis A, flu, MMR, or varicella vaccines were the cause-in-fact of M.W.'s death. Accordingly, the Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, available through the Court's website.

**IT IS SO ORDERED**.

s/Christian J. Moran
Christian J. Moran
Special Master