IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 06-469V
Filed: January 7, 2013
(To Be Published)

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TERESA FRESCO and ANTHONY FRESCO, as best friends of their son, DANIEL FRESCO, a minor, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	* * * * * * * * * * *	Autism; Causation in Fact; Expert Qualifications; OAP Test Case Theories; Misinterpretation of Records

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Teresa Fresco and Anthony Fresco, West Orange, NJ, *pro se* petitioners.
Lynn Ricciardella, Esq., U.S. Department of Justice, Washington, DC for respondent.

DECISION[1]

VOWELL, Special Master:

On June 20, 2006, Teresa and Anthony Fresco ["Mrs. Fresco," "Mr. Fresco" or "petitioners"], acting *pro se*, timely filed a petition under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq*.[2] [the "Vaccine Act" or "Program"], on behalf of their minor son, Daniel S. Fresco ["Danny"]. The petition alleges that Danny received "numerous vaccinations at a time when his immune system was compromised by an infection." Petition, ¶ 4.[3] "Petitioners assert that it is more likely than not that one of (sic) more vaccines administered to Daniel action (sic) alone

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[1]Because I have designated this decision to be published, each party has 14 days to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be publicly available. 42 U.S.C. § 300aa12(d)(4)(B).

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (2006). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa.

[3] A second copy of this petition was filed on November 3, 2010, as a part of what I later ordered designated as Petitioners' Exhibit ["Pet. Ex."] 6, pp. 2-3. *See* Order, issued Dec. 28, 2011.

or in concert with each other or with other drugs administered to Daniel caused his Autism." Petition, ¶ 5; Pet. Ex. 6, p. 2.

In order to prevail under the Program, a petitioner must prove either a "Table" injury[4] or that a vaccine listed on the Table was the cause-in-fact of an injury. Autism is not a Table injury, thus petitioners must show that one or more vaccinations actually caused Danny's autism. To do so, petitioners must demonstrate by preponderant evidence "(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, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) and *Hines v. Sec'y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

Although petitioners have established that Danny received routine childhood vaccinations covered under the Vaccine Act and subsequently received a diagnosis on the autism spectrum, the evidence in the record fails to demonstrate that any of the vaccines Danny received can, alone or together, cause autism or that they did so in his case. Petitioners have therefore failed to link Danny's vaccinations to any illness, disability, injury, or condition. *See* § 11(c)(1)(C)(i). After considering the record as a whole,[5] I hold that petitioners have failed to establish Danny's entitlement to compensation.

Although petitioners did not prevail in proving vaccine causation, Mrs. Fresco did an admirable job in drafting and filing the petition, collecting and filing numerous medical records, and finding a physician willing to opine on vaccine causation. She spent a significant period of time reviewing Danny's medical records and consulting reference materials in an effort to find a cause for Danny's condition. Like countless other parents of children with autism spectrum disorders, she has done everything in her power to have Danny diagnosed and appropriately treated. She cogently argued Danny's case. Her belief that Danny's condition is the result of his vaccinations is sincerely held, but inadequately supported, and ultimately rested on misinterpretations of Danny's medical records and some of the same theories considered and rejected in the Omnibus Autism Proceeding test cases.[6]

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[4] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified. Autism spectrum disorders are not listed as Table injuries for any vaccine appearing on the Table.

[5] *See* § 13(a) ("Compensation shall be awarded . . . 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)."); *see also* § 13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation).

[6] Mrs. Fresco participated fully in all status conferences in this case. She and her husband were unable to find an attorney willing to take Danny's case in spite of diligent efforts. *See* Pet. Ex. 1, Affidavit of

I. Procedural History.

This petition is one of approximately 5700 petitions filed between 1997 and 2012 alleging that various vaccines were responsible for causing a neurodevelopmental disorder variously referred to as autism spectrum disorder or pervasive developmental disorder or as one of several specific diagnoses contained within these umbrella terms. Most of these cases were consolidated into the Omnibus Autism Proceeding ["OAP"]. On June 23, 2006, the special master then assigned to this case sent the parties a "Notice Regarding Omnibus Autism Proceeding," which indicated that this case would be placed in the OAP.

In the OAP, six "test cases" were tried under two theories presented by the Petitioners' Steering Committee.[7] The first three test cases presented the causation theory that a combination of the measles, mumps, and rubella ["MMR"] vaccine and thimerosal-containing vaccines caused autism spectrum disorders ["Theory 1"]. The second group of three test cases presented the causation theory that thimerosal-containing vaccines alone can cause autism spectrum disorders ["Theory 2"]. The three special masters assigned to hear the test cases ruled that there was no reliable evidence that the vaccines caused autism spectrum disorders. The courts that heard the appeals in the test cases all agreed with the special masters that there was no reliable evidence supporting vaccine causation.[8]

Once the final appeals in the OAP test cases were exhausted, I ordered petitioners to inform the court whether, in light of the test case decisions,[9] they wished

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Teresa Fresco. Although they found a physician willing to opine in favor of vaccine causation, his report was inadequate to establish vaccine causation of Danny's condition.

[7] The Petitioners' Steering Committee was comprised of petitioners' counsel selected by their peers to represent the interests of all petitioners in the OAP throughout the discovery period and in the test case hearings and appeals. *Dwyer v. Sec'y, HHS,* No. 03-1202V, 2010 WL 892250, *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

[8] The Theory 1 cases were *Cedillo v. Sec'y, HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y, HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y, HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009). Petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims. The Theory 2 cases were *Dwyer v. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y, HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y, HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

[9] Unlike either class actions or multi-district litigation in state or other federal court systems, the remaining OAP petitioners are not bound by the results in the test cases. Nevertheless, by design, the OAP test cases produced a body of evidence available to both petitioners and respondent to use in litigating OAP cases in which petitioners elected to go forward with their claims. *Dwyer,* 2010 WL 892250 at *2; *Snyder*, 2009 WL 332044 *a*t *2 – 3; *see also* Transcript of April 24, 2012 Oral Arguments ["Tr."] at 6-7.

to pursue their claim.[10] They informed me that they intended to pursue Danny's case and a series of status conferences[11] and orders ensued to move the case towards resolution.

Petitioners filed some medical records (three exhibits labeled A, B, and C) and a declaration with their petition on June 20, 2006. Additional medical records were filed on February 6, 2009, November 3, 2010, and July 8, 2011. These additional records were not assigned exhibit letters or numbers by petitioners and each filing was partially duplicative of their previous filings. To prevent confusion when the parties referenced particular pages of Danny's medical records, I issued an order on December 28, 2011, that assigned exhibit numbers 1-7 to these filings.[12]

On February 14, 2011, after a status conference in which I explained why the opinion of a medical expert on causation was needed, I ordered petitioners to file an expert report. They did so on August 11, 2011, filing a report from Dr. Harold Buttram (designated as Pet. Ex. 8 in my order filed Dec. 28, 2011) that is primarily comprised of excerpts from an on-line article[13] co-authored by Dr. Buttram. Supplemental materials from Dr. Buttram, including a biographical sketch of his background and qualifications,[14] were filed on January 26, 2012, along with Petitioners' Exhibits 9-13. Although respondent contended at a status conference held on August 25, 2011, that Dr. Buttram's report was inadequate to carry petitioners' burden,[15] she complied with my

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[10] As Danny never received a measles, mumps, and rubella vaccine, the evidence from the Theory 2 test cases has the most relevance to petitioners' claim. Although their precise theory of causation is somewhat amorphous, petitioners filed evidence concerning the thimerosal content of the hepatitis B vaccine Danny received, and their expert addresses, at least in passing, the thimerosal causation theory.

[11] Most of the status conferences were digitally recorded and were followed by written orders summarizing the matters discussed.

[12] I attached copies of all of the filed documents, identified by their new exhibit numbers and including page numbers, to my order. The declaration and three lettered exhibits filed on June 20, 2006, were designated by Exhibit Numbers 1-4, respectively; the February 6, 2009 filing was designated Exhibit 5; the November 3, 2010 filing was designated Exhibit 6; and the July 8, 2011 filing was designated Exhibit 7.

[13] H. Buttram and C. Frompovich, *Vaccines and Brain Inflammation,* International Medical Council on Vaccination ["IMCV"] (June 1, 2011), available at http://vaccinationcouncil.org/2011/06/01/vaccines-and-brain-inflammation/ (last visited Jan. 4, 2013) ["Buttram Article"]. A printout of the article was included in the materials petitioners filed on July 8, 2011. Pet. Ex. 7, pp. 9-26. IMCV is an anti-vaccination organization. *See* http://www.vaccinationcouncil.org/about/ (last visited Jan. 4, 2013) (describing IMCV as "profoundly critical of the practice of vaccination"). Doctor Buttram sits on its board of Advisors. *Id.* Additionally, the article does not appear to have been peer reviewed before publication.

[14] Petitioners did not assign this biographical material an exhibit number. I will refer to it as "Buttram CV."

[15] Doctor Buttram's lack of qualifications to opine on causation of autism spectrum disorders is discussed below.

order to file an expert report. Respondent filed the report of Dr. Max Wiznitzer and his curriculum vitae ["CV"] on November 11, 2011, as Respondent's Exhibits ["Res. Exs."] A and B, respectively. Tab A1, "Guide to Contraindications and Precautions to Immunizations, 2009" was filed with Dr. Wiznitzer's report.

At status conferences, held on August 25, 2011 and December 20, 2011, we discussed how best to resolve the contested issues in this case. I explained that once the records were complete and the experts' reports were filed, the next step would ordinarily be an entitlement hearing.[16] Mrs. Fresco was nervous about her ability to present witnesses and to cross-examine any witnesses presented by respondent at a hearing. She also expressed concern about care for Danny during any hearing. After considerable discussion, I presented Mrs. Fresco with options for proceeding. I explained that she and her husband could have a hearing conducted either in person or telephonically. Alternatively, I indicated that petitioners could present their case in the form of written submissions to the court. I also explained that she could make oral arguments to explain why petitioners believed they had met their burden of proof. I noted that in a hearing, the parties would have an opportunity to question witnesses and their experts could testify as to petitioners' theory of causation, and that in the written or oral submissions options the parties would present their arguments, referencing medical records and the expert opinions, without the testimony of others. I also explained that I would consider all of the medical records and any other evidence filed, regardless of how petitioners wanted to proceed.

Mrs. Fresco indicated her preference for presenting her case by oral argument. Respondent did not object to proceeding in that manner. *See* Order, issued Dec. 21, 2011. I therefore heard the parties' arguments on April 17, 2012, in a digitally recorded proceeding, with Mrs. Fresco representing petitioners and Ms. Ricciardella representing respondent. Prior to beginning the argument, I again informed Mrs. Fresco that petitioners could have a hearing if they desired, and she again opted to present Danny's case via the evidence of record and her oral arguments.[17] Tr. at 2-3.

The issues are therefore fully joined and the case is ripe for resolution.[18] As respondent noted during the oral argument (Tr. at 62), petitioners' medical theory of causation remains unclear. Their own contentions, raised in the petition and during oral argument, differ from some of the theories raised by Dr. Buttram, and Dr. Buttram's report fails to address some of the issues petitioners have personally raised.

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[16] Although hearings are common in causation-in-fact cases, they are not required by the Vaccine Act. § 12(d)(2)(D); *see also* Vaccine Rule 8(d).

[17] I ordered a transcript of the oral argument to be prepared; citations to "Tr." are to the transcript of the oral argument.

[18] Petitioners filed Exhibits 14-16 after the oral arguments. I have also considered the matters contained in these exhibits, which are discussed *infra*.

Petitioners contend that all of Danny's vaccinations, coupled with his "vulnerable" physical condition, caused his autism. Tr. at 52-53. Their theories encompass the following contentions regarding the vaccines: (1) Danny received vaccines containing thimerosal; (2) he received a "hot lot" diphtheria, tetanus, and acellular pertussis ["DTaP"] vaccination; (3) he received vaccinations simultaneously that should not be combined; and (4) he received vaccines while on antibiotics. Petitioners also make certain factual assertions regarding Danny's condition at the time he received his vaccinations, maintaining that: (1) he was vaccinated shortly after birth while ill; (2) he was vaccinated again at 11 days of age while he was spitting up; (3) he was not well on July 16, 2004 when he received his last vaccinations; and (4) he was ill with a fever and turned blue shortly after these last vaccinations. Their causation theory is not well articulated, but it appears to be that vaccinations, which were administered to a medically vulnerable child, caused brain inflammation resulting in an autism spectrum disorder. They rely on increases in Danny's head circumference to show this brain inflammation and on Dr. Buttram's report to link vaccines, brain inflammation, and autism. Doctor Buttram's theories largely reprise those considered and rejected in the OAP test cases.

I conclude that petitioners have not presented a reliable medical theory for vaccine causation of Danny's autism. *See Althen,* 418 F.3d at 1278; *Veryzer v. Sec'y, HHS,* 100 Fed. Cl. 344, 352-53 (2011). To the extent that petitioners rely on the thimerosal, brain inflammation, and excitotoxicity theories presented in the Theory 2 OAP test cases,[19] Dr. Buttram's report and the other evidence submitted are inadequate to counter the body of evidence presented in those test cases. The only new evidence Dr. Buttram discusses involves a study that has nothing to do with autism and is inapplicable to Danny. Respondent's expert, Dr. Wiznitzer, who is far more qualified than Dr. Buttram to opine on autism spectrum disorders, cogently explains why Dr. Buttram's theories are not reliable and why the alternate theories presented by petitioners are unsupported by the medical evidence in this case.

Without a reliable medical theory, there can be no logical connection between vaccines and Danny's condition. Moreover, the factual underpinnings for many of petitioners' assertions regarding Danny's condition and his vaccinations are lacking, further undercutting any attempted link between their theory and Danny's condition. *See Broekelschen v. Sec'y, HHS,* 618 F.3d 1339, 1345 (Fed.Cir. 2010) (noting that "[b]ecause causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case").

Finally, nothing in Dr. Buttram's report or in any of the other evidence submitted sets forth any medically appropriate temporal interval between vaccinations and onset of the behavioral symptoms that led to Danny's autism diagnosis. *See de Bazan v. Sec'y, HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (noting that "the proximate temporal

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[19] *See Dwyer,* 2010 WL 892250.

relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact”).

Based on petitioners’ presentation of evidence and arguments, I have broken Danny’s medical history, set forth in Section II below, into three separate time frames. First, I discuss Danny’s birth, hospital stay, and his initial pediatric visits, and address the issues Mrs. Fresco raised in her oral argument and other submissions with regard to Danny’s initial vaccinations and state of health. Next, I discuss the period from Danny’s April 3, 2002 pediatric visit, where he received his first set of multiple vaccinations, through July 16, 2003, when Danny received his last vaccinations. I also discuss the issues Mrs. Fresco raises about vaccines in general in this subsection. The third period involves Danny’s evaluation for and diagnosis with an autism spectrum disorder [“ASD”]. Following each of these time frames, I set forth my analysis of the competing positions of the parties, and my factual conclusions.

II. Relevant Medical History.

A. Issues Pertaining to Danny’s Birth and Perinatal Period.

1. Information from the Medical Records.[20]

Danny was born on January 27, 2002, at St. Barnabas Medical Center in Livingston, NJ. [21] Pet. Ex. 4, p. 8. He appeared to be a healthy and alert newborn, weighing seven pounds, nine ounces,[22] with a five minute Apgar score of 9.[23] Pet. Ex.

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[20] Records pertaining to Danny’s birth were filed on a number of occasions. They appear, in whole or in part, in Pet. Exs. 4, 5, 6, 7, 9, and 14.

[21] Danny was born at about 37 1/2 weeks of gestation, about 2 1/2 weeks before his due date. The records variously refer to him as “preterm” “near term,” and “full term.” *Compare* Pet. Ex. 4, p. 13 *with* Pet. Ex. 4, p. 12 and Pet. Ex. 4, p. 11. A preterm infant is one “born before the thirty-seventh completed week (259 days) of gestation.” DORLAND’S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) [“DORLAND’S”] at 933. His birth weight placed him around the 50th percentile for full term newborns. *See* Pet. Ex. 5, p. 138.

[22] Danny’s birth weight is listed elsewhere as seven pounds, four ounces. *See* Pet Ex. 4, pp. 17-18. Both weights would be in the average range for a full term male infant.

[23] The Apgar score is a numerical assessment of a newborn’s condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant’s heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. *See* DORLAND’S at 1682. The medical records are in conflict about whether Danny’s one-minute Apgar was 8 (*see* Pet. Exs. 4, p. 18; 14, p. 1 (labor and delivery summary)) or 9 (*see* Pet. Ex. 4, p. 17). It is not necessary to resolve this conflict, as either score would indicate that Danny was an apparently healthy newborn.

4, p. 9. He was placed in the regular newborn nursery for "routine care." *Id.*, p. 11. Danny's initial physical examination found no abnormalities.[24] *Id.,* p. 8.

A complete blood count ["CBC"] and blood cultures were ordered because Mrs. Fresco tested positive for group B streptococcus (referred to in the records as "GBS+") when she presented to the hospital in active labor. Pet. Ex. 4, pp. 5, 9. At the time of Danny's birth, Mrs. Fresco had received one dose of penicillin[25] administered while she was in labor, which was considered only a partial treatment for her infection. *Id.*, pp. 4, 9. Because the amniotic membranes[26] had ruptured seven hours before Danny's birth, he could have been exposed to the streptococcus bacteria present in Mrs. Fresco, and the blood tests were necessary to determine if Danny had been infected by this exposure. Pet. Ex. 4, pp. 4, 5, 9.

Danny's blood counts were normal. Pet. Ex. 4, p. 11. However his blood cultures grew gram positive cocci in clusters, and he was therefore transferred to the Newborn Intensive Care Unit ["NICU"] on January 28, 2002, where he received antibiotics orally and intravenously to treat possible sepsis, while further tests were performed. *Id.*, pp. 9-10, 18. In the NICU, Danny was initially placed on oxygen and cardiac monitors, but they were discontinued on the same day they were ordered. *Id.*, p. 10.

On the day Danny was transferred to the NICU, he was examined by two physicians, a Dr. Franco, and a neonatologist whose signature is undecipherable. According to the neonatologist, Danny's vital signs were within normal limits, and he was "not in distress." Pet. Ex. 4, p. 12. Doctor Franco's examination, completed on

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[24] During oral argument, Mrs. Fresco contended that this form (Pet. Ex. 4, p. 8) showed Danny to have a birth defect, referencing the scrawled signature extending upward from the "Physician's Signature" line in the bottom left side of the form, and extending into the "Birth Defects Registration" section immediately above the signature line. Tr. at 11-12. I conclude that Mrs. Fresco is mistaken in her assertion. "Birth defect" is defined as a defect present at birth, either a morphological defect or an inborn error of metabolism. DORLAND'S at 477. This physical examination form reflects that Danny had no abnormal physical findings. Thus, he did not have a morphological defect. *See also* Pet. Ex. 14, p. 1 (indicating that the initial newborn examination found no abnormalities). Likewise, there is no evidence that Danny has an inborn error of metabolism.

[25] During oral argument, Mrs. Fresco asserted that she received "gentamicin," an antibiotic to which she was allergic, and indicated that this may have contributed to Danny developing autism. Tr. at 8-9, 45, 57. The records filed do not reflect any drug allergies, but more significantly, they reflect that she received penicillin, not gentamicin. *See* Pet. Exs. 4, p. 9; 5, p. 123. Gentamicin is an antibiotic effective against a wide range of gram negative bacteria and some gram positive bacteria. DORLAND'S at 771. Penicillin is an antibiotic effective against many gram positive bacteria, including streptococci, and some gram negative bacteria. DORLAND'S at 1405. Group B streptococcus bacteria are gram positive. *Id.* at 1782-83. Danny, however, did receive gentamicin. Pet. Ex. 4, pp. 10, 13.

[26] During oral argument, Mrs. Fresco's description differed from the medical records. She indicated that her membranes had not ruptured; she was simply in labor and bleeding when her physician sent her to the hospital to give birth. Tr. at 8. It is unnecessary to resolve this dispute.

Danny's arrival at the NICU, found Danny awake, alert, and not in distress. *Id.*, p. 13. Danny's head, eyes, ears, nose, and throat (abbreviated on the form as "HEENT"[27]) were "normocephalic." His anterior fontanel (abbreviated on the form as "AF"[28]) was open. No bulging or swelling of the fontanel was described. Danny had positive Moro reflex, good tone, and appropriate sucking reflex. *Id.*, p. 13. He had been circumcised and had passed his newborn hearing screen on the same day he was admitted to the NICU. *Id.*, pp. 11-12, 14. The neonatologist indicated that Danny was admitted to "rule out"[29] sepsis, and he planned to repeat the CBC and blood cultures while continuing antibiotic treatment. *Id.*, p. 12. Danny received two different antibiotics, ampicillin, a type of penicillin (*see* DORLAND'S at 66), and gentamicin. *Id.*, p. 13.

Progress notes from Danny's second day in the NICU indicated that he was asymptomatic.[30] He was feeding well and he was otherwise stable. Pet. Ex. 4, p. 15.

A progress note from his third day in the NICU indicated that the first blood culture grew a "staph species," but that the second blood culture showed no growth of bacteria.[31] Pet. Ex. 4, p. 16. The progress note further reflected that Danny was alert, in no apparent distress, and was feeding and voiding normally. *Id.* The plan was to complete 48 hours of antibiotics and then to discharge him after a check of the blood cultures. *Id.*

On January 31, 2002, Danny was still feeding and voiding well and his vital signs were stable. He was discharged at 2:00 PM that day, with a follow up appointment

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[27] Neil M. Davis, MEDICAL ABBREVIATIONS (15th Ed. 2011) ["MED. ABBREV."], at 155.

[28] MED. ABBREV. at 39.

[29] "Rule out" is a commonly used medical term. *See Hernandez v. Astrue, Commissioner of Social Security*, 814 F. Supp. 2d 168, 175 (E.D. NY 2011) citing MedicineNet, "Definition of Rule Out," available at http://www.medterms.com/script/main/art.asp?articlekey=33831 ("Term used in medicine, meaning to eliminate or exclude something from consideration.") As used in this context, I conclude that Danny, although apparently healthy, was being admitted to the NICU for empirical treatment of possible sepsis, pending more complete analysis of his blood cultures to determine what, if any, pathogen was present in his blood. In empirical treatment, antibiotics or other drugs are administered to treat a possible or probable disease, without a definitive diagnosis, because they have proven effective against the possible or probable diagnosis in other cases of the suspected disease. *See* DORLAND'S at 1957.

[30] The date of the note reads "10-29-02." I conclude that this date was recorded in error, and should read 1-29-02, based on the content of the note and Danny's (identified as "Fresco Boy") medical bar code and header at the top of the page. A Case Management checklist at the bottom of this page (Pet Ex. 4, p. 15) contains the correct date ("1/29/02"). The checklist indicates that there were "[n]o continuum of care needs identified at present." *Id.*

[31] Mrs. Fresco tested positive for a form of streptococcus, not staphylococcus, bacteria. As respondent's expert, Dr. Max Wiznitzer, indicated in his report, the growth of "staph" bacteria in Danny's culture most likely represented a contaminant of the culture. Res. Ex. A at 7. The second culture showed no bacterial growth, further indicating that the first test result was an anomaly. *Id.*

scheduled for February 8, 2002. Pet. Ex. 4, pp. 16-17. On discharge, Mr. Fresco signed a document which indicated he would like to participate in the New Jersey Immunization Information System ["NJIIS"] program. The two page form explained that the program's purpose was to keep a centralized record of all of Danny's immunizations and to remind his parents when immunizations were due.[32] Pet. Ex. 4, pp. 19-20.

Danny visited his pediatrician on February 8, 2002. Pet. Ex. 12, p. 1. The pediatrician examined Danny, noted that he was a well baby, and administered a hepatitis B vaccine.[33] At Danny's next health care provider visit on February 22, 2002, the nurse who examined him indicated that he appeared to be in good health, and made an appointment for Danny's two month immunizations.[34]

2. Matters in Dispute during this Period.

a. Was a Hepatitis B Vaccination Administered at the Hospital?

(1) Petitioners' Position.

Petitioners contend that Danny received a hepatitis B vaccination as an ill newborn and that this vaccination began the cascade of events that resulted in Danny's autism diagnosis. In support of their position that Danny actually received this vaccination, petitioners point to the standard newborn orders (Pet. Ex. 4, p. 5), the consent to participate in the NJIIS form signed by Mr. Fresco (*Id.*, pp. 19-20), and Mrs. Fresco's arguments that, when she tried to obtain Danny's records for filing, a hospital employee was unable to tell her for certain whether Danny actually received the vaccination. Tr. at 10-11, 20, 50-51.

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[32] Comments made by Mrs. Fresco during the oral arguments in this case suggest that she considered this form as a consent form for administration of the hepatitis B vaccine in the hospital. *See* Tr. at 11. It is not a consent form.

[33] According to Pet. Ex. 16, pp. 5-6, the hepatitis B vaccine Danny received contained thimerosal. However, the list of ingredients contains an asterisk after "thimerosal," which is explained at *id.*, p. 9: "Where 'thimerosal' is marked with an asterisk (*) it indicates that the product should be considered equivalent to thimerosal-free products. This vaccine may contain trace amounts (<0.3 mcg [micrograms]) of mercury left after post-production thimerosal removal, but these amounts have no biological effect." In contrast, children used to receive, on average, 187.5 mcg of mercury from the thimerosal in the vaccines administered to them in their first six months of life, and the children in the test cases received 12.5 mcg of mercury in each of their hepatitis B vaccinations. *Dwyer,* 2010 WL 892250 at *82.

[34] Although the month of this visit is cut off on the exhibit, the initial entry refers to Danny as a "3 wk old baby." Pet. Ex. 5, p. 149. The form itself does not reflect whether this was another visit to Danny's pediatrician's office or to the health clinic where Danny received his immunizations. Based on later entries following one by this same nurse (an "RN" appears after the signature) referring Mrs. Fresco to her private physician (*see* second entry on Pet. Ex. 5, p. 150) and the fact that the notes from Danny's private physician jump from February 8, 2002 to May 4, 2002 (*see* Pet. Ex. 12, p. 1), it is likely that these records were created by the health clinic.

(2) Respondent's Position.

Respondent contends that the weight of the evidence is that Danny did not receive a hepatitis B vaccination in the hospital. Tr. at 67.

(3) Analysis and Conclusions.

As noted by petitioners (Tr. at 10), a "Doctor's Order Sheet" containing pre-printed routine newborn nursery orders and dated January 27, 2002, indicated that Danny was to receive his initial hepatitis B vaccination prior to discharge. *See* Pet. Ex. 4, p. 5. However, a similar sheet dated January 28, 2002, includes a handwritten order reading "NO Hepatitis B Vaccine." *Id.*, p. 6 (emphasis original). The January 28, 2002 sheet contains the signature of a registered nurse and another signature without a title. There is no record showing the administration of a hepatitis B vaccination during Danny's newborn hospitalization.[35] Danny's vaccination records, Pet. Ex. 2, do not reflect receipt of a hepatitis B vaccination during his neonatal hospitalization.

Apparently Danny's pediatrician did not think he received a hepatitis B vaccination as a newborn, because, on February 8, 2002, Danny received a hepatitis B vaccine at his pediatrician's office.[36] *See* Pet. Exs. 2, p. 1; 12, p. 1. The recommended dosing schedule for hepatitis B vaccinations in infants includes an initial vaccination at birth, followed by a second vaccination one month later, and a third vaccination six months after the initial vaccination. Pet. Ex. 14 at 4 (Table 1). Thus, if Danny had actually received the newborn hepatitis B vaccination as petitioners allege, it is unlikely that his pediatrician would have administered another one just 12 days after his birth.[37]

Moreover, petitioners' own expert expressed doubts that Danny received a hepatitis B vaccination when hospitalized as a newborn. In his report, Dr. Buttram referred to Mrs. Fresco's contention that Danny received such a vaccination, and noted that "a careful review (including nurse's notes) failed to reveal that it was administered." Pet. Ex. 8 at 1.[38]

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[35] By law, health care providers are required to record the manufacturer, lot number, and the name of the person administering the vaccine for each vaccination given. § 25(a). No hospital record filed contains that information.

[36] Danny's subsequent vaccinations were all administered at the town health clinic, as petitioners' insurance did not cover vaccinations. Tr. at 21; Pet. Ex. 2.

[37] One of petitioners' causation theories involves the administration of a "double dose" of hepatitis B vaccine, based on this vaccination, plus one received as a newborn at the hospital. Doctor Buttram's expert report, filed as Pet. Ex. 8, at 1. This theory is discussed below in Section III.

[38] Within this decision, citations to petitioners' exhibit 8 refer to the printed numbers on the pages within Dr. Buttram's report. Unlike petitioners' other exhibits, the cover page Mrs. Fresco included with the filing was not assigned a page number in my December 28, 2011 order.

The weight of the evidence is that Danny did not receive a hepatitis B vaccine while hospitalized after his birth, and I so conclude.

b. Was Danny Ill at the Time of Discharge?

(1) Petitioners' Position.

In support of her claim that Danny was ill at the time of his hospital discharge, Mrs. Fresco points to his transfer to the NICU, his receipt of antibiotics, and various entries on the discharge face sheet (filed as Pet. Ex. 7, p. 4). *See* Tr. at 13, 15.

Mrs. Fresco claims that Danny was not fully recovered at the time of his discharge from the hospital because the discharge face sheet indicates that his condition was "improved," not "recovered." See Pet. Ex. 7, pp. 1, 4; Tr. at 15. She also relies on codes appearing on the discharge face sheet (Pet. Ex. 7, p. 4) to establish that Danny suffered from "viral encephalitis transmitted by other and unspecified arthropods" (Pet. Ex. 7, p. 1), as well as infections specific to the perinatal period and septicemia[39] (*see* handwritten notations on Pet Ex. 7, p. 4 and attached code sheets[40] at *id.*, pp. 5-8).

(2) Respondent's Position.

Respondent argues that the claim Danny suffered from encephalitis during his hospital stay is without support. Tr. at 70-71. An infant suffering from encephalitis would display symptoms of an impaired consciousness, such as impaired feeding and abnormal tone and reflexes. Res. Ex. A at 7. During the four days Danny was hospitalized, he was alert with normal vital signs and was feeding by his mouth. Res. Ex. A at 7.

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[39] Septicemia is a systemic disease associated with pathogens (or their toxins) in the blood. DORLAND'S at 1693. It is sometimes called sepsis or blood poisoning. *Id.* I note that the medical records reflect that Danny was being tested to rule out sepsis. *See* Pet. Ex. 4, p. 12 (admission to NICU to rule out sepsis).

[40] The code sheets in petitioners' exhibit 7 contain pages from volumes 1 and 2 of the ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification). The ICD-9-CM codes are used by medical providers and insurers to code medical diagnoses (diseases and injuries) and clinical procedures, with volumes 1 and 2 containing the diagnostic codes and volume 3 containing the procedure codes. The ICD-9-CM codes are overseen by the National Center for Health Statistics and the Centers for Medicare and Medicaid Services. *See* http://www.cdc.gov/nchs/icd/icd9cm.htm (last visited Jan. 4, 2013). The ICD-9-CM codes are based on the ICD-9 codes, which are used internationally to standardize the coding of a person's cause of death, as reported on a death certificate, and the generation of mortality statistics. *See* http://www.cdc.gov/nchs/icd/icd9.htm (last visited Jan. 4, 2013). The nature of the ICD-9-CM codes and their relevance to petitioner's contentions are discussed in more detail below.

(3) Analysis and Conclusions.

(a) The Discharge Face Sheet.

Mrs. Fresco's claims that Danny was not well when he was discharged are primarily based on the codes that appear on a form called a "Discharge Face Sheet."[41] The discharge face sheet consists of a header (which includes the notation "FRESCO BOY"), followed by a section including the date of discharge and a list of possible outcomes or reasons for discharge. Additional sections of the form are devoted to "principal diagnosis," "other diagnosis," and "principal procedure," all of which contain either handwritten notations accompanied by codes or simply codes. It appears that Mrs. Fresco has also made handwritten notations in these sections reflecting her interpretations of the codes on the copy designated as Pet. Ex. 7, p. 4. I review this form, section by section.

Mrs. Fresco is correct in her assertion that on this discharge form Danny was listed as "Improved" and that "Recovered" was not checked. The significance of or distinction between these two blocks is not further elucidated on the form or elsewhere in the records. This is the only entry anywhere in Danny's hospital records that provides any support for her contention that he was not completely well when discharged. Other evidence, however, establishes that Danny was in good health when he left the hospital.

The principal diagnosis section contains the hand written notation "FT Male NB," which, based on my experience in reviewing medical records and a review of a medical abbreviations handbook, most likely translates to "Full Term Male Newborn." MED. ABBREV. at 140, 222. The code that accompanies the principal diagnosis can be read as either "V30.00" or "130.00." *See* Pet. Exs. 7, p. 4; 9, p. 1. There are also faint handwritten notations on the copy filed as Pet. Ex. 7, p. 4 that appear to read "single live birth". These do not appear on the copy filed as Pet. Ex. 9, p. 1.

Although petitioners filed an ICD-9-CM code sheet as Pet. Ex. 7, p. 6, that implies (based on a check mark next to the entry) that code 130.0 is used to reflect "Meningoencephalitis due to toxoplasmosis,"[42] I find that this page is not relevant to an interpretation of Pet. Ex. 7, p. 4. There is nothing in the medical records filed that

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[41] This form appears in several exhibits. Petitioners' Ex. 7, p. 4 is a poor copy of the Discharge Face Sheet that appeared in petitioners' July 8, 2011 filing. In that filing, the pages were unnumbered and no exhibit number was assigned. Another copy of the Discharge Face Sheet, without the handwritten notations (presumably made by Mrs. Fresco), appears as Pet. Ex. 9, p. 1, filed on January 26, 2012.

[42] Toxoplasmic meningoencephalitis is a form of meningoencephalitis (an inflammation of the brain and the meninges that surround it) that sometimes occurs in toxoplasmosis (an infection with protozoa found in cat feces). DORLAND'S at 1133 (meningoencephalitis); 1944 (toxoplasmosis). Toxoplasmic meningoencephalitis is characterized by seizures and mental confusion which may result in coma and death. *See id*. at 1134. Danny had no symptoms associated with any form of encephalitis. *See* Res. Ex. A at 7.

suggests Danny had toxoplasmic meningoencephalitis during his newborn stay at the hospital. Although a fetus may be infected with this disease based on in utero exposure of the mother (*see* DORLAND'S at 1134), it is extremely unlikely, in view of the notations accompanying the coding on Pet. Ex. 7, p. 4, the benign clinical course Danny experienced perinatally, and the lack of any other reference in his medical records to such an infection or treatment for such an infection, that this code means what petitioners interpret it to mean.

Notwithstanding petitioners' interpretations, there is a more logical explanation for the code. V30 is the prefix for the ICD-9-CM diagnostic codes that cover single live births.[43] Specifically, V30.00 is the code for a "single liveborn, born in hospital, delivered without mention of cesarean section."[44] This code would be consistent with the section heading, as Danny's birth would be the "principal diagnosis" for Danny's hospitalization. I thus conclude that the code should be read as "V30.00," a reference to a single live birth.

The "other diagnosis" section of Pet. Ex. 7, p. 4 contains two codes, 771.8 and 038.9, along with a notation I am unable to decipher, followed by "R/O." Faint handwritten notations appear on the copy of this document found in petitioners' July 8, 2011 filing, and appear to read "infection specific to the perinatal period" (next to code 771.8) and "septicemia" (next to code 038.9). These handwritten notations do not appear on the copy of the discharge face sheet filed as Pet. Ex. 9, p. 1, and I thus conclude that they were likely made by Mrs. Fresco.[45] The ICD-9-CM code "771.8" is, according to Pet. Ex. 7, p. 7, "Other infection specific to the perinatal period." ICD-9-CM code "038.9" is, according to *id.*, p. 8, "Unspecified septicemia."

Although petitioners rely on these codes to establish that Danny was ill during his stay in the newborn nursery and NICU, the notation "R/O" accompanying these codes indicates that Danny was not actually ill. He was treated to "rule out" a possible infection or septicemia. This interpretation is supported by other notations in the medical records regarding Danny's test results and by his benign clinical course.

Finally, in the section of Pet. Ex. 7, p. 4 regarding principal procedure, there is a machine-printed parenthetical reference reading "the procedure most related to the

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[43] Other ICD-9-CM prefixes denote other types of childbirth. For example, V31 is used for twins.

[44] The numbers after the decimal point in the ICD-9-CM code reflect whether the child was born in a hospital (.0), born before admission to hospital (.1), born outside the hospital and not hospitalized (.2), and whether the child was born without mention of cesarean section (._0) or born by cesarean section (._1). *See* ICD-9-CM*; see also* MJ Bowie and RM Schaffer, *Understanding ICD-9-CM Coding: A Worktext* (3rd ed., 2012) at 348.

[45] I do not mean to imply that Mrs. Fresco altered these records with any nefarious purpose. Rather, it appears that she was making notes to assist herself in understanding the codes on Danny's records, and either inadvertently or unknowingly filed with the court the medical records containing her personal notes.

principal diagnosis, performed for definite treatment." The code "64.0" follows. Although they are entirely illegible on Pet. Ex. 7, p. 4, in the copy of this discharge face sheet filed on July 8, 2011, there are faint handwritten notations reading "viral encephalitis," although the rest of the of the entry remains undecipherable. These notations do not appear on the copy of the same document filed as Pet. Ex. 9, p. 1.

Based on the ICD-9-CM coding sheet found at Pet. Ex. 7, p. 5, petitioners contend that this reference means that Danny had "viral encephalitis transmitted by other and unspecified arthropods."[46] In this instance, petitioners mistakenly used the ICD-9-CM code for medical diagnoses (found in volumes 1 and 2 of the ICD-9-CM) instead of the ICD-9-CM code for medical procedures (found in volume 3). The ICD-9-CM code for a circumcision, a procedure performed the same day Danny was transferred to the NICU, is 64.0. I note that there is no evidence in the medical records suggesting that Danny (or Mrs. Fresco) had been exposed to a virus, much less one transmitted by an insect, spider, or tick bite. The concern about possible transmission of group B streptococcus from Mrs. Fresco to Danny that prompted his transfer to the NICU involved a bacterial, not a viral, infection. I thus conclude that this reference on the discharge face sheet was to Danny's circumcision, not to viral encephalitis.

(b) Regarding the Treatment Records.

Putting the ICD codes aside, nothing in the hospital records supports a finding that Danny was actually ill at the time of his transfer to the NICU. His physical examination in the NICU was normal in every respect. He had no fever, lethargy, or other signs of illness. There is no notation reflecting a diagnosis of sepsis, encephalitis, encephalopathy,[47] or any other illness. Although his initial blood tests showed the presence of bacteria, when a second blood culture grew no pathogens, the physicians concluded that the initial positive culture represented a contaminant.

Danny's treating physicians came to similar conclusions regarding Danny's NICU stay. In January 2004, Dr. Barbie Zimmerman-Bier, the Director of Child Development at the New Jersey Medical School, performed a neurodevelopmental evaluation of

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[46] Arthropods include spiders and insects. DORLAND'S at 158.

[47] Mrs. Fresco argued that Danny had an encephalopathy at this point, and points to a prescription written in 2010 (Pet. Ex. 10, p. 1) in which Danny is diagnosed with encephalopathy as well as autism, as evidence that he was ill at birth and that the encephalopathic condition persisted. Tr. at 16; *see also* Pet. Ex. 7, p. 1. Her expert, Dr. Buttram, does not opine that Danny had an encephalopathy at any point. Respondent's expert, Dr. Wiznitzer, opines that "there is no history of an acute encephalopathy within days of any of the immunizations that Daniel Fresco received." Res. Ex. A at 4. In the absence of any medical record reflecting that Danny had an encephalopathy at or near birth, I cannot credit Mrs. Fresco's argument in this regard. Doctor Wiznitzer, a pediatric neurologist, opined that Danny's condition after birth was "not consistent with a neonatal encephalopathy (sustained impairment in consciousness with abnormal tone and reflexes, impaired feeding and seizures)." Res. Ex. A at 7. His report is not rebutted by anything in Dr. Buttram's report.

Danny. She reviewed the records from Danny's hospitalization after birth and noted that:

> [Danny] was essentially asymptomatic and he had no fever [or] distress and[] was feeding well. After 48 hours [of] treatment was completed, the cultures were identified as a staphylococcal species. Based on that and repeat cultures taken in the NICU which [were] negative at the time, antibiotics were discontinued. Bacteremia was ruled out and the patient was discharged on January 31, 2002.

Pet Ex. 5, p. 36.

Doctor Ling Yu Shih, the geneticist who evaluated Danny in 2006, also recited Danny's birth history and indicated that there were no complications. Pet. Ex. 5, p. 57. Doctor Buttram, who relied upon Mrs. Fresco's report that both she and Danny tested positive for Group B strep,[48] noted that while in the NICU, Danny was "asymptomatic, afebrile and feeding well." Pet. Ex. 8 at 1.

Finally, Danny was seen by his pediatrician 12 days after his birth (eight days after his discharge from the hospital). After examining Danny and noting his food intake and elimination patterns, the pediatrician called him a "Well Baby." Pet. Ex.12, p. 1. Similarly, the nurse who examined him when he was three weeks old indicated that he appeared to be in good health. Pet. Ex. 5, p. 149.

Furthermore, Dr. Wiznitzer notes that Danny did not have any evidence of infection shortly after birth. Res. Ex. A at 7. He points out that Danny had an elective medical procedure, circumcision, and intimates that such a procedure would not have been performed if Danny had been acutely ill at the time. *Id.* He also opined that Danny's clinical presentation and history were not consistent with viral encephalitis. *Id.*

I find that Danny was not ill when he was placed in the NICU and was not ill at the time of his discharge. He was well at the time he received his initial hepatitis B vaccination, which occurred on February 8, 2002.

B. Danny's Care and Treatment between April 3, 2002 and July 16, 2003.

1. Information from the Medical Records.

There were no records filed for any medical visits between Danny's February 22, 2002 visit and his two month well child visit on April 3, 2002. At this April visit, Danny's hearing and vision were within normal limits. He had a slight runny nose, but was

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[48] Although the medical records establish that Mrs. Fresco was positive for Group B strep, there are no records supporting such a finding with regard to Danny.

assessed as a well child. An entry indicated that Danny had no reactions to his earlier vaccination, which was the hepatitis B vaccination received on February 8, 2002. Danny received his initial DTaP,[49] polio ["IPV"], haemophilus influenzae B ["Hib"], and pneumonococcal conjugate ["Prevnar"] vaccinations, and his second hepatitis B vaccination at this visit. Pet. Exs. 2, p. 1; 5, pp. 142, 149.

His next visit was his four month well child visit on June 5, 2002. Danny was reported to have been cranky and running a slight fever after his last set of vaccinations two months earlier. On examination, Danny was alert, smiling, and following objects. He was taking cereal and soy formula. Mrs. Fresco reported he was constipated and "not eating great." Pet. Ex. 5, pp. 143, 149. A second set of vaccinations was administered, which included Danny's second DTaP, IPV, Hib, and Prevnar vaccinations. *Id.*, p. 143; Pet. Ex. 2, p. 1.

Twelve days later, Danny was seen by his primary physician for foreskin adhesions and a rash on his face. He was reported to be feeding well on formula, cereal, and fruits. Pet. Ex. 5, p. 4.

At Danny's six month well child visit on August 7, 2002, Mrs. Fresco reported that he had no reactions to his last set of immunizations. Danny was smiling and alert, and his development was assessed as grossly within normal limits. Mrs. Fresco reported that his head always seemed warm and requested that his temperature be taken. It was recorded as 98.6° Fahrenheit. Pet. Ex. 5, pp. 144, 149. Danny received his third DTaP, IPV, Hib, and Prevnar vaccines at this visit. Pet. Exs. 2, p. 1; 5, p. 149.

Danny's next visit was on September 23, 2002, nearly six weeks after the six month immunizations. Danny was reported to be vomiting with his meals and had experienced diarrhea for three days the previous week. He did not have fever or appear to be in pain and was diagnosed with a viral infection. Pet. Ex, 5, p. 4. Danny missed his next scheduled appointment on October 9, 2002. *Id.*, pp. 145, 149.

At a well child visit on December 4, 2002, Danny had sniffles and was teething. His hearing and vision appeared to be normal. Danny was reported to babble, to say a few words, and to pull himself to standing. He was eating a varied diet, including meat, cereal, vegetables, and fruit, along with soy-based formula. He was sleeping well. Danny was observed to be active and verbal, and a "high forehead" was noted. He received his third hepatitis B vaccination at this visit. Pet. Exs. 2, p. 1; 5, pp 146, 149-50.

The next chronological entry in the medical records is comprised of notes from a conversation between Mrs. Fresco and a public health nurse at the clinic where Danny

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[49] Danny received "Infanrix," the trade name for GlaxoSmithKline's formulation of DTaP, at this visit and at the two subsequent visits. *See* Pet. Ex. 2, p. 1; DORLAND'S at 933. The formulation of his fourth DTaP vaccination is discussed in 2.b. below.

received his vaccinations. The note is dated, but the month is cut off on the filed copy. The day and year read "25/03." From context, the note was written prior to March 26, 2003, as it indicates Mrs. Fresco wanted to delay the vaccinations scheduled for March 26, 2003 to August 2003, when her husband would be on vacation. The conversation included a disagreement between Mrs. Fresco and the public health nurse about following the American Academy of Pediatrics' recommended vaccination schedule, with Mrs. Fresco indicating that she had "read differently" regarding scheduling vaccinations. The nurse referred Mrs. Fresco to her private physician for his recommendations on vaccination scheduling. It concluded with the notation that Mrs. Fresco wanted to withhold additional vaccinations. Pet. Ex. 5, p. 150.

Another telephone call is also documented, and once again, the month of the call is not legible, although the day and year are reflected as "26/03." The note indicates that Mrs. Fresco called to schedule an appointment for vaccination. *Id.* During oral argument, Mrs. Fresco indicated that she was concerned about vaccinations at this point because of Danny's "spitting up" and differences in his development from that of his older brother. Tr. at 55-56. From context, I conclude that this call most likely took place on either March 26 or April 26, 2003.

At Danny's 15 month well child visit on April 23, 2003, he was walking, saying a few words, eating well, and beginning to drink from a cup. He had not yet cut any teeth. A note indicated that Mrs. Fresco had spoken with the doctor regarding vaccines, and would return for them. Pet. Ex. 5, pp. 147, 150.

The first reference in the medical records that Danny might be developmentally delayed appears in the records from a July 14, 2003 visit.[50] Danny was reported to be teething, with no teeth yet, and very cranky. He was still saying only a few words. His pediatrician diagnosed speech delay and delayed tooth eruption, and referred Danny for early intervention evaluation. Pet. Ex. 5, p. 5. Blood tests were ordered. Most of the results were within the reference ranges, but his polymorpholeukocyte count was low.[51] *Id.*, pp. 153-55.

Danny received his last two vaccinations two days later, on July 16, 2003. He was noted to have occasional fever after receiving his vaccinations. He was described at this visit as crying a lot and unmanageable, with inadequate language development. The health care provider observed that he was irritable, running back and forth "inappropriately," and failing to follow commands, but there is no indication in the

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[50] I accept Mrs. Fresco's assertions that her concerns about Danny's development prompted her to question the vaccine schedule at least three months before this visit. This record, however, is the first one in which concerns by one of Danny's health care providers were recorded.

[51] Petitioners' expert, Dr. Buttram, considers the "low polymorpholeukocyte count" on this test to be significant for his opinion on causation. *See* II.B.2.a. *infra*. No physician, including Dr. Buttram, attached any significance to any of the other out-of-range test results on this blood test.

records that Danny was ill, and the assessment was "well child." Pet. Ex. 5, pp. 148, 150.

The record from this visit contained a notation that Danny's immunizations had been delayed pending the results of the lead and liver profile testing done by his pediatrician two days earlier. He received his fourth DTaP and Hib vaccinations[52] at this visit, suggesting that the lab results did not indicate any problems. Pet. Exs. 2, p. 1, 5, pp. 148, 150. Although there was a notation that the initial MMR and varicella vaccines were being postponed until August at his mother's request, there is no record that Danny ever received these vaccinations. Pet. Ex. 5, p. 150.

2. Matters in Dispute during this Period.

Petitioners assert that Danny received vaccinations when he was ill or on antibiotics, and that his vaccinations were improperly "mixed." Petitioners also contend that the final DTaP vaccination on July 16, 2003 was from a "hot lot"[53] and that he experienced fever and other ill effects after it. Additionally, during oral argument Mrs. Fresco contended that Danny's head circumference inappropriately increased over time, constituting evidence of brain inflammation. *See* Tr. at 28.

a. Were Vaccines Administered when Danny was Ill or on Antibiotics?

I have already indicated that Danny showed no signs of illness at the time he received his initial hepatitis B vaccination. A review of the medical records establishes the following facts regarding Danny's health at the time of administration of his other vaccinations:

(1) Danny's two month vaccinations were administered at a time when he had a slight runny nose, but was otherwise assessed as a well child.

(2) Danny's four month vaccinations were administered when he was assessed as smiling and alert, but having some problems with feeding and constipation. There is no indication that Danny was ill.

(3) Danny's six month vaccinations were administered when Danny was well. His temperature was not elevated, and there was no indication in the records of any illness.

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[52] Petitioners identified these two vaccines as causal in a filing made on November 3, 2010. However, during oral argument, Mrs. Fresco was clear that she considered all of Danny's vaccinations as causal. Tr. at 52-53.

[53] "Hot lot" is a term used to refer to a vaccine lot with an unusual number of reported side effects, suggesting a possible problem in the vaccine manufacturing process for that particular lot. *See Grimes v. Sec'y, HHS*, No. 02-1491V, 2007 WL 5160377 (Fed. Cl. Spec. Mstr. Jan. 31, 2007) at *4, n.11.

(4) Danny's third hepatitis B vaccination was administered when he was a little over 10 months of age.[54] He was teething and had "sniffles" at the time. Nevertheless, Danny was assessed as a well child.

(5) His final vaccinations (DTaP and Hib) were received when Danny was assessed as a well child. Although he was crying and described as "unmanageable," there is no indication that these conditions were attributable to illness rather than simply to behavioral problems.

(6) On August 6, 2003, about three weeks after his last vaccinations, Danny was seen for a middle ear infection. Pet. Ex. 5, p. 5. He was diagnosed with a mild cold and mild serous otitis media. There is no indication in the filed records that Danny had a fever or that the cold and ear infection were somehow related to his July 16, 2003 vaccinations.

(7) There is no evidence that Danny was on antibiotics at the time he received any of his vaccinations.

I thus conclude that Danny did not receive any vaccinations while he was acutely ill or on antibiotics. At most, Danny had a runny nose or "sniffles" when he received his final vaccinations.

b. "Mixing" Vaccines or Vaccinations.

Mrs. Fresco argued that "mixing" vaccines was improper and could cause a "problem." *See* Tr. at 14, 17. Her argument appears to be based on the portions of Pet. Ex. 14 that contain package inserts for hepatitis B and the DTaP vaccines. With regard to hepatitis B, the package insert states: "When concomitant administration of other vaccines or immune globulin is required, they should be given with different syringes and at different injections sites. Do not mix [brand name of hepatitis B vaccine Danny received] with any other vaccine or product in the same syringe or vial." Pet. Ex. 14 at 9. It appears that some portions of the last line of these instructions are underlined by hand.

With regard to the DTaP vaccine, Mrs. Fresco has underlined and starred the following passage: "Sufficient data are not available on the safety and effectiveness of interchanging INFANRIX [the brand name of the DTaP vaccine Danny received at his two, four, and six month vaccination appointments] and [DTaP] vaccines from different manufacturers for successive doses of the DTaP vaccination series." *Id.* at 16. This package insert also contains information on studies conducted involving concurrently administered vaccines.

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[54] Danny was recorded as a "no show" for the vaccination appointment scheduled for October 9, 2002.

Based on these package inserts and her comments during the oral argument (*see* Tr. at 14, 17), it appears that Mrs. Fresco has confused concurrent administration of vaccines with mixing different vaccines in the same syringe. An examination of Danny's medical records shows concurrent administration of Danny's second hepatitis B vaccine with his initial DTaP, IPV, Hib, and Prevnar vaccines.[55] This is in accordance with the recommended childhood vaccination schedule.[56] However, there is no indication anywhere in Danny's records that the vaccines were mixed in the same vial or syringe or injected into the same spot.[57]

Alternatively, Mrs. Fresco may be concerned about mixing DTaP vaccines from different manufacturers. See Pet. Ex. 14 at 16 (starred and underlined portion). Danny's first three DTaP vaccinations all list the same brand name, Infanrix, on his shot record. *See* Pet. Ex. 2, p. 1. According to Pet. Ex. 14, Infanrix is manufactured by GlaxoSmithKline. The shot record at Pet. Ex. 2, p. 1 lists a different manufacturer (Merck) for Danny's fourth DTaP vaccine. However, other copies of the shot record for this vaccination have "Merck" crossed out and various versions of "GlaxoSmithKline" handwritten in its place. Pet. Exs. 5, p. 133; 6, p. 8. Based on information from the CDC and the Physicians' Desk Reference ["PDR"], it does not appear that Merck manufactured a DTaP vaccine during the relevant period.[58] Additionally, the lot number for Danny's fourth DTaP vaccine is very similar in configuration to the lot numbers for the other DTaP vaccines he received.[59] Pet. Ex. 2, p. 1. I thus conclude that Danny received all four DTaP vaccinations based on vaccines from the same manufacturer.

In any event, there is absolutely no evidence anywhere in the record that causally links concurrent administration, mixed administration, or using vaccines from

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[55] When Danny received his first and third hepatitis B vaccines, on February 8 and December 4, 2002, respectively, they were the only vaccinations administered on those days. *See* Pet. Ex. 2, p. 1.

[56] *See* Centers for Disease Control and Prevention ["CDC"] Recommended Immunization Schedule, available at http://www.cdc.gov/vaccines/schedules/downloads/child/0-6yrs-schedule-pr.pdf (last visited Jan. 4, 2013).

[57] Doctor Buttram asserts that a child should never receive more than two vaccinations at a time. Buttram Article, filed as Pet. Ex. 7, at 17. However, he does not attribute any specific ill effect to the concurrent receipt of more than two vaccines at once, and does not assert that concurrent receipt of multiple vaccines causes autism spectrum disorders.

[58] *See* 2002 and 2003 CDC's Vaccines for Children Program Price Lists, available at http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/archive.html (last visited Jan. 4, 2013)(noting the only DTaP manufacturers were GlaxoSmithKline and Aventis Pasteur); PDR at 201 (58th ed. 2004) (table of contents listing 10 vaccines manufactured by Merck; none of which were DTaP).

[59] Different manufacturers use very different conventions for lot numbers. For example, compare the lot numbers for the Hib vaccines manufactured by Merck (1548K, 1416L, 1136L) with those for the pneumococcal vaccines manufactured by Wyeth (484-857, 485-995, 485-047), as reflected on Pet. Ex. 2.

different manufacturers to autism spectrum disorders. In other words, even if Mrs. Fresco's arguments about Danny receiving mixed vaccines are factually correct, those facts are without medical or legal consequence.

c. Did Danny Receive a "Hot Lot" DTaP Vaccine?

There is no reliable evidence in this record that Danny's fourth DTaP vaccine was from a so-called "hot lot."[60] The only support for Mrs. Fresco's assertions is a printout from a website maintained by the National Vaccine Information Center,[61] filed as Pet. Ex. 11. This printout lists the lot number 575A2 for Danny's fourth vaccine under the heading "Hot Lot" for GlaxoSmithKline vaccines.

I do not consider this printout to be reliable evidence of problems with this lot number of the GlaxoSmithKline DTaP vaccine. The printout indicates that there were 12 complaints of an unspecified nature among recipients of vaccine lot number 575A2. Pet. Exs. 11, p. 1; 2, p. 1. It does not indicate how many total recipients of this lot there were. Thus, it is impossible to determine what percentage of the recipients experienced ill effects or what those ill effects were. Furthermore, there is no evidence whether these were passive reports, such as those made to the Vaccine Adverse Event Reporting System, or were collected in some more controlled fashion.[62]

The nature of the website where the "hot lot" list was posted is also a matter affecting its reliability. Although its mission statement states that it "does not advocate for or against the use of vaccines," the content on the website suggests that the National Vaccine Information Center is an anti-vaccine organization. Moreover, even if I considered this printout as reliable evidence of problems with this lot number of the DTaP vaccine, there is still no evidence that causally links Danny's fourth DTaP vaccine to autism spectrum disorders.

I also note that Danny was displaying behavioral and developmental symptoms that concerned his mother before the end of March, 2003, and that were documented by his physician in July, 2003, two days before this vaccine was administered. Danny had

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[60] During oral argument, Mrs. Fresco also asserted that this vaccine lot had been recalled. When pressed to cite to something in the evidentiary record that demonstrated this recall, she switched her argument to it being a "hot lot."

[61] The complete website address is not included at the bottom of the printout, but it appears to be the results from a search conducted on medalerts.org, which is a website maintained by the National Vaccine Information Center.

[62] VAERS reports are inadequate evidentiary sources to establish vaccine causation of any injury. *See e.g. Manville v. Sec'y, HHS*, 63 Fed. Cl. 482, 494 (2004); *Capizzano v. Sec'y, HHS*, 63 Fed. Cl. 227, 231 (2004)(placing limited value on VAERS reports due to the manner in which they are completed); *Ryman v. Sec'y, HHS,* 65 Fed. Cl. 35, 40 (2005)(commenting that VAERS reports tend to be biased toward prevailing concepts of adverse events); *Analla v. Sec'y, HHS*, 70 Fed. Cl. 552, 558 (2006) (noting VAERS reports offer very little with regards to causality).

evidence of delays in expressive speech (speech delay), receptive speech (responding to verbal commands), and uncontrollable behavior, all of which are symptoms of an emergence of autism spectrum disorder. See Res. Ex. A. at 5.

d. Illness Following the Fourth DTaP Vaccination.

Although Mrs. Fresco asserted that Danny had fever and possible seizures after this vaccination (Pet. Exs. 6, p.1; 7, p.1; Tr. at 22-23), the only medical record reflecting a concern about fever and seizures referred to a visit when Danny was 25 months of age. *See* Pet. Ex. 5, p. 8. Although the exact date of this visit does not appear in the medical records, based on Danny's birth date it likely took place in February or March, 2004, at least six months after the fourth DTaP vaccine was administered. Danny did not have any documented illness shortly after his fourth DTaP vaccination on July 16, 2003, other than a middle ear infection three weeks later. Pet. Ex. 5, p. 5. He had recovered from this ear infection by August 26, 2003.

I have no doubts as to Mrs. Fresco's sincerity in temporally linking Danny's last DTaP vaccination with a febrile illness, turning blue, and possible seizures, but I am convinced by the medical records and, in particular, the reference to Danny's age at the time of the visit where these symptoms were recorded, that at least six months had expired between his July 2003 vaccinations and this event in February or March, 2004. *See Shapiro v. Sec'y, HHS*, 101 Fed. Cl. 532, 537-38 (2011) ("There is little doubt that the decisional law in the vaccine area favors medical records created contemporaneously with events they describe over subsequent recollections."); *see also Cucuras*, 993 F.3d at 1528 (holding that "oral testimony in conflict with contemporaneous documentary evidence deserves little weight").

e. "Inappropriate Increases" in Head Circumference.

During oral argument, Mrs. Fresco asserted that a health care provider had noted that Danny's head circumference was growing more rapidly than would typically be expected, and that the provider did not seem concerned about the increase nor did the provider suggest it could be a marker of a problem. Tr. at 28. However, in hindsight, Mrs. Fresco asserts that the changes in Danny's head circumference were a sign of inflammation and an indication that he should not have received additional vaccinations. *Id.* The only evidence of Danny's increasing head circumference is on a chart appearing at Pet. Ex. 5, p. 135. The chart demonstrates that Danny's head circumference was 15 inches when first measured on April 3, 2002, and 18.5 inches at the final measurement recorded, on April 23, 2003. *Id.* However, there is no evidence that this increase is abnormal, unusual in any respect, or particularly alarming. Danny's height and weight likewise increased over this time period. *Id*. at 138-39. Growth charts that appear elsewhere in Danny's pediatric records plot his increased stature and weight over time, but do not plot his head circumference. *See* Pet. Ex. 5, pp. 138-40 (growth charts).

The CDC provides growth charts to use in plotting height, weight, and head circumference of infants over time which are similar to those used by Danny's pediatrician.[63] When Danny's head circumference measurements are plotted on the CDC chart for head circumference, his measurements do not appear to be markedly abnormal.[64]

C. Danny's Autism Spectrum Disorder Evaluations and Diagnosis.

There do not appear to be any issues pertaining to Danny's subsequent evaluations and treatment for autism. In summary, Danny was initially evaluated at the Children's Hospital of New Jersey by Dr. Vinod Goyal, a developmental pediatrician, on September 29, 2003. *See* Pet. Ex. 5, pp. 18-20. Doctor Goyal concluded that Danny, then 20 months of age, had a significant communication disorder, with delays in expressive and receptive language. Danny had poor oral motor skills and was unable to handle solid food. Doctor Goyal noted that, in addition to the speech problems he displayed, Danny had other behaviors "consistent with ASD." She diagnosed Danny with pervasive developmental delay, not otherwise specified ["PDD-NOS"]. She also commented that Mrs. Fresco seemed to be well aware of Danny's problems. Pet. Ex. 5, p. 20.

Danny continued to be followed by Dr. Goyal. *See* Pet. Ex. 5, pp. 24-26 (noting improvement in eye contact, interaction, and vocabulary, but continued problems with feeding, drooling, balance and coordination); Pet. Ex. 3, pp. 1-2 (noting diagnoses of autism with hypotonia, failure to thrive, and global developmental delay, as well as continued problems with language, toe walking, and fine motor skills).

Danny was also evaluated at The Autism Center, a part of the New Jersey Medical School in Newark, NJ in January, 2004. Mrs. Fresco reported at this visit that she became concerned about Danny's development when he was 18 months old in that he did not always respond to his name or follow commands. Pet. Ex. 5, p. 36.[65] She

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[63] The CDC has growth charts designed for use by medical professionals. *See* http://www.cdc.gov/growthcharts/clinical_charts.htm and http://www.cdc.gov/growthcharts/charts.htm. (last accessed Jan. 4, 2013).

[64] Danny's head circumference was at the 10th percentile at two months of age, just under the 50th percentile at four months of age, and between the 50th and 75th percentiles between six and fourteen months of age. I note that evidence in the Theory 2 OAP test cases indicated that many children with autism spectrum disorders have heads of normal size or smaller than normal at birth, but head circumference increases disproportionally between birth and one year of age. The disproportionate increase in brain circumference of children with autism was attributed to an elaboration of neural interconnections at a time when the brains of typically developing children are not experiencing the same elaboration. *Dwyer*, 2010 WL 892250 at *44. *See* the discussion of the brain inflammation theory in Section III.B.1.

[65] The pages of Exhibit 5 from The Autism Center (pp. 36-40) appear to be paginated out of order.

also provided a history of allergies to milk and soy and symptoms of autism, such as head banging, echolalia, lack of functional or imaginative play, a fixation on strings, problems with textures, hand splaying, and bringing objects close to his eyes for observation. *Id.*, p. 39. Doctor Barbie Zimmerman-Bier, a developmental pediatrician, indicated that a diagnosis of PDD-NOS was appropriate. *Id.*, p. 40. She noted that Danny was receiving speech, occupational, and behavioral therapy through an early intervention program. Pet. Ex 5, p. 39. He was seen again by Dr. Zimmerman-Bier in October, 2005, who, noting diagnoses of ASD, failure to thrive, and hypotonia, described Danny as "medically fragile"[66] and observed continued limited speech, fixation on objects, and echolalia. Pet. Ex. 5, pp. 30-32.

Danny was seen by several other specialists, including an immunologist, an endocrinologist, a nutritionist, and a pediatric gastroenterologist for issues involving his short stature, low weight, and feeding difficulties. Pet. Exs. 5*,* pp. 7, 24; 12, p. 4.

Danny received genetic and metabolic evaluations in December 2005 and January 2006 for his failure to thrive. In a summary addressed to Dr. Zimmerman-Bier, the evaluation team noted that Danny was in the 1st percentile for height and the 9th percentile for weight, and, per Mrs. Fresco, that his growth had started to slow at 18 months of age. The letter also noted that Danny's had delayed tooth eruption and a bone age younger than his calendar age. Danny's older brother was reported to stutter and have some possible attention deficits. A screening for possible metabolic disorders found slight elevations in some tests, but these are "most likely of no clinical significance." His genetic testing was all normal. Pet. Ex. 5, pp. 57-58.

Although Mrs. Fresco indicated that Danny's immune system was somehow deficient (Pet. Ex. 6, p. 2), there were no medical records filed that reflected any immune dysfunction. Danny's relatively good health was remarked upon during his genetics and metabolic evaluation. *Id.*, p. 57.

Doctor Buttram evaluated Danny on June 23, 2006,[67] and wrote a brief note to an attorney who frequently represents petitioners in the Vaccine Program indicating that he believed that Danny's autism was caused by his vaccines. Pet. Ex. 8, 1-2. He did not provide any reasons for his conclusion.

Medical records for any subsequent treatment were not filed. During the oral argument, Mrs. Fresco indicated that Danny currently attends school, looks young for his age, and is very active. Tr. at 58. She also noted that he remains diagnosed with

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[66] The characterization as medically fragile appears to apply to problems with Danny's weight, often in the 10th percentile or below, and his small stature. There were no indications in the records filed that Danny had any immune system dysfunction or other problems that might account for this characterization.

[67] In an email to Mrs. Fresco, Dr. Buttram also referenced an evaluation that occurred on July 14, 2006, but no record was filed for a visit on that date. Pet. Ex. 7, p. 2.

autism and also has been diagnosed with attention deficit hyperactivity disorder. Tr. at 59.

III. Expert Opinions.

A. Contrasting Qualifications.

The two physicians who opined in this case differed markedly in their qualifications to opine on a neurological disorder and their experience in diagnosing and treating autism spectrum disorders. This difference was reflected in the quality of the opinions they provided, and the support for those opinions in the medical literature referenced.

Doctor Buttram, who is board certified in environmental medicine,[68] had the advantage of seeing Danny once in 2006 before opining in a letter that Danny's vaccinations were responsible for his autism spectrum disorder. Pet. Ex. 8 at 1-2. The letter was addressed to an attorney who represents petitioners in the Program, and I thus do not consider Dr. Buttram to be a treating doctor.[69] The nine page opinion of Dr. Buttram filed in this case in August 2011[70] is poorly written, inadequately supported, and largely irrelevant to a conclusion that Danny's vaccines were responsible for his autism diagnosis.[71] As indicated earlier, much of it consists largely of excerpts from a June 2011 article he co-authored.

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[68] The biographical information provided in lieu of a CV in petitioners' January 26, 2012 filings reflects that Dr. Buttram practices in the areas of internal and family medicine. He has received some additional unspecified training in complementary and integrative medicine, nutritional medicine, allergies, chelation therapy, bio oxidative therapies, and preventive and functional medicine. Buttram CV at 1.

[69] Doctor Buttram acknowledged that after his 2006 evaluation he "had no further role as Daniel's treating physician." Pet. Ex. 8 at 2.

[70] On January 26, 2012, Mrs. Fresco filed a short note from Dr. Buttram to herself , along with three supplemental pages to his expert report and identified the filing as Pet. Ex. 8, pages 10 -13. The additional pages are replacement pages for pages 7-9 of his original report. The last two pages primarily contain his list of references. The revised reference list includes one additional source: *The Age of Autism – Mercury, Medicine, and a Man-made Epidemic,* a 2010 book authored by Dan Olmsted and Mark Blaxill. On the new page seven, Dr. Buttram added a short section describing the autism free zones discussed in the book (which was not filed as an exhibit in this case). He suggests that reports of a low incidence of autism in Amish communities, home-schooling families in Florida, and non-vaccinated families in Chicago is a result of parents in those areas declining vaccinations for their children. Without more information regarding these assertions, I decline to accord them any weight.

[71] I note that expert opinions of Dr. Buttram in other vaccine cases have been similarly described. *See e.g., Meyers v. Sec'y, HHS*, No. 04-1771V, 2006 WL 1593947, *5-7 (Fed. Cl. Spec. Mstr. May 22, 2006) (commenting that his report primarily relied on articles and theories previously rejected as unreliable and based on flawed methodologies and discussed causation theories unrelated to the injury alleged in the case).

In contrast, respondent's expert, Dr. Max Wiznitzer, is truly an expert on autism spectrum disorders. He is board certified in both pediatrics and neurology, with special qualifications in both child neurology and neurodevelopmental disorders. He has published many articles in peer reviewed medical journals concerning the diagnosis and treatment of such disorders, and serves as a reviewer and on the editorial boards of several journals. He has an active clinical practice involving individuals with autism and related conditions, and has participated in National Institutes of Health funded research on autism. He holds a medical school appointment as an associate professor of pediatrics, neurology, and international health, and teaches medical students, residents, and fellows. He lectures locally, nationally, and internationally on autism spectrum disorders, sits on the board of directors for autism support groups, and is a member of autism committees for the Departments of Education and Health. Res. Ex. A (Expert Report of Dr. Wiznitzer) at 1-2; Res. Ex. B (CV of Dr. Wiznitzer).

Although special masters can decline to consider an expert's opinion based on lack of qualifications and other factors, such cases are rare. *Veryzer v. Sec'y, HHS,* No. 06-522V, 2010 WL 2507791 (Fed. Cl. Spec. Mstr. June 15, 2010) (granting respondent's motion to exclude petitioner's expert report). More frequently, special masters consider all of the evidence and testimony produced by the parties, and rather than using the *Daubert* criteria to screen out evidence at the gate to the courthouse, they use the non-exhaustive *Daubert* criteria to determine what, if any, weight to give to expert opinions. *Terran v. Sec'y, HHS,* 195 F.3d 1302, 1316 (Fed. Cir. 1999) (approving a special master's use of the *Daubert* factors "as a tool or framework for conducting the inquiry into the reliability of the evidence"); *Cedillo v. Sec'y, HHS,* 617 F.3d 1328, 1339 (Fed. Cir. 2010) (noting that special masters are to consider all relevant and reliable evidence filed in a case and may use *Daubert* factors in their evaluation of expert testimony); *Davis v. Sec'y, HHS*, 94 Fed. Cl. 53, 67 (2010) (describing the *Daubert* factors as an "acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted . . . by special masters in vaccine cases"). Doctor Buttram's opinion falls quite close to the line between these two alternatives. I considered his opinion, but did not accord it much weight.

When experts disagree, many factors influence a fact-finder to accept some testimony and reject other contrary testimony. As the Federal Circuit noted, "[a]ssessments as to the reliability of expert testimony often turn on credibility determinations, particularly in cases . . . where there is little supporting evidence for the expert's opinion." *Moberly v. Sec'y, HHS*, 592 F.3d 1315, 1325-26 (Fed. Cir. 2010). Objective factors, including the qualifications, training, and experience of the expert witnesses; the extent to which their proffered opinions are supported by reliable medical research and other testimony; and the factual basis for their opinions are all significant factors in determining what testimony to credit and what to reject. Neither expert testified, therefore the objective standards were applied to evaluate their expert reports.

In finding Dr. Wiznitzer's opinion to be more reliable than Dr. Buttram's, I have carefully considered their relative qualifications to opine, as well as the substance of and support for their conclusions, addressed below. Because this is an OAP case, I

have considered these opinions in light of the impressive body of evidence adduced in the OAP test cases as well. I add that the result would be the same, even if I had not considered the OAP test case evidence.

B. The Causation Opinions.

1. Doctor Buttram's Report.

The substance of and problems with Dr. Buttram's causation opinion are set forth below. Doctor Buttram does not address the assertions made in the petition in this case. Rather, he attempts to resurrect theories considered and rejected in the OAP test cases, notably that autism is the result of brain inflammation caused by immune system responses to vaccines, and that children with autism have difficulty excreting mercury, without providing any new evidence on these theories. He relies primarily upon a 2007 study by Massroor Pourcyrous[72] that is, at best, only tangentially relevant to whether vaccines can cause autism and whether they did so in Danny's case.

In a continuation of his shotgun approach to vaccines in general, he asserts that vaccine adjuvants overstimulate brain cells, that toxic chemicals in combination are more toxic than each is separately, and that the hepatitis B vaccine has many reported complications, without specifically asserting that autism or autism spectrum disorders are the probable result of adjuvants, combined chemical reactions, and/or the hepatitis B vaccine.

Much of Dr. Buttram's report (Pet. Ex. 8) consists of an anti-vaccine polemic which is simply not relevant to this case. He devotes one and one half pages to discussing "gross deficiencies" in vaccine safety testing. Pet. Ex. 8 at 2-3. He discusses brain hemorrhages and shaken baby syndrome. Id. at 5. He alleges that children who have received a full set of vaccinations have higher rates of asthma than those with some or no vaccinations. *Id.* He claims that combinations of toxic chemicals cause increased health risks, and blames adjuvants in vaccines for various problems. *Id.* at 6-7. These inadequately supported allegations are not causally linked in any way to autism or the facts of Danny's case.

Less than two pages of his report are specific to Danny. He briefly recites Danny's medical history, and appears to rely on Mrs. Fresco's statements for his conclusion that Danny tested positive for Group B streptococcus at birth, an assertion contradicted by the medical records filed. Pet. Ex. 8 at 1; *see* II.A. above for a discussion of Danny's birth and treatment. He mentions laboratory tests performed at a time when Danny was already displaying some symptoms of autism and asserts that a low percentage of a particular type of white blood cells is a "marker for ongoing vaccine

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[72] M. Pourcyrous et al., *Primary Immunization of Premature Infants with Gestational Age < 35 Weeks: Cardiorespiratory Complications and C-reactive Protein Responses Associated with Administration of Single and Multiple Separate Vaccines Simultaneously*, J. PEDIATRICS 151:167-172 (2007).

reaction." Pet. Ex. 8 at 2. He notes that Danny's genetic test and amino acid profiles were normal. *Id.* Although he agrees that it is unlikely that Danny received a hepatitis B vaccination at birth (*id.* at 1), he calls it "unjustifiable" to administer hepatitis B to newborns. *Id*. at 7. He asserts that a "double dose" of hepatitis B vaccine (referring to Mrs. Fresco's assertion that a hepatitis B vaccine was administered shortly after birth, in addition to the hepatitis B vaccination administered on February 8, 2002) provides "valid grounds for suspecting that the double dose may have played a causal role in Daniel's autism." *Id.* at 1. He never elucidates those "valid grounds."

Doctor Buttram's theory of causation does not directly address autism. Rather, he asserts that "adverse vaccine reactions" can be explained by a "unified theory." Pet. Ex. 8, p. 4. He explains that theory thusly: vaccines cause brain inflammation, resulting in brain swelling, triggering potentially lethal cardiorespiratory events and brain hemorrhages. *Id.*

Doctor Buttram primarily based this theory on a study of vaccines administered to premature, low birth-weight infants. The Pourcyrous study examined cardiorespiratory events and measured C-reactive protein ["CRP"] levels[73] in premature infants with birth weights under 1000 grams who were administered either single vaccines or multiple vaccines at two months of age. Doctor Buttram reported that this study found elevations of CRP in 70% of these infants administered single vaccinations and in 85% of those administered multiply vaccines. Abnormally high levels of CRP were found in 43% of the infants. He contends that this finding is a marker for brain inflammation and that brain inflammation produces swelling or edema.

Doctor Buttram also reported that about 16% of the infants in the Pourcyrous study had "vaccine-associated" cardiorespiratory events, including apnea and bradycardia, and characterized these problems as "potentially lethal" events. He also claimed that intraventricular brain hemorrhages occurred in 17% of the infants receiving single vaccinations and in 24% of those receiving multiple vaccines. *Id*. at 4. Doctor Buttram acknowledged that brain hemorrhages in infants may have causes other than vaccines, such as the use of surfactants in premature infants and may be a complication of cardio-pulmonary resuscitation or the use of mechanical ventilators. *Id*. at 5.

In asserting that it "can only be a matter of time until vaccine-induced brain inflammation becomes recognized as a primary cause of the current epidemic of autism spectrum disorders" (Pet. Ex. 8 at 5), Dr. Buttram implicitly acknowledges that his theory of inflammation being responsible for autism is not accepted by the medical community at large. He relies on the Vargas study[74] to draw a connection between brain

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[73] C-reactive protein' ["CRP"] is a protein used as a marker for inflammatory illness. K. & T. Pagana MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS ["MOSBY'S LABS"] at 197 (4th ed. 2010). It is primarily used as a marker for cardiac problems. *Id.*

[74] D. Vargas et al., *Brain Inflammation Found in Autism*, ANNALS OF NEUROLOGY 57:67-81 (2005).

inflammation and autism. He also relies on studies by Blaylock[75] to assert that adjuvants in vaccines are responsible for "intense reactions of microglial and astrocyte cells, which serve as the brain's immune system, with each successive series of vaccinations." *Id.* at 6. Doctor Buttram contends that this process results in over-activation of proinflammatory cytokines, and increases in excitotoxins and glutamate in the brain, resulting in autism. *Id.* at 7.

Although he acknowledges that vaccines no longer contain "large amounts" of thimerosal, he relies on a study by Dr. Amy Holmes[76] to show that autistic children have more difficulty excreting heavy metals. Pet. Ex. 8 at 4-5. He then goes on to argue that mercury is still used as a preservative in multi-dose vials of tetanus booster vaccines,[77] and in trace amounts in other vaccines. Added to aluminum adjuvants present in vaccines, the combined toxic effect of even very small amounts of these metals "can be dangerous," according to Dr. Buttram. *Id.* at 8. He relies on a rat study involving combined doses of two heavy metals, lead and mercury, for this assertion.[78] He does not assert that autism is the result of this danger.

In summary, Dr. Buttram's report reprises nearly all of the mechanisms by which vaccines purportedly cause or contribute to autism that were considered and rejected in the OAP test cases.

Petitioners did not provide a copy of this study to the court. However, this study was included in the medical literature filed in the Theory 2 OAP test cases. *See Dwyer,* 2010 WL 892250 at *49-50. (discussing the key findings of the study).

[75] R. Blaylock, T*he Danger of Excessive Vaccination During Brain Development*, MEDICAL VERITAS 5(1): 1727-41 (2008); R. Blaylock , *Chronic microglial activation and excitotoxicity secondary to excessive immune stimulation: possible factors in Gulf War Syndrome and autism*, J. AM. PHYSICIANS AND SURGEONS, 9(2):46-52 (2004); R. Blaylock, *Vaccines, depression, and neurodegeneration after age 50: Another reason to avoid the recommended vaccines*, Vaccine Risk Awareness Network (VRAN) Newsletter, Spring 2008.

[76] He did not cite directly to the study, but rather to a presentation made at an autism conference. A. Holmes, *Impaired Mercury Excretion*, Defeat Autism Now [DAN!] Conference, Syllabus Spring 2004, April 16-19, page 22, Washington, DC. The actual study was filed in the Theory 2 OAP test cases, where its findings and conclusions were questioned because they could not be duplicated. *Dwyer*, 2010 WL 892250 at *102-03.

[77] He also asserts that mercury is present in multi-dose vials of flu vaccines. As there is no evidence that Danny ever received an influenza vaccine, Dr. Buttram's assertions about this are irrelevant to Danny's case.

[78] I note that aluminum is not classified as a "heavy metal," although lead and mercury are.

2. Doctor Wiznitzer's Report.

Doctor Wiznitzer opined that Dr. Buttram's hypothesis was not supported by his references and was inapplicable to Danny. Res. Ex. A at 5 -7.

a. Blood Tests as Evidence of Immunosuppression.

Doctor Wiznitzer opined that Danny's white blood cell and leukocyte tests on July 14, 2003, were normal, and thus not supportive of Dr. Buttram's "speculation" about immunosuppression and an on-going vaccine reaction. Res. Ex. A at 5. The white cell count Dr. Buttram found abnormal was actually in the normal range (2300, with a normal range of 1500-7100). Although the percentage of total white cells was low, the absolute value was the important finding, and thus there is no evidence of immune suppression.

I place more reliance on Dr. Wiznitzer's report than Dr. Buttram's. I note that none of Danny's treating physicians recorded any concerns about Danny's immune status or functioning, and that Danny's pediatric records reflect very few illnesses prior to his autism diagnosis. *See* Res. Ex. A at 7-8 (noting that Danny had a normal number of illnesses for a child of his age).

b. The Pourcyrous Study.

Doctor Wiznitzer called Dr. Buttram's reliance on the Pourcyrous study "flawed and incorrect." *Id.* at *5.* According to Dr. Wiznitzer, Dr. Buttram misrepresented some of the study's findings. Doctor Wiznitzer reported that the study did not find any evidence of brain swelling after vaccinations, and that the brain hemorrhages Dr. Buttram mentioned predated the administration of the vaccines. He noted that the study's authors did not conclude that the CRP elevations were a marker for brain inflammation. Res. Ex. A at 5-6. Doctor Wiznitzer noted that this study involved premature infants who were still hospitalized two months after their birth, and asserted that the study's findings and conclusions could not be applied to Danny. Although neither expert filed a copy of the Pourcyrous study as evidence, I place more reliance on Dr. Wiznitzer's interpretation of what the study said. I note that, in particular, Dr. Wiznitzer's comments about the pre-existing nature of brain hemorrhages in premature infants track evidence in other cases. *See, e.g.,* Huffman v. Sec'y, HHS, No. 07-81V, 2011 WL 995958, *23-24 (Fed. Cl. Spec. Mstr. Feb. 28, 2011). In any event, the study does not appear to address autism at all.

c. The Vargas Study.

As Dr. Wiznitzer pointed out, there was no evidence linking Danny's case to any of the findings in the Vargas study. Res. Ex. A at 6. The Vargas study was filed in the OAP test cases, and thus is available to petitioners or respondent in any OAP case. The authors did find, as Dr. Buttram reports, evidence of activation of microglia and astroglia based on brain autopsies of children with autism that were absent in

neurotypical controls. However, as the Vargas study authors noted, they could not determine if the inflammation was the result of autism or somehow causally related to autism. *Dwyer*, 2010 WL 892250 at *49-50.

d. Metal Toxicity.

According to Dr. Wiznitzer, there is no evidence that metals in vaccines are linked to autism. Res. Ex. A at 6. This was also the finding in the OAP test cases. The Holmes study, relied upon by Dr. Buttram, purported to show that children with autism had difficulty excreting mercury, but it was thoroughly discredited in the OAP test cases (five separate studies were unable to duplicate the results and the mercury levels reported in the children used as controls were approximately 15 times the average for children of similar ages). *Dwyer,* 2010 WL 892250 at *102. Moreover, Danny received, in total, less than 0.10 micrograms of mercury in his three hepatitis B vaccines. The children in the OAP test cases received 37.5 micrograms of mercury in the same three vaccines, as they received their vaccinations prior to the removal of thimerosal as a preservative in multi-dose vials of hepatitis B vaccines. Each of the special masters who heard this evidence in the OAP test cases concluded that there was inadequate evidence to link mercury in vaccines to autism.[79] As Dr. Wiznitzer noted, the 2004 Institutes of Medicine report by the Immunization Safety Review Committee "concluded that the body of evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." Res. Ex. A at 6.

Assuming that Danny received vaccines containing aluminum adjuvants, petitioners produced no reliable evidence that aluminum adjuvants can cause autism or that they did so in Danny's case. There is also no evidence that mercury and aluminum in vaccines potentiate in their effects so as to cause autism.

e. Excitotoxins and Glutamate.

Although Dr. Wiznitzer did not directly address Dr. Buttram's vague assertions about vaccines producing imbalances in pro-inflammatory cytokines, excitotoxins, and glutamate in the brain, these theories were also considered and rejected in the OAP test cases. *See Dwyer,* 2010 WL 892250 at *163. There is no evidence in Dr. Buttram's report or otherwise in this record that there is an excess of excitotoxins or glutamate in the brains of children with autism, much less that they are present in Danny's brain.

C. Legal Standards and Conclusions on Causation.

To establish legal cause in an off-Table case, Vaccine Act petitioners must establish each of the three *Althen* factors: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the

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[79] *Cedillo*, 2009 WL 331968; *Hazlehurst*, 2009 WL 332306; *Snyder*, 2009 WL 332044; *Dwyer*, 2010 WL 892250; *King*, 2010 WL 892296; *Mead*, 2010 WL 892248.

vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. 418 F.3d 1274, 1278 (Fed. Cir. 2005). The applicable level of proof is the "traditional tort standard of 'preponderant evidence.'" *Moberly*, 592 F.3d at 1322 (citing *de Bazan v. Sec'y, HHS*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); *Pafford v. Sec'y, HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *Althen,* 418 F.3d at 1278). The preponderance standard "requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring) (internal quotation and citation omitted).

An alternate formulation of the causation requirement in off-Table cases is the "Can it cause?" and "Did it cause?" inquiry used in toxic tort litigation. Prong 1 of *Althen* has been characterized as an alternative formulation of the "Can it cause?" query. Prong 2 of *Althen*, the requirement for a logical sequence of cause and effect between the vaccine and the injury, has been characterized as addressing the "Did it cause?" query. *See Pafford v. Sec'y, HHS*, No. 01-165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). Even if a vaccine has been causally associated with an injury, petitioner must still establish facts and circumstances that make it more likely than not that the vaccine caused his particular injury. The third *Althen* factor is subsumed into the "Did it cause?" inquiry.

Regardless of whether a case is analyzed under *Althen* or the "Can it cause?" formulation, petitioners are not required to establish identification and proof of specific biological mechanisms, as "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. The petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the injury or condition; showing that the vaccination was a "substantial factor"[80] in causing the condition and was a "but for" cause are sufficient for recovery. *Shyface v. Sec'y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); *see also Pafford,* 451 F.3d at 1355 (petitioner must establish that a vaccination was a substantial factor and that harm would not have occurred in the absence of vaccination). Petitioners cannot be required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect . . . ." *Capizzano*, 440 F.3d at 1325. Causation is determined on a case by case basis, with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y, HHS,* 35 F.3d 543, 548 (Fed. Cir. 1994).

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[80] The recently approved Restatement (Third) of Torts has eliminated "substantial factor" in the factual cause analysis. § 26 cmt. j (2010). Because the Federal Circuit has held that the causation analysis in Restatement (Second) of Torts applies to off-Table Vaccine Act cases (*see Walther v. Sec'y, HHS*, 485 F.3d 1146, 1151 (Fed. Cir. 2007); *Shyface v. Sec'y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)), this change does not affect the determination of legal cause in Vaccine Act cases: whether the vaccination is a "substantial factor" is still a consideration in determining whether it is the legal cause of an injury.

Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. *But see Knudsen*, 35 F.3d at 550 (stating that when evidence is in equipoise, the party with the burden of proof fails to meet that burden).

The medical theory must be a reputable one, although it need only be "legally probable, not medically or scientifically certain." *Knudsen,* 35 F.3d at 548-49. The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, likewise requires that courts determine expert opinions to be reliable before they may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." 509 U.S. 579, 590 (1993) (footnote omitted). The Federal Circuit has stated that a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly,* 592 F.3d at 1324.

Here, there is really no contest between the experts. Doctor Buttram and his report barely pass the very generous standards applied in Vaccine Act cases in favor of hearing nearly any evidence a party submits. Were I to have conducted a *Daubert*[81] hearing in this case, I would not have permitted Dr. Buttram to testify. His "board certification"[82] in environmental medicine does not qualify him to opine on the causes of autism, a neurological disorder, particularly in the absence of any training or research credentials in the field of neurology or neurological disorders in children. Although he cites to some mainstream and peer reviewed medical journals for the assertions in his report, he also cites to an article about subdural infusion of blood and horseradish peroxidase in pigs; a "telephone survey" conducted by an organization that has publicly espoused support for vaccine causation of autism; and articles linking autism, a disorder manifesting in early childhood, and Gulf War syndrome, which manifests in adults. To say that I find Dr. Buttram's assertions unreliable is a serious understatement.

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[81] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U. S. 579 (1993).

[82] Doctor Buttram is a Fellow of the American Academy of Environmental Medicine ["AAEM"]. To become a Physician Member of AAEM one must possess a doctorate degree, a current medical license, and meet unspecified additional requirements which may be imposed by the Board of Directors. To become a Fellow, a Physician Member must request the title, which is awarded after "successful completion of the requirements as determined by the Board of Directors" and represents "recognition of their contribution to the Academy." AAEM Membership Information, available at http://aaemonline.org/Membership.html (last visited Jan. 4, 2013). By contrast, Dr. Witnitzer's board certifications are overseen by the American Board of Medical Specialties ["ABMS"], the principal credentialing body for physicians. To obtain board certifications from ABMS one must possess a medical degree, complete a three to five year residency training program, and pass a written and oral examination. Additionally, to maintain and keep a board certification, a physician must attend continuing medical education programs and complete additional examinations. ABMS Certification Information, available at http://www.abms.org/About_Board_Certification/means.aspx and http://www.abms.org/Maintenance_of_Certification/MOC_competencies.aspx (last visited Jan. 4, 2013). *See also* JK Iglehart and RB Baron, *Ensuring Physicians' Competence – Is Maintenance of Certification the Answer?*, New Eng. J. Med. 367:2543 (Dec. 27, 2012).

I also note that no treating physician—and I do not include Dr. Buttram in this category, as his 2006 evaluation of Danny was clearly for the purpose of litigation not treatment—has linked Danny's autism to his vaccines. While circumstantial evidence and medical opinions may be sufficient to satisfy *Althen*'s second prong, and opinions of treating physicians may also provide the logical connection, there are none providing that link in this case. *See Capizzano*, 440 F.3d at 1325-26; *Andreu v. Sec'y, HHS*, 569 F.3d 1367, 1376 (Fed. Cir. 2009); *Moberly,* 592 F.3d at 1323.

The requirement of temporal connection necessitates a showing that the injury occurred in a medically or scientifically reasonable period after the vaccination, not too soon (*see de Bazan*, 539 F.3d at 1352) and not too late (*see Pafford*, 451 F.3d at 1358). Merely showing a proximate temporal connection between a vaccination and an injury is insufficient, standing alone, to establish causation. *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A proximate temporal relationship, even when coupled with the absence of any other identified cause for the injury, is not enough to demonstrate probable cause under the Vaccine Act's preponderance standard. *Moberly*, 592 F.3d at 1323 (citing *Althen*, 418 F.3d at 1278). Here, Dr. Buttram does not provide any information regarding a medically appropriate interval between any vaccination and onset of autism. Moreover, Danny displayed symptoms of autism before the last set of vaccinations in July, 2006. These were the vaccines that petitioners primarily relied upon in the filing of their petition, although they later extended their causation arguments to all of the vaccines Danny received.

IV. Conclusion.

Petitioners are required by the Vaccine Act to produce preponderant evidence of vaccine causation in an off-Table injury case. § 13(a). The claims set forth in their petition are not supported by the medical records filed or by Dr. Buttram's report. In turn, Dr. Buttram's opinions are largely irrelevant to the facts of Danny's case, unsupported by reliable scientific research, and set forth theories already considered and rejected in the OAP test cases.

I conclude that petitioners failed to demonstrate any of the *Althen* factors by preponderant evidence. Petitioners have not demonstrated that Danny's autism was either caused in fact or significantly aggravated by the vaccinations he received. The petition for compensation is therefore DENIED. The clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

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Denise K. Vowell
Special Master