In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 04-1717V
(To be published)

* *

ELLENA PROKOPEAS and
CHRIS PROKOPEAS,
parents of C.A.P., a minor,

Petitioners,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

* *

Filed: June 14, 2017

Ruling on factual issues; Autism

Clifford Shoemaker, Shoemaker, Gentry & Knickelbein, Vienna, VA, for Petitioners
Voris Johnson, U.S. Department of Justice, Washington, DC, for Respondent

RULING ON FACTUAL ISSUES

HASTINGS, *Special Master*.

This is an action in which the Petitioners, Ellena and Chris Prokopeas, request compensation under the National Vaccine Injury Compensation Program (hereinafter "the Program"[1]), on behalf of their minor son, C.A.P., for injuries allegedly suffered from vaccinations administered to him during his first year of life. C.A.P.'s vaccinations to which Petitioners point include the following: diphtheria-tetanus-acellular pertussis (DTaP), haemophilus influenza (Hib), inactivated polio (IPV), pneumococcal conjugate (Prevnar), and hepatitis B (Hep B) vaccines. Petitioners allege that C.A.P. suffered from an encephalopathy that was "caused-in-fact" by the cumulative effects of those vaccinations. Among C.A.P.'s many neurodevelopmental conditions, he has been diagnosed with an autism spectrum disorder (ASD).

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[1] The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2012 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2012 ed.). I will also sometimes refer to the statutory provisions defining the program as the "Vaccine Act."

In this case, Petitioners presented certain facts concerning C.A.P.'s symptomatology from the early years of his life that are *at variance* with his contemporaneous medical records. Thus, a "fact hearing" was held on August 1, 2016, to resolve the disputed facts. For all of the reasons set forth below, I find that C.A.P.'s contemporaneous medical records are the most reliable source of evidence reflecting C.A.P.'s condition during his first year of life. In this regard, I *reject* parental allegations made during the course of this litigation, alleging that C.A.P. suffered from *additional* post-vaccination symptoms not reflected in his contemporaneous medical records.

I

THE APPLICABLE STATUTORY SCHEME

I begin with the relevant law concerning this "fact ruling," which states that Petitioners are required to establish the facts supporting their causation theory by a "preponderance of the evidence." 42 U.S.C. § 300aa–13(a)(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. HHS*, 592 F.3d 1315, 1322, n.2 (Fed. Cir. 2010) (citations omitted).

When confronted with discrepancies among medical records and affidavits, special masters often elect to hold "fact hearings" to evaluate the testimony of the affiants. *See Campbell v. HHS*, 69 Fed. Cl. 775, 779-80 (2006). The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa–11(c)(2). In this regard, the relevant caselaw states that medical records "warrant consideration as trustworthy evidence." *Cucuras v. HHS,* 993 F.2d 1525, 1528 (Fed. Cir. 1993). Accordingly, where subsequent testimony conflicts with contemporaneous medical records, special masters usually accord more weight to the medical records. *See, e.g., Reusser v. HHS,* 28 Fed. Cl. 516, 523 (Fed. Cl. 1993) ("[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.").

To be sure, "it must [also] be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." *Murphy v. HHS*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992). However, in balancing these considerations, special masters in this Program have in most cases declined to credit later testimony over *contemporaneous* records. *See, e.g., Stevens v. HHS*, No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990); *Vergara v. HHS*, No. 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. July 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony."); s*ee also Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight").)

Decisions by judges of the Court of Federal Claims have followed *Cucuras* in affirming findings by special masters that the lack of symptoms being reported in contemporaneously created medical records can contradict a testimonial assertion that symptoms appeared on a certain date. *See, e.g., Doe/70 v. HHS*, 95 Fed. Cl. 598, 608 (2010) (stating, "[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd sub nom*. *Rickett v. HHS*, 468 Fed. Appx. 952 (Fed. Cir. 2011); *Doe/17 v. HHS*, 84 Fed. Cl. 691, 711 (2008); *Ryman v. HHS*, 65 Fed. Cl. 35, 41-42 (2005); *Snyder v. HHS*, 36 Fed. Cl. 461, 465 (1996) ("[t]he special master apparently reasoned that, if Frank suffered such [developmental] losses immediately following the vaccination, it was more likely than not that this traumatic event, or his parents' mention of it, would have been noted by at least one of the medical record professionals who evaluated Frank during his life to date. Finding Frank's medical history silent on his loss of developmental milestones, the special master questioned petitioner's memory of the events, not her sincerity."), *aff'd*, 117 F.3d 545, 547-48 (Fed. Cir. 1997).

The presumption that contemporaneously-created medical records are accurate and complete is rebuttable, of course. Special masters are expected to consider whether medical records are accurate and complete. To overcome the presumption that written records are accurate, testimony is required to be "consistent, clear, cogent, and compelling." *Blutstein v. HHS*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). Special masters will consider various explanations for inconsistencies between contemporaneously created medical records and later given testimony. The Court of Federal Claims listed four such explanations. Inconsistencies can be explained by: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. HHS*, 110 Fed. Cl. 184, 203 (Fed. Cl. 2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

In weighing divergent pieces of evidence, special masters usually find contemporaneously-written medical records to be more significant than oral testimony. *Cucuras*, 993 F.2d at 1528. Testimony offered after the events in question is less reliable than contemporaneous reports when the motivation for accurate explication of symptoms is more immediate. *Reusser v. HHS*, 28 Fed. Cl. 516, 523 (1993). However, compelling oral testimony may be more persuasive than written records. *Campbell*, 69 Fed. Cl. at 779 ("[l]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); *Camery v. HHS*, 42 Fed. Cl. 381, 391 (1998) (this rule "should not be applied inflexibly, because medical records may be incomplete or inaccurate").

II

BACKGROUND: THE OMNIBUS AUTISM PROCEEDING ("OAP")

This case is one of more than 5,400 cases filed under the Program in which petitioners alleged that conditions known as "autism" or "autism spectrum disorders" ("ASD")[2] were caused by one or more vaccinations. A special proceeding known as the Omnibus Autism Proceeding ("OAP") was developed to manage these cases within the Office of Special Masters ("OSM"). A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in the six entitlement decisions issued as "test cases" for two theories of causation litigated in the OAP (see cases cited below), and will only be summarized here.

A group called the Petitioners' Steering Committee ("PSC") was formed in 2002 by the many attorneys who represented Vaccine Act petitioners who raised autism-related claims. About 180 attorneys participated in the PSC. Their responsibility was to develop any available evidence indicating that vaccines could contribute to causing autism, and eventually present that evidence in a series of "test cases," exploring the issue of whether vaccines could cause autism, and, if so, in what circumstances. Ultimately, the PSC selected groups of attorneys to present evidence in two different sets of "test cases" during many weeks of trial in 2007 and 2008. In the six test cases, the PSC presented two separate theories concerning the causation of ASDs. The first theory alleged that the *measles* portion of the measles, mumps, rubella ("MMR") vaccine could cause ASDs. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that the mercury contained in *thimerosal-containing vaccines* could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC's *first* theory rejected the petitioners' causation theories. *Cedillo v. 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);

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[2] "Autism Spectrum Disorder" is a *general* classification which as of 2010 included five different specific disorders: Autistic Disorder, Childhood Disintegrative Disorder, Asperger's Syndrome, Rett Syndrome, and Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). *King v. HHS*, No. 03-584V, 2009 WL 892296 at *5 (Fed. Cl. Spec. Mstr. Feb. 12, 2010). The term "autism" is often utilized to encompass *all* of the types of disorders falling within the autism spectrum. (*Id.*) I recognize that since the OAP test cases, the consensus description of ASDs, contained now in the "DSM-V" as opposed to the prior "DSM-IV," revises the prior subcategories of ASD set forth in the first sentence of this footnote. However, the DSM-V retains the same *general description* of ASDs. An ASD is a serious form of neurodevelopmental disorder defined by a collection of symptoms and behaviors, including significant impairment of social interaction and language skills, and the presence of repetitive, stereotyped interests. *E.g.*, *Snyder v. HHS*, No. 01-162V, 2009 WL 332044, at *31 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

Hazlehurst v. 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. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).[3] Decisions in each of the three "test cases" pertaining to the PSC's *second* theory also rejected the petitioners' causation theories, and the petitioners in each of those three cases chose not to appeal. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

The "test case" decisions were comprehensive, analyzing in detail all of the evidence presented on both sides. The three test case decisions concerning the PSC's *first* theory (concerning the MMR vaccine) totaled more than 600 pages of detailed analysis, and were solidly affirmed in many more pages of analysis in three different rulings by three different judges of the United States Court of Federal Claims, and in two rulings by two separate panels of the United States Court of Appeals for the Federal Circuit. The three special master decisions concerning the PSC's *second* theory (concerning vaccinations containing the preservative "thimerosal") were similarly comprehensive.

All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit *unanimously rejected* the petitioners' claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism.

Thus, the proceedings in the six "test cases" concluded in 2010. Thereafter, the Petitioners in this case, and the petitioners in other cases within the OAP, were instructed to decide how to proceed with their own claims. The vast majority of those autism petitioners elected either to withdraw their claims or, more commonly, to request that the special master file a decision denying their claim on the written record, resulting in a decision rejecting the petitioner's claim for lack of support. However, a small minority of the autism petitioners have elected to continue to pursue their cases, seeking other causation theories and/or other expert witnesses. A few such cases have gone to trial before a special master, and in the cases of this type decided thus far, all have resulted in *rejection* of petitioners' claims that vaccines played a role in causing their child's autism. *See*, *e.g.*, *Henderson v. HHS*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2012) (autism not caused by pneumococcal vaccination); *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *Murphy v. HHS*, No. 05-1063V, 2016 WL 3034047 (Fed. Cl. Spec. Mstr. Corcoran Apr. 25, 2016) (autism not caused by DTaP or MMR vaccines), *aff'd*, 2016 WL 4926207 (Fed. Cl. Aug. 15, 2016); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Hastings Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines); *Long v. HHS*, No. 08-792V, 2015 WL 1011740 (Fed. Cl. Spec. Mstr. Hastings Feb. 19, 2015) (autism not caused by influenza vaccine); *Brook v. HHS*, No. 04-405V, 2015 WL 3799646 (Fed. Cl. Spec. Mstr. Hastings May 14, 2015) (autism not caused by MMR or Varivax vaccines);

[3] The petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims.

Holt v. HHS, No. 05-136V, 2015 WL 4381588 (Fed. Cl. Spec. Mstr. Vowell June 24, 2015) (autism not caused by hepatitis B vaccine), *aff'd*, (not yet published); *Lehner v. HHS*, No. 08-554V, 2015 WL 5443461 (Fed. Cl. Spec. Mstr. Vowell July 22, 2015) (autism not caused by influenza vaccine); *Miller v. HHS*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Vowell August 18, 2015) (ASD not caused by combination of vaccines); *Allen v HHS*, No. 02-1237V, 2015 WL 6160215 (Fed. Cl. Spec. Mstr. Vowell Sept. 26, 2015) (autism not caused by MMR vaccination); *R.K. v. HHS*, No. 03-632V, 2015 WL 10936124 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2015) (autism not caused by influenza vaccine), *aff'd*, 125 Fed. Cl. 57 (2016), *aff'd*, 2016 WL 7174139 (Fed. Cir. Dec. 9, 2016); *Hardy v. HHS*, No. 08-108V, 2015 WL 7732603 (Fed. Cl. Spec. Mstr. Hastings Nov. 3, 2015) (autism not caused by several vaccines); *Sturdivant v. HHS*, No. 07-788V, 2016 WL 552529 (Fed. Cl. Spec. Mstr. Hastings Jan. 21, 2016) (autism not caused by Hib and Prevnar vaccines); *R.V. v. HHS,* No. 08-504V, 2016 WL 3882519 (Fed. Cl. Spec. Mstr. Corcoran Feb. 19, 2016) (autism not caused by influenza vaccine), *aff'd*, 2016 WL 3647786 (Fed. Cl. June 2, 2016); *Cunningham v. HHS*, No. 13-483V, 2016 WL 4529530 (Fed. Cl. Spec. Mstr. Hastings Aug. 1, 2016) (autism not caused by MMR vaccine), *aff'd*, 2017 WL 1174448 (Fed. Cl. Jan. 25, 2017); *T.M. v. HHS*, No. 08-284V (Fed. Cl. Spec. Mstr. Corcoran Aug. 9, 2016) (not yet published) (autism not caused by DTaP vaccine) (on review); *Anderson v. HHS*, 02-1314V, 2016 WL 8256278 (Fed. Cl. Spec. Mstr. Corcoran Nov. 1, 2016) (autism not caused by MMR vaccination), *aff'd*, 2017 WL 1787975 (Fed. Cl. May 5, 2017); *Dempsey v. HHS*, No. 04-394V, 2017 WL 105840 (Fed. Cl. Spec. Mstr. Hastings Feb. 23, 2017).

In addition, some autism causation claims have been rejected *without trial*, at times over the petitioner's objection, in light of the failure of the petitioner to file plausible proof of vaccine-causation. *See, e.g., Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Campbell-Smith Sept. 19, 2012) (autism not caused by MMR vaccination); *Fester v. HHS*, No. 10-243V, 2016 WL 1745436 (Fed. Cl. Spec. Mstr. Dorsey April 7, 2016) (autism not caused by measles, mumps, rubella, and varicella (MMRV) vaccine); *Fresco v. HHS*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Vowell Jan. 7, 2013) (autism not caused by multiple vaccines); *Fesanco v. HHS*, No. 02-1770, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Hastings Nov. 9, 2010) (autism not caused by multiple vaccines); *Miller v. HHS*, No. 06-753V, 2012 WL 12507077 (Fed. Cl. Spec. Mstr. Hastings Sept. 25, 2012) (autism not caused by DTaP or MMR vaccines); *Pietrucha v. HHS*, No. 00-269V, 2014 WL 4538058 (Fed. Cl. Spec. Mstr. Hastings Aug. 22, 2014) (autism not caused by multiple vaccines); *Bushnell v. HHS*, No. 02-1648, 2015 WL 4099824 (Fed. Cl. Spec. Mstr. Hastings June 12, 2015) (autism not caused by multiple vaccines); *Bokmuller v. HHS*, No. 08-573, 2015 WL 4467162 (Fed. Cl. Spec. Mstr. Hastings June 26, 2015) (autism not caused by multiple vaccines); *Canuto v. HHS*, No. 04-1128, 2015 WL 9854939 (Fed. Cl. Spec. Mstr. Hastings Dec. 18, 2015) (autism not caused by DTP and DTaP vaccines); *Valle v. HHS*, No. 02-220V, 2016 WL 2604782 (Fed. Cl. Spec. Mstr. Hastings April 13, 2016) (autism not caused by DTaP vaccine); *Hooker v. HHS*, 02-472V, 2016 WL 3456435 (Fed. Cl. Spec. Mstr. Hastings May 19, 2016) (autism not caused by multiple vaccines). Judges of this court have affirmed the practice of dismissal without trial in such cases. *E.g.*, *Fesanco v. HHS*, 99 Fed. Cl. 28 (2011) (Judge Braden affirming); *Canuto v. HHS*, No. 04-1128V, 2016 WL 2586510 (Fed. Cl. Apr. 18, 2016) (Judge Yock affirming), *aff'd*, 2016 WL 5746370 (Fed. Cir. Oct. 4, 2016).

In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can contribute to causing autism.[4]

III

PROCEDURAL HISTORY

A. Petitioners' filing of a "Short-Form Autism Petition"

On November 29, 2004, Chris and Ellena Prokopeas ("Petitioners") filed a Short-Form Autism Petition for Vaccine Compensation on behalf of their minor son, C.A.P. (ECF No. 1.) This case was assigned to my docket at that time. By filing that "Short Form" petition,

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[4] I am well aware, of course, that during the years since the "test cases" were decided, in two cases involving vaccinees suffering from ASDs, Vaccine Act compensation was granted. But in *neither* of those cases did the Respondent concede, nor did a special master find, that there was any *"causation-in-fact"* connection between a vaccination and the vaccinee's ASD. Instead, in both cases it was conceded or found that the vaccinee displayed the symptoms of a *Table Injury* within the Table time frame after vaccination. (See Section I above).

In *Poling v.* HHS, the presiding special master clarified that the family was compensated because the Respondent conceded that the Poling child had suffered a *Table Injury--not* because the Respondent or the special master had concluded that any vaccination had contributed to causing or aggravating the child's ASD. *See Poling v.* HHS, No. 02-1466V, 2011 WL 678559, at *1 (Fed. Cir Spec. Mstr. Jan. 28, 2011) (a fees decision, but noting specifically that the case was compensated as a Table Injury).

Second, in *Wright v. HHS*, No. 12-423, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015), Special Master Vowell concluded that a child, later diagnosed with ASD, suffered a "Table Injury" after a vaccination. However, she stressed that she was *not* finding that the vaccinee's ASD in that case was "caused-in-fact" by the vaccination--to the contrary, she specifically found that the evidence in that case did *not* support a "causation-in-fact" claim, going so far as to remark that the petitioners' "causation-in-fact" theory in that case was "absurd." *Wright v. HHS*, No. 12-423, 2015 WL 6665600, at *2 (Fed. Cl. Spec. Mstr. Sept. 21, 2015).

The compensation of these two cases, thus, does *not* afford any support to the notion that vaccinations can contribute to the *causation* of autism. In setting up the Vaccine Act compensation system, Congress forthrightly acknowledged that the Table Injury presumptions would result in compensation for some injuries that were *not*, in fact, truly vaccine-caused. H.R. Rept. No. 99-908, 18, 1986 U.S.C.C.A.N. 6344, 6359. ("The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of a vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.")

Petitioners in effect alleged that C.A.P. suffered from autism, and that his autism was caused by either or both (1) the MMR (measles, mumps, rubella) vaccine, and (2) vaccines containing "thimerosal", a mercury-based preservative contained in a number of childhood vaccines until about 1999 (but removed from most childhood vaccines soon after that year). *Autism General Order #1*, Exhibit A, Master Autism Petition for Vaccine Compensation, 2002 WL 31696785, at *8 (Fed. Cl. Spec. Mstr. July 3, 2002). By filing the "Short Form" petition, the Petitioners also were, in effect, making their case part of the "Omnibus Autism Proceeding" (OAP). On December 8, 2004, this case, along with many others, was stayed indefinitely pending completion of the *general inquiry* under the Omnibus Autism Proceeding (OAP) regarding the possible causal relationship between certain vaccines and autistic spectrum disorders. (ECF No. 2; *See also* Section II of the Fact Ruling above.)

On January 26, 2007, this case was reassigned to Special Master Campbell-Smith. (ECF No. 12.) Thereafter, Petitioners filed medical records (marked as Exhibits 1 to 16) on September 24, 2007. (ECF No. 13.)

On October 15, 2008, Special Master Campbell-Smith issued an order updating Petitioners on the status of the OAP and explaining how their case would proceed. (ECF No. 14.) Between May of 2009 and August of 2010, Petitioners submitted numerous medical records. (*See* Exs. 17-57[5]; ECF Nos. 22-23, 25, 34-35, 39, 41, 43-45.)

Petitioners filed a statement on August 20, 2010, indicating that they had filed all requested records ordered by the special master. (ECF No. 46.) Thereafter, on September 16, 2010, Respondent submitted a statement indicating that she would not oppose further processing of this case. (ECF No. 47, p. 3.)

B. First and second Amended Petitions

In light of the OAP "test cases," on June 14, 2011, Special Master Campbell-Smith issued an order requiring the Petitioners to state whether they wished to pursue their claim further. (ECF No. 48.) That order also instructed that, if the Petitioners wished to proceed further with this case, then they should file an Amended Petition, which, among other things, clearly explained their theory of vaccine causation. (*Id.*)

Petitioners filed an Amended Petition on August 15, 2011, alleging that C.A.P. "developed encephalopathy from repeated exposures to mercury and other vaccine ingredients" found in certain vaccinations C.A.P. received during his first year of life. (ECF No. 51, p. 3.) The vaccinations alleged to have caused C.A.P.'s injuries included: diphtheria-tetanus-acellular pertussis (DTaP), haemophilus influenzae (Hib), inactivated polio (IPV), pneumococcal conjugate (Prevnar), and hepatitis B (Hep B). (*Id.*, pp. 2-3.)

On January 11, 2012, Special Master Campbell-Smith held a status conference to discuss her concerns about the Petitioners' claim. (ECF No. 54.) Specifically, she noted that Petitioners' causation theory in this case, alleging that C.A.P. developed an "encephalopathy

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[5] Petitioners filed Exhibit 54 on both July 26, 2010 and July 29, 2010. (ECF Nos. 41, 43.) On July 29, 2010, Petitioners moved to strike the documents filed on July 26, 2010, due to an inadvertent filing mistake by Petitioners' counsel. (ECF No. 42.)

from repeated exposure to mercury and other vaccine ingredients," was "without more, a reprise of aspects of theories asserted, considered, and rejected in both the first and second rounds of test cases litigated during the Omnibus Autism Proceeding (OAP)." (*Id.*) Moreover, she highlighted her concern that "there is a lack of factual support for the allegation that [C.A.P.] had a fever following the administration of vaccines." (*Id.*, p. 2.) Thus, she ordered Petitioners to (1) file updated medical records supporting the allegation that C.A.P. suffered fevers following the administration of his vaccinations, and (2) an annotated Amended Petition containing specific citations to the supporting medical records. (*Id.*)

In response, on March 12, 2012, Petitioners filed a joint affidavit from Chris and Ellena Prokopeas (Ex. 58, ECF No. 56), and a second Amended Petition (ECF No. 57), virtually identical to the Amended Petition filed on August 15, 2011, except that it added certain citations to the exhibits. Between June of 2012 and September of 2012, Petitioners submitted numerous updated medical records (Exs. 59-86; ECF Nos. 60, 63-67). This case was then reassigned to the docket of Special Master Vowell on March 8, 2013. (ECF No. 70.)

C. Expert reports and evidentiary hearing

On July 9, 2013, Petitioners filed the expert report and *curriculum vitae* of Dr. Joseph Bellanti, M.D. (Exs. 87-88; ECF No. 72.) Dr. Bellanti's expert report of July 9, 2013, however, indicated that his opinion was "subject to further consultation with colleagues in the field of genetics." (ECF No. 73.) Thus, on July 12, 2013, Special Master Vowell ordered Petitioners to file a supplemental report from Dr. Bellanti addressing the aforementioned statement contained in that expert report. (*Id.*) After several extensions of time (ECF Nos. 74-75, 78), Petitioners eventually filed the supplemental expert report of Dr. Bellanti on February 12, 2014 (Ex. 89; ECF No. 80).

On June 3, 2014, Respondent filed the expert reports and *curricula vitae* of Dr. Gerald Raymond, M.D. (Exs. A-B), and of Dr. Judith Miller, Ph.D. (Exs. H-I). (ECF No. 83.) Additionally, Respondent also filed medical literature supporting both Dr. Raymond's expert report (Exs. C-G), and Dr. Miller's expert report (Exs. J-K). (*Id.*)

On September 16, 2014, Special Master Vowell ordered Petitioners to file all outstanding medical records, including C.A.P.'s most recent lab results and reports from C.A.P.'s genetic specialist. (ECF No. 88.) Petitioners continued to file outstanding medical records from October to December of 2014. (Exs. 90-91, 93; ECF Nos. 89, 91, 93.) Thereafter, on February 13, 2015, Petitioners filed medical records[6] from C.A.P.'s treating geneticist, Dr. Aparna Rajadhyaksha, M.D. (Ex. 94), and additional medical literature (Ex. 95). (ECF No. 96.) Thereafter, on April 3, 2015, Petitioners filed the expert report and *curriculum vitae* of Dr. Brett Abrahams, Ph.D. (Exs. 96-97, ECF No. 97.)

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[6] In filing Exhibit 94, Petitioners' counsel inadvertently marked that exhibit as an "Expert Report," instead of properly marking that exhibit as "medical records." (Ex. 94, ECF No. 96.) Exhibit 94 contains only C.A.P.'s medical records, including genetic test results from his medical examination by Dr. Rajadhyaksha. (*Id.*)

On June 8, 2015, this case was reassigned to my docket due to the impending retirement of then-Chief Special Master Vowell. (ECF No. 103.) Thereafter, on December 1, 2015, Petitioners filed the expert report of Jean-Ronel Corbier, M.D. (Ex. 98; ECF No. 112.) Subsequently, on December 4, 2015, Petitioners filed the *curriculum vitae* and supplemental expert report of Dr. Corbier. (Ex. 99; ECF No. 113.) On March 29, 2016, Respondent submitted the supplemental expert report of Dr. Raymond (Ex. L), and the corresponding medical literature cited in that report (Exs. M-S). (ECF No. 116.)

I held a telephonic status conference with both parties on April 7, 2016. (ECF No. 118.) At that time, Petitioners' counsel observed that the viability of the Petitioners' expert reports was predicated on the accuracy of parental reports describing symptoms not reflected in the contemporaneous medical records. (*Id.*) Thus, Petitioners' counsel proposed a "fact hearing" in order to determine whether such family reports can be found credible in light of the contemporaneous medical records. (*Id.*) On June 13, 2016, Petitioners' counsel filed a status report informing the Court that four witnesses would testify at the "fact hearing" -- Ellena Prokopeas; Chris Prokopeas; Nick Chrissikos; and Naomi de la Torre. (ECF No. 124.) Concurrently, Petitioners submitted the statement of Nick Chrissikos (Ex. 100); Amendment to Ellena Prokopeas' Affidavit (Ex. 101); and the statement of Naomi de la Torre (Ex. 102).[7] (ECF No. 125.)

I conducted the requested "fact hearing" in Washington, D.C. on August 1, 2016. At that time, only Ellena Prokopeas testified for the Petitioners. (ECF No. 130; Tr. 4-5.) This matter is now ripe for a ruling on the disputed facts.

IV

FACTS

A. Medical history appearing in C.A.P.'s medical records

1. C.A.P.'s first month of life

C.A.P. was born on December 6, 2001. (Ex. 1, pp. 1-2.) During his first month of life, C.A.P. was seen by Pediatric Associates of Dallas for routine childhood illnesses. (*See* Ex. 34-2 generally.) Specifically, on December 11, 2001, jaundice was noted (Ex. 34-2, p. 30); and on December 27, 2001, he was treated for a fever, congestion, runny nose, and decreased appetite (*id.*, pp. 31-32). However, at both his two-week well visit of December 20, 2001, and his one-month well-visit of January 8, 2002, C.A.P. was recorded as being a "well" baby. (*Id.*, pp. 32-33.)

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[7] Petitioners filed a status report on June 24, 2016, indicating that they did not intend to file an additional affidavit for Chris Prokopeas, choosing, instead, to rely on the signed joint statement of Chris and Ellena Prokopeas (filed as Exhibit 58), to be the entirety of Mr. Prokopeas' testimony in this case. (ECF No. 127.)

2. C.A.P.'s first set of vaccinations and following care

C.A.P. had his two-month well-visit on February 5, 2002. (Ex. 34-2, p. 34.) At that time, he presented with a "stuffy nose" and diarrhea, and was recorded to be sleeping three to four hours per night. (*Id.*) He was described as a "well baby," and was administered the following vaccinations: DTaP, IPV, Comvax (combination dose of the Hib and hepatitis vaccines), and Prevnar. (*Id.*)

3. C.A.P.'s second set of vaccinations and following care

C.A.P. was next seen by his pediatrician for his four-month well-visit on April 9, 2002. (Ex. 34-2, p. 35.) No reaction to the vaccinations of February 5, 2002, was recorded. (*Id.*) At that time, he was recorded to be sleeping up to five hours a night, was assessed as a "well baby," and was administered the DTaP, IPV, Hib, and Prevnar vaccinations. (*Id.*) C.A.P. saw his examining physician again on April 30, 2002,[8] presenting with a cough, runny nose, and a rash throughout his body -- symptoms that were reported to have persisted for one week. (*Id.*) At that visit, he was reported, among other things, to be "happy," and was diagnosed with having an upper respiratory infection ("URI"). (*Id.*)

4. C.A.P.'s third set of vaccinations and following care

C.A.P. had his seven-month well-visit on July 22, 2002. (Ex. 34-2, p. 36.) C.A.P.'s pediatrician recorded that he was sleeping approximately four hours per night, and was assessed as a "well child" overall, receiving the DTaP, Hib, Hep B, and Prevnar vaccinations at that visit. (*Id.*)

On July 23, 2002, C.A.P.'s medical records include a notation of a phone call from Mr. Prokopeas, relaying that C.A.P. had a fever of 102-103 degrees Fahrenheit. (Ex. 34-2, p. 36.) Mr. Prokopeas described C.A.P. as being "fussy," but reported that he was feeling better with Motrin, and was "eating ok." (*Id.*) However, Mr. Prokopeas reported that both parents were concerned because C.A.P.'s fever had not come down. (*Id.*) That medical record further reveals that a staff member from C.A.P.'s pediatrician's office documented discussing a variety of topics concerning fevers with C.A.P.'s parents, including fever control, and fever as a reaction to immunizations. (*Id.*) Specifically, that staff member documented advising the parents that fevers as a reaction to immunizations can last up to 24 to 36 hours post-immunizations, and documented advising them to call back the next day (*i.e.*, on July 24, 2002), if C.A.P. still had a fever the next morning, or if any new symptoms developed during that time period. (*Id.*)

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[8] This medical record from April of 2002 (Ex. 34-2, p. 35) is unclear at first glance as to the precise date. At the fact hearing, Mrs. Prokopeas testified that she believed that C.A.P.'s visit was most likely on April 13, 2002. (Tr. 17-18.) As discussed at Section VII(A)(2) below, however, I *do not* accept Mrs. Prokopeas' interpretation of C.A.P.'s sick visit to be on April 13, 2002. Instead, I find that that medical visit was on April 30, 2002.

C.A.P.'s medical records also reflect a notation[9] of a second phone call at a later time on July 23, 2002, by Mrs. Prokopeas. (*Id.*, p. 37.) That phone call notation reflects Mrs. Prokopeas reporting that C.A.P. had a temperature of 102-103 degrees Fahrenheit; however, she also reported C.A.P. as being "playful," and having no additional symptoms other than his fever. (*Id.*)

On July 24, 2002, C.A.P. was taken back to his pediatrician, and his fever symptoms were reported to have continued for the past two days. (Ex. 34, p. 37.) That medical record reflects C.A.P.'s parents describing C.A.P. as "not himself," and reporting his temperature to be as high as 103 degrees Fahrenheit. (*Id.*) C.A.P.'s temperature was taken during that examination visit, and was recorded to be 101.4 degrees Fahrenheit. (*Id.*) Moreover, C.A.P. was reported to be taking "Tylenol/Motrin" to control his fever. [10] (*Id.*)

On July 25, 2002, Mrs. Prokopeas took C.A.P. to see another pediatrician, Dr. Porter. (Ex. 10, p. 4.) During that visit, Dr. Porter recorded Mrs. Prokopeas' accounts of C.A.P.'s ongoing symptomatology, noting that C.A.P. was experiencing a fever for four days ("F x 4"), with his highest temperature reaching 103.9 degrees Fahrenheit. (*Id.*) Mrs. Prokopeas also reported that C.A.P. had vomited three times ("V x 3 times"), had diarrhea twice ("D x 2 times") since the previous day, was fussy, and could not "keep anything down." (*Id.*) However, on the day of the visit, C.A.P. was reported to have been successfully breast-fed three times that day, with no further diarrhea, and observed by Dr. Porter to be "happy" and "playful." (*Id.*) Dr. Porter diagnosed C.A.P. with "viral gastroenteritis," recommending that C.A.P. stay "well hydrated," and asked Mrs. Prokopeas to call back if C.A.P. exhibited increased listlessness, increased vomiting, or if his fever persisted for more than 48 hours. (*Id.*)

Thereafter, C.A.P.'s medical records reflect that Mrs. Prokopeas contacted C.A.P.'s pediatrician's office on August 13, 2002. (Ex. 10, p. 4.) That notation reflects a phone call from Mrs. Prokopeas, relaying her worries that C.A.P. had diarrhea again for the past week ("D again x 1 wk"), had no appetite ("no app."), was not nursing well, had some dry diapers, and wanted C.A.P. to be seen by the pediatrician. (*Id.*) C.A.P. was seen by Dr. Porter on August 14, 2002, at which time Mrs. Prokopeas reported that C.A.P. was not sleeping well, was fussy, had a cough for the past three days ("C x 3 days"), had diarrhea for 7 days ("D x 7 days"), and spat up yellow mucus. (*Id.*) C.A.P.'s pediatrician diagnosed him with oral thrush ("thrush"), and "feeding issues." (*Id.*) He was prescribed Gentian Violet (a common medication to treat oral thrush), and the pediatrician encouraged his parents to feed him solids, and asked to be updated by the parents if C.A.P.'s symptoms persisted. (*Id.*)

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[9] Mrs. Prokopeas testified at the fact hearing that the second phone call of July 23, 2002, was initiated by C.A.P.'s pediatrician, who was calling her back to check on C.A.P.'s condition. (Tr. 22.)

[10] This medical record of C.A.P.'s sick visit of July 24, 2002, is partly illegible. (Ex. 34-2, p. 37.) One of the notations on that medical note may possibly read "? Rx to shot" (that is, "reaction" to shot). (*Id.*)

5. C.A.P.'s vaccination on September 24, 2002, and following care.

C.A.P. had his nine-month well-visit on September 24, 2002. (Ex. 10, p. 3.) That medical record, among other things, reflects that C.A.P. "crawls," and "stands with assistance." (*Id.*) He was assessed as being a "well" nine-month old, and was administered his third dose of the Hepatitis B vaccine. (*Id.*)

Mrs. Prokopeas took C.A.P. to his pediatrician on September 30, 2002, reporting, among other things, that C.A.P. had congestion, and a runny nose ("RN") for the past three days ("x 3 day"). (Ex. 10, p. 3.) Moreover, Mrs. Prokopeas reported that C.A.P. was sneezing, had vomited once a day for seven days, was teething, and was not sleeping well. (*Id.*) Dr. Porter recorded that C.A.P. was alert and cooperative during the medical examination, and diagnosed him as suffering from a viral upper respiratory infection ("URI/Viral"), vomiting phlegm ("Vom phlegm"), and having feeding problems. (*Id.*)

On October 13, 2002, C.A.P. was seen in the Emergency Department of the Medical City of Dallas Hospital, for complaints of vomiting and diarrhea that had started on the same day. (Ex. 35, pp. 16-19.) Upon examination, C.A.P. was diagnosed with having "[g]astroenteritis." (*Id.*, p. 19.)

6. C.A.P.'s medical care from November of 2002 to August of 2003. [11]

In an affidavit of December 1, 2014, Mrs. Prokopeas reported that "there are no medical records for C.A.P. from 11 months old to 20 months old" (covering the time period from November of 2002 to August of 2003), stating that she did not take C.A.P. to a physician during that time period, as she could not find a pediatrician amenable to postponing C.A.P.'s future vaccinations. (Ex. 91, p. 1.) However, in her affidavit of June 13, 2016, Mrs. Prokopeas indicated that "Dr. Kotsanis," a family friend, provided some care when C.A.P. was 12 months of age until he was 20 months of age. (Ex. 101, p. 1, ¶ 4.) In any event, Petitioners have not submitted records of any medical care received by C.A.P. between October 13, 2002, and October 23, 2003. (*See generally* Exs. 10 and 34.)

7. C.A.P.'s playground head injury and following care.

C.A.P.'s medical records reflect that he was examined by Dr. Kotsanis[12] on October 23, 2003, for a head injury. (Ex. 67, p. 3.) At that time, Dr. Kotsanis recorded a medical history of

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[11] C.A.P.'s vaccination administration record from Dr. Porter (Ex. 10, p. 1) reflects a stamped date of December 10, 2002 ("Dec 10 2002"), with a notation of "n/s" next to the rows entitled "MMR1"; "Varivax"; and "Prevnar." (Ex. 10, p. 1.) The exact meaning of the notation of "n/s" is not clear in that record; however, that notation could possibly mean "no show." (*Medical Abbreviations: 32,000 Conveniences at the Expense of Communication and Safety*, 15th ed., p. 232.)

In closely examining Ex. 10, p. 1, I note the contrast between C.A.P.'s documented vaccination of September 24, 2002, versus the stamped notation of December 10, 2002. (Ex. 10, p. 1.) In this regard, I point out that, on the column entitled "Signature of Parent or Guardian," that record reflects Mrs. Prokopeas' signature by the corresponding row, documenting C.A.P.'s administered Hep B vaccination of September 24, 2002. (*Id.*) In contrast, there is no such corresponding signature by the date stamps of December 10, 2002, by the "MMR1," "Varivax," and "Prevnar" columns. (*Id.*) Moreover, I note that while there is documentation by Dr. Porter of C.A.P.'s office visit of September 24, 2002 (Ex. 10, p. 3), no such documentation exists for any such visit from December 10, 2002 (*see generally* Ex. 10). Thus, it seems unclear whether C.A.P. was administered any vaccinations on December 10, 2002.

Regardless of the precise significance of the "n/s" notation, I note that *none* of Petitioners' pleadings (ECF Nos. 1, 51, 57), affidavits (Exs. 58, 91, 100-102), or expert reports (Exs. 87, 89, 96, 98-99) submitted in this case allege that C.A.P.'s present condition is due to any potential vaccinations received by C.A.P. on December 10, 2002.

[12] I note that the extent to which Dr. Kotsanis was a treating physician of C.A.P. is unclear in this case. Several of C.A.P.'s medical records submitted in this case reflect Dr. Kotsanis serving as a non-primary care provider to C.A.P. (*E.g.*, Exs. 5, 25, and 48 generally.) Moreover, in one of those medical records, Dr. Kotsanis himself stated that his role in C.A.P.'s treatment was limited to that of "being supportive for convenience reasons." (Ex. 48, p. 2.) However, in her affidavit of June 13, 2016, Mrs. Prokopeas referenced Dr. Kotsanis as being C.A.P.'s sole

C.A.P., as reported by Mrs. Prokopeas. (*Id.*) That note indicates that, on September 20, 2003,[13] C.A.P. suffered a head injury in a fall and was taken to the emergency room to be further evaluated.[14] (*Id.*) C.A.P. had a "very large" head hematoma (swelling due to collection of blood in the blood vessels), and underwent a CT scan, among other additional testing, during that emergency room visit. (*Id.*) Mrs. Prokopeas reported that those test results from C.A.P.'s emergency room visit "appeared to be normal."[15] (*Id.*)

Furthermore, Mrs. Prokopeas relayed that, after C.A.P.'s head injury accident, he was "a bit unsteady," and that he had "decreased in verbalization." (Ex. 67, p. 3.) Dr. Kotsanis recorded in the oral history section that, besides the playground head injury, "other active problems at this time are none." (*Id.*) Upon examination at that time, Dr. Kotsanis recorded that the "area of the trauma has healed very nicely," but that C.A.P. appeared to "drift slightly to the right side," and that he was "irritable." (*Id.*) Overall, Dr. Kotsanis diagnosed C.A.P. with "post-concussion syndrome," referring him for hearing and speech evaluations. (*Id.*)

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medical care provider when C.A.P. was 12 months of age until he was 20 months of age, alleging as follows:

> From 12-20 months old, [C.A.P.] was cared for by his mother and a family doctor friend, Dr. Kotsanis. Before moving to New Orleans, Dr. Kotsanis ran a variety of lab test [sic] on [C.A.P.] as indicated in his medical records.

(Ex. 101, p. 1, ¶ 4.)

[13] This medical record is not completely clear as to the exact date of C.A.P.'s head injury. (Ex. 67, p. 3.) The type-written date of C.A.P.'s head injury appears to be on "10/20/2003." (*Id.*) However, there is a hand-written "9" transposed on top of the "10," seeming to reflect Dr. Kotsanis' hand-written correction that C.A.P.'s head injury occurred a month prior, on "9/20/2003." (*Id.*) Thus, based on a close examination of that record, and the surrounding context, it appears that C.A.P.'s playground injury likely occurred in September of 2003. However, I am also mindful that C.A.P.'s medical records reflect alternating references to C.A.P.'s head injury in either September *or* October of 2003. (*See* Ex. 54-2, pp. 43-44; Ex. 16, p. 1.)

[14] Petitioners did not submit C.A.P.'s medical records from the emergency room visit of September or October of 2003 seeking treatment for C.A.P.'s head injury. As a result, the record of this case contains only *secondary* medical records describing C.A.P.'s head injury of September or October of 2003. Thus, all the medical records which reflect C.A.P.'s head injury of September or October of 2003, reflect parental descriptions of C.A.P.'s playground accident during which C.A.P. injured his head, as relayed to subsequent medical care providers while seeking treatment for C.A.P.'s developmental issues. (*See* Ex. 67, p. 3; Ex. 54-1, p. 3; Ex. 54-1, p. 4; Ex. 54-2, pp. 43-44; and Ex. 16, p. 1.)

[15] Petitioners have not submitted C.A.P.'s emergency room diagnostic testing results to the record in this case.

8. C.A.P.'s medical care subsequent to October of 2003

a. C.A.P.'s care from November of 2003 to January of 2004

A referral form dated November 17, 2003, from Early Childhood Intervention of Richardson/North Dallas (hereafter "ECI"), indicates that C.A.P. was referred to that practice to be evaluated for speech delay. (Ex. 54-1, p. 3.) Under the "Additional Information" section of that referral form, the following information was stated:

> Child was hit by an iron gate and was hit in the fore head. Child had a big bump. The accident happen [sic] in September. Child is not speaking like he use [sic] to speak before the accident.

(Ex. 54-1, p. 3.)

On November 20, 2003, C.A.P. underwent an evaluation by ECI. (Ex. 54-1, p. 4.) The intake form of that evaluation, which appears to be filled out by Mrs. Prokopeas, reflects that she was "most concerned" about C.A.P.'s "speech delay and temper tantrums." (*Id.*) The medical care provider examining C.A.P. at that time also recorded an oral history, as given by Mrs. Prokopeas, describing the circumstances of C.A.P.'s head injury in September of 2003. (*Id.*) That medical evaluation note recorded that C.A.P. was "hit by an iron gate" while at Disneyland, and that he was "not talking much at all" after his accident. (*Id.*) Moreover, that medical note records Mrs. Prokopeas as saying that prior to C.A.P.'s head injury accident in September of 2003, C.A.P. "only had about 10 words"; however, by the time of his evaluation as of November 20, 2003, he was unable to speak any words, and was using "a lot of gestures." (*Id.*)

On December 5, 2003, C.A.P. was once again evaluated by ECI. (Ex. 54-1, pp. 29-31.) During that evaluation (when C.A.P. was approximately two years of age), several of his developmental parameters were listed as being "of concern." (*Id.*, pp. 29-30.) Specifically, his social-emotional development was listed to be within the 18-month age range; his communication development was listed to be at 15-months of age; his expressive development was listed as being in the 15-month age range; his cognition was listed to be within the 18-month age range; and his fine-motor development was listed to be within the 15.5 month age range. (*Id.*) Also, C.A.P.'s gross-motor development (within the 21-month age range) and self-help skills (within the 24-month age range) were noted to be "WNL" (within normal limits). (*Id.*, p. 31.)

On December 11, 2003, C.A.P. underwent an evaluation by ECI of Richardson's Individual Family Service Plan ("ECI IFSP"). (Ex. 54-2, pp. 43-51.) The "Integrated Summary" section of that evaluation reflects an accounting given by Mrs. Prokopeas concerning C.A.P.'s medical history, relaying that he "had no significant medical problems" until his head injury accident at Disney land in October of 2003.[16] (*Id.*, pp. 43-44.) At that time, Mrs. Prokopeas

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[16] The "Integrated Summary" section of this medical record summarizes that:

> [W]hen [C.A.P.] was in Disney Land in October he was accidentally hit with a hard iron gate/door. His mother is unsure if he was knocked unconscious. She did not see it happen. She heard him crying and was told what had happened. It is unknown how hard

relayed her concerns that C.A.P.'s skills appeared to have regressed since the head injury accident, observing C.A.P. to be "speaking more before the accident," whereas after his accident C.A.P. was using "gestures or screaming cries to get his needs met." (*Id*., pp. 43-44.) That medical note also reflects that C.A.P.'s parents were "researching other areas," such as an "autism spectrum" disorder, for C.A.P.'s apparent regression. (*Id*., p. 44.)

From December of 2003 to August of 2004, C.A.P. continued to receive regular development therapy by ECI IFSP. (Exs. 54-1 through 54-4.)

b. C.A.P.'s medical history reflected in certain of Dr. Kotsanis' treatment notes

An undated medical record from Dr. Kotsanis reveals the following medical history of C.A.P.:

> In October 2003 the child came to my office for the first time because of a head injury while at Disney World. The CT [at] the ER in Florida was normal. The trauma did not change anything.

(Ex. 5, p. 1.) Additionally, Dr. Kotsanis recorded the following relevant medical history:

> The postvaccination injury that is reported by the parents goes along with my knowledge about [C.A.P.] socially from our Church gatherings and eventually as a doctor in my office. I remember that [C.A.P.] was initially a normal healthy child and eventually matched the traits of autistic spectrum disorder children that visit my office.

(Ex. 5, p. 1.) Moreover, his impression was that C.A.P. had an "Autistic Spectrum Disorder most likely secondary to vaccination injury." (*Id*.)

On January 6, 2004, Mr. and Mrs. Prokopeas had a telephonic consultation with Dr. Kotsanis. (Ex. 5, pp. 2-4.) Dr. Kotsanis' recorded notes from that phone consultation reveals that C.A.P.'s parents believed that he suffered a "vaccination injury." (*Id*., p. 2.) At that time, C.A.P.'s parents also reported that he suffered from allergies and behavior problems that were "out of control." (*Id*., p. 2.)

Moreover, Dr. Kotsanis' medical notes from the phone consultation of January 6, 2004, state that he "conducted an extended history" of C.A.P.'s "progress and problems since birth." (Ex. 5, p. 2.) In this regard, Dr. Kotsanis recorded an oral medical history, as given by C.A.P.'s parents, concerning C.A.P.'s early years of life. (*Id*.) At that time, C.A.P.'s parents reported that he had "met all" of his developmental milestones until July of 2002, but that they started noticing problems after his vaccinations administered later that month. (*Id*., pp. 2-3.) They further described C.A.P.'s condition after his vaccinations of July 22, 2002, stating that C.A.P. had "diarrhea for two consecutive weeks after the vaccinations," in addition to having a "persistent

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> his head was hit, but family took him to hospital immediately following. Cat scan showed nothing.

(Ex. 54-2, pp. 43-44.) (*Compare* Ex. 67, p. 3, reflecting that C.A.P.'s head injury accident possibly occurred in September of 2003.)

dry cough," a fever, refusing to breast feed, difficulties sleeping, and being in constant motion when awake. (*Id*., p. 3.) They additionally reported that "as time went on," C.A.P. exhibited additional symptoms, such as: "head banging;" "uncontrollable crying for no reason;" "increased hyperactivity;" displaying a "fear of being alone;" having worsening sleeping patterns; and being "nonverbal." (*Id*.)

Furthermore, in his phone consultation note of January 6, 2004, Dr. Kotsanis also recorded that "[i]n the summer/fall of 2002," C.A.P.'s parents attended one of Dr. Kotsanis' "public lectures," during which he advised them to "do a comprehensive pediatric evaluation with a pediatrician that is aware of possible postvaccination injury," thus reinforcing the parents' decision to "withhold vaccinations." (Ex. 5, p. 3.) Overall, Dr. Kotsanis recommended that C.A.P. be seen by a new pediatrician, Dr. Hamel, but noted that he would continue to monitor C.A.P.'s condition by phone until C.A.P. found "proper care." (*Id*., p. 4.)

c. C.A.P.'s continuing care from February of 2004

On February 9, 2004, C.A.P. underwent an audiological evaluation during which his treating audiologist recorded Mrs. Prokopeas' concerns about C.A.P.'s condition. (Ex. 16, p. 1.) Mrs. Prokopeas reported that C.A.P. was "not talking as well as his peers," was "having periods when he is not verbal," and was having "problems with behavior." (*Id.*) Moreover, Mrs. Prokopeas stated that her concerns "began in October 2003, when [C.A.P.] had an injury to his forehead." (*Id.*) Upon examination, the treating audiologist diagnosed C.A.P. with having "abnormal auditory signs and symptoms." (*Id.*)

C.A.P.'s medical records additionally reflect that, on June 23, 2004, Mrs. Prokopeas filled out a "Review Of Systems By Symptoms" intake history form in preparation to be seen by Charles Hamel, M.D. (Ex. 18, pp. 3-6 of 14.) Within the "Patient History Questionnaire" section of that intake form, Mrs. Prokopeas described the purpose of her visit with Dr. Hamel to be to "[h]elp my son recover from PDD (pervasive development delay) which is part of the 'autism spectrum disorder.'"[17] (*Id*., p. 6.)

On June 25, 2004, C.A.P. went to the emergency room to be evaluated for head lacerations sustained when he fell in his bathtub. (Ex. 17, p. 10.) Thereafter, on July 19, 2004, C.A.P. was seen by Dr. Hamel. (Ex. 18, p. 7.) During that visit, Dr. Hamel's impression was that C.A.P., among other things, had autism, a possible pervasive developmental disorder ("? PDD"), and food allergies. (*Id.*)

On July 22, 2004, C.A.P. was seen by Gordon Bourland, Ph.D., for an evaluation of an autism spectrum disorder (ASD) diagnosis. (Ex. 9, p. 1.) At that time, Dr. Bourland took a history of C.A.P.'s symptoms, and recorded Mrs. Prokopeas' recollections of C.A.P.'s

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17 Mrs. Prokopeas also listed that C.A.P. had magnetic resonance imaging (MRI) testing done on "9-20-03." (Ex. 18, p. 6.) The context indicates that Mrs. Prokopeas was possibly referring to the MRI testing conducted at the time of C.A.P.'s head injury accident during September or October of 2003. (*Compare* Ex. 67, p. 3; and Ex. 54-1, p. 3.)

developmental history. Specifically, Dr. Bourland recorded the following oral history, as reported by Mrs. Prokopeas:

> This past November [of 2003] [C.A.P.]'s parents noted a substantial change in his behavior. He began fussing and crying much more than previously had been the case, his eye contact, reported as previously typical became briefer and less consistent, he responded less consistently to people speaking to him, and his attention span shortened considerably, as well as he became more insistent upon things and activities being as he preferred.

(Ex. 9, p. 1.) Dr. Bourland diagnosed C.A.P. with Pervasive Developmental Disorder-Not Otherwise Specified (PDD-NOS), a form of autism. (*Id*., p. 4.) Also on July 22, 2004, Mrs. Prokopeas had a phone consultation with Dr. Kotsanis, who noted that Mrs. Prokopeas "had a lot of questions on chelation and vaccination injury," but that he addressed both of her concerns in detail, and that C.A.P. was "scheduled to start chelation with Dr. Hamel." (Ex. 5, p. 5.) In his notes from the phone consultation of July 22, 2004, Dr. Kotsanis recorded that C.A.P. had an "autistic spectrum disorder by history from my office," which he classified as being secondary to "vaccination trauma syndrome." (*Id.*)

On October 11, 2004, C.A.P. underwent a psychological evaluation by William Brasted, Ph.D. (Ex. 69.) In relevant part, Dr. Brasted recorded the following accounting of C.A.P.'s developmental history, as given to him by Mr. Prokopeas:[18]

> At 9-12 months, the family noticed that [C.A.P.] was not achieving developmental milestones within normal limits. He (sic) speech appeared delayed. At 9 months of age, [C.A.P.] appeared to have a reaction to his immunization shots. He began having temper tantrums and banging his head at 12 to 14 months of age and was easily irritated.

(Ex. 69, p. 4.) During that visit, C.A.P. was classified as functioning in the "Mild Range of Mental Retardation with regard to both intellectual abilities and the performance of adaptive skills." (*Id*., p. 5.)

A letter dated March of 2005, from Carmela Tardo, M.D., reflects that she evaluated C.A.P. for autism on November 8, 2004. (Ex. 75, p. 2.) In that letter, Dr. Tardo stated that during her consultation with C.A.P. on November 8, 2004, she had "no records available for review". (*Id.*) As such, at that time, Dr. Tardo recorded an oral history of C.A.P.'s condition, as reported to her by Mrs. Prokopeas. (*Id.*) Mrs. Prokopeas stated that she became concerned about C.A.P.'s development "when he was approximately 20 months of age," initially thinking that C.A.P. was "just a late talker," but subsequently became concerned about his socialization. (*Id.*) Mrs. Prokopeas additionally relayed to Dr. Tardo that C.A.P. walked at 14 months of age, and that at around one year of age, C.A.P. had approximately ten words in his expressive vocabulary, but that his speech had subsequently regressed since that time. (*Id.*)

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[18] That medical record lists "Chris Prokopeas (father)" as the "Informant" on that evaluation report. (Ex. 69, p. 2.) Additionally, that record states that C.A.P. "was accompanied to the current testing session by his father, Chris Prokopeas." (*Id*., p. 4.)

In her letter from March of 2005, Dr. Tardo further stated that during C.A.P.'s consultation visit of November 8, 2004, she could not conclusively diagnose C.A.P. with autism due to her limited examination of C.A.P. at that time; however, she believed that an autism diagnosis "would be a strong possibility" in explaining his condition. (Ex. 75, p. 2.)

From May to September of 2005, C.A.P. continued to receive developmental therapy from the Central Texas Autism Center ("Autism Center"). (*See* Exs. 19 and 49.) An evaluation note generated from one of C.A.P.'s visits to the Autism Center reflects C.A.P.'s parents reporting that C.A.P. was diagnosed with autism on November 8, 2004.[19] (Ex. 19, pp. 4, 12.)

Additionally, a letter dated July 26, 2005, from Anju Usman, M.D., documents C.A.P.'s consultation visits under her care. (Ex. 23.) In relevant part, Dr. Usman's records state the following treatment history:

> [C.A.P.] was originally seen on 12/13/04. His mother reported a history of aggressive outbursts *** and headbanging. He was also diagnosed with toxic encephalopathy.

(Ex. 23, p. 2.)

On May 4, 2007, C.A.P. was examined by Mark Geier, M.D., who conducted a neurodevelopmental disorder assessment of C.A.P. (Ex. 25-2, pp. 43-53.) As part of that evaluation, Mrs. Prokopeas filled out a form in which she relayed C.A.P.'s developmental history. In the "developmental history" section of that form, Mrs. Prokopeas[20] reported that C.A.P. regressed at "19-20 months," with "loss of language," "behavioral problems," "hand flapping/head banging," and "stereotypic behaviors." (*Id.*, p. 48.)

In a letter dated April 9, 2010, Dr. Kotsanis stated that he had "seen [C.A.P.] as a patient on and off since 2002-2003," and that his "working diagnosis was 'autistic spectrum disorder.'" (Ex. 48, p. 2.)[21] Furthermore, Dr. Kotsanis stated as follows:

> My role in [C.A.P.]'s treatment had only being (sic) supportive for convenience reasons. I was never his primary care physician. Over the years I have ordered a few tests and written a few prescriptions as per parent's request and Dr. Edelson's recommendation.

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[19] As noted immediately above, however, Dr. Tardo's letter from March of 2005 reveals that she had not diagnosed C.A.P. with an autism spectrum disorder on November 8, 2004, but was simply of the belief that an autism diagnosis "would be a strong possibility." (*See* Ex. 75, p. 2.)

[20] That medical record reflects that the "Autism Treatment Evaluation Checklist" (ATEC) was completed by "Ellena Prokopeas." (Ex. 25-2, p. 43.)

[21] That letter from Dr. Kotsanis additionally stated that to the best of his knowledge, C.A.P.'s parents had decided over time to "seek medical advice and treatment by Stephen B. Edelson MD in Atlanta, Georgia." (Ex. 48, p. 2.)

(Ex. 48, p. 2) Additionally, Dr. Kotsanis remarked that he could not find medical records of C.A.P.'s treatment under his care from 2002 to 2003; however, he stated that to the best of his recollection, C.A.P. had an "autistic spectrum disorder." (*Id.*)

9. C.A.P.'s genetic testing

Starting in May of 2007, C.A.P. also underwent genetic testing. (Ex. 25, p. 8.) However, the existence of these genetic testing results is not disputed by the parties, and thus is not relevant in resolving the disputed facts in this case. Thus, I will not discuss his genetic testing results further in this ruling.

B. Additional medical history reported by C.A.P.'s parents and family friends

In this section, I list additional allegations, made by C.A.P.'s parents and family friends, which are *at variance* with his medical records concerning two key issues: (1) C.A.P.'s symptomatology following each set of vaccinations administered to him in his first year of life; and (2) C.A.P.'s alleged neuro-developmental medical history from his early months of life -- a medical history which, according to his parents, is not properly documented in his medical records.

1. Ellena Prokopeas

Mrs. Prokopeas submitted affidavits on March 12, 2012 (Ex. 58), December 1, 2014 (Ex. 91), and June 13, 2016 (Ex. 101). She also testified at the "fact hearing" held on August 1, 2016. (Tr. 4-41.) Her first affidavit (Ex. 58) was a *joint* affidavit with her husband, Chris Prokopeas. (Ex. 58, p. 4.)[22] However, only Mrs. Prokopeas, and not her husband, testified at the "fact hearing." Accordingly, while in this section of this Ruling, for convenience's sake, I summarize the affidavits and testimony of Ellena Prokopeas, I am well aware that Ex. 58 contains the joint representations of both Ellena *and* Chris Prokopeas.

a. C.A.P.'s alleged symptoms following his first set of vaccinations.

Mrs. Prokopeas testified that "within a few minutes" of C.A.P.'s first set of vaccinations of February 5, 2002, he began to scream and cry uncontrollably, followed by a "deep sleep for many hours." (Ex. 58, p. 1; Tr. 11-14.) She alleged that even after C.A.P. woke up, he was "red and swollen" at the place of the vaccination site; was screaming, crying, and being very fussy; rejected nursing, had lost his appetite, appeared "very weak," and ran a high fever of 103.9 degrees Fahrenheit overnight. (Tr. 14-15.) Mrs. Prokopeas added that she called C.A.P.'s pediatrician the next morning (*i.e.*, on February 6, 2002), and was told that a fever due to his vaccinations could last up to 24 to 48 hours. (Tr. 15.) She testified that C.A.P.'s fever did go down within 24 to 48 hours, and that "some" of his additional symptoms had also decreased during that timeframe. (*Id.*) Additionally, in her affidavit of March 12, 2012, Mrs. Prokopeas alleged that C.A.P.'s "injection site was swollen and red on both legs for days," and that he rejected nursing for five days following his vaccinations of February 5, 2002. (Ex. 58, p. 1, ¶ 4.)

[22] Although that exhibit was filed on March 12, 2012, it appears that Mr. and Mrs. Prokopeas signed and dated that affidavit on October 21, 2004. (Ex. 58, p. 4.)

b. C.A.P.'s alleged symptoms following his second set of vaccinations.

Mrs. Prokopeas asserted that after receiving his vaccinations of April 9, 2002, C.A.P. experienced symptoms "very similar" to those that he had after his first set of vaccinations (*i.e.*, instant screaming, uncontrollable crying, rejecting nursing, falling into a deep sleep, having "swelling and redness on both legs," and developing a fever). (Tr. 16-17; Ex. 58, p. 1, ¶ 5.) Moreover, she relayed that C.A.P. "developed a cough, runny nose, and a rash that lasted for a week." (Ex. 58, p. 1, ¶ 5.)[23] In an affidavit, Mrs. Prokopeas averred that she called C.A.P.'s pediatrician's office after that incident, but was assured that C.A.P.'s symptoms were normal, and that they would "pass within 48 hours." (Ex. 58, p. 1, ¶ 5.)

At the fact hearing, Mrs. Prokopeas testified that, on April 13, 2002,[24] she took C.A.P. to the pediatrician, since he continued to suffer from the above-mentioned symptoms. (Tr. 17-19.) She stated that at that visit, C.A.P. still had a rash throughout his body, was coughing, and had a runny nose, but that his fever had resolved. (*Id.*)[25]

c. C.A.P.'s third set of vaccinations and alleged ensuing symptoms

Recounting C.A.P.'s symptomatology after his vaccinations of July 22, 2002, Mrs. Prokopeas indicated by affidavit that his third set of vaccinations "seemed to do the most harm so far." (Ex. 58, p. 1, ¶ 6.) She stated that C.A.P. had "[v]ery much the same symptoms" as he had after his first two rounds of vaccinations (*i.e.*, instant screaming, uncontrollable crying, rejecting nursing, falling into a deep sleep, having swelling and redness on both legs, and developing a fever). (Tr. 20; Ex. 58, pp. 1-2.) She testified that C.A.P. had a fever of 103.9 degrees Fahrenheit on the night of July 22, 2002 -- a temperature that she alleged lasted "for days." (Ex. 58, pp. 1-2; Tr. 20-21.)

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[23] At the "fact hearing," Mrs. Prokopeas, after consulting her written notes, eventually stated that C.A.P. suffered those same symptoms that were listed in her affidavit filed on March 12, 2012, testifying as follows:

> [L]ooking at my notes, in addition to that, I also noticed that he also started coughing – well it didn't happen right away, but later in the night, he started running – he had a runny nose, he was coughing, and he had a rash throughout his body.

(Tr. 17.) As discussed further in Section VII(B)(1) below, throughout her fact hearing testimony, Mrs. Prokopeas appeared to be reading from her notes to refresh her memory of certain events. (*E.g.*, Tr. 21-22; 29-30; 34.)

[24] As noted above in footnote 8, Mrs. Prokopeas was referring to the trip to C.A.P.'s pediatrician on April 30, 2002, which she believed occurred on April 13, 2002. (Tr. 17-19.)

[25] As further discussed in Section VII(B)(1)(b) of this fact ruling below, I note that in questioning Mrs. Prokopeas about C.A.P.'s visit to the pediatrician in April of 2002, Petitioners' counsel asked several leading questions in an attempt to somehow relate C.A.P.'s condition to his vaccinations of April 9, 2002. (Tr. 18-19.)

Mrs. Prokopeas testified that she called C.A.P.'s pediatrician's office on July 23, 2002, and spoke with a nurse, reporting that C.A.P. had a fever, was miserable, could not open his eyes, rejected nursing, seemed to be "very weak," and "appeared lifeless." (Tr. 21-22.) Additionally, she recalled stating to the nurse that C.A.P.'s fever "had dropped slightly to 102 to 103" degrees, as he was taking Motrin and Tylenol to control his fever. (*Id.*)

She further testified that C.A.P.'s pediatrician called her back later that same day (*i.e.*, on July 23, 2002), and that she told the pediatrician that C.A.P. had the "same symptoms" as when she spoke with the nurse earlier that day. (Tr. 22.) Notably, Mrs. Prokopeas testified that C.A.P.'s pediatrician's note of the phone call of July 23, 2002, stating that C.A.P. was "playful," and that he had "no other symptoms" beyond fever, was inaccurate. (Tr. 22; *compare* Ex. 34-2, p. 37.) In this regard, she averred that C.A.P. was "very sick" at that time, and thus, would not have been playful at the time of the pediatrician's phone call. (*Id.*)

Mrs. Prokopeas also described taking C.A.P. to his pediatrician on July 24, 2002, because she was "increasingly concerned" that he was "very fussy" all day, "was crying,"[26] and was not being himself. (Tr. 23.) In her affidavit, Mrs. Prokopeas reported being told at that visit that C.A.P.'s symptoms were not related to his recent vaccinations, and that those symptoms would eventually pass. (Ex. 58, p. 2.)

Mrs. Prokopeas further asserted that on the night of July 24, 2002, C.A.P. "was getting even worse," and he had started vomiting. (Tr. 24.) Thus, on July 25, 2002, Mrs. Prokopeas recalled taking C.A.P. to another pediatrician, Dr. Porter. (Tr. 24-28.) She testified that at that time, C.A.P.'s symptoms from the previous two days had continued, and that he had additionally developed diarrhea, and was vomiting. (*Id.*) She asserted that Dr. Porter's assessment of C.A.P. was that he was suffering from a "virus," but she was assured that "everything would be fine." (Tr. 27; Ex. 58, pp. 1-2.)

At the fact hearing, Mrs. Prokopeas asserted that, after his visit with Dr. Porter on July 25, 2002, C.A.P. "seemed to have been getting better." (Tr. 29-30.) She testified that starting on July 26, 2002, C.A.P.'s symptoms were "slowly getting better," but that he continued to have diarrhea, vomiting, and a cough. (Tr. 28.) Additionally, she stated that he was "very fussy," was not sleeping, and did not nurse well for "a few days." (*Id.*) Notably, however, in her affidavit of March 12, 2012, Mrs. Prokopeas asserted that C.A.P.'s diarrhea symptoms were still ongoing "even three weeks later" after his vaccinations of July 22, 2002. (Ex. 58, p. 2.)

Mrs. Prokopeas also testified about taking C.A.P. to his pediatrician on August 13, 2002, as he had a cough due to a cold, was not nursing, was fussy, was screaming, was unhappy, and was uncontrollable. (Tr. 29-30; Ex. 58, p. 2.) Mrs. Prokopeas recalled C.A.P.'s pediatrician

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[26] At that point in the fact hearing, Petitioners' counsel stated that C.A.P.'s pediatrician's handwritten note from C.A.P.'s consultation of July 24, 2002, was partly illegible. (Tr. 23-24.) Similarly, Petitioners' counsel stated that the pediatrician's notation about C.A.P.'s sick visit of July 25, 2002, was also partly illegible. (Tr. 25.) For both of these medical records, Petitioners' counsel suggested that he would get interpretations of those medical records prior to the fact hearing transcript being published in this case. (Tr. 25-26.) As of the release of the fact hearing transcript on August 1, 2016, however, Petitioners' counsel did not submit any interpretations of those medical notes, nor have any such interpretations have been submitted thereafter.

prescribing an over-the-counter medication to treat his "thrush," which subsequently cleared "within a few days," at which point C.A.P. started nursing again. (*Id.*)

In summary, in her affidavits, Mrs. Prokopeas alleged that after his third round of vaccines, on July 22, 2002, C.A.P. experienced a variety of symptoms. (Ex. 58, p. 2.) Collectively, these symptoms included: crying, being miserable, only sleeping two hours per night, having intermittent "high fevers," being difficult and demanding, having a "lack of eye contact," and developing random outbursts for no apparent reason. (*Id.*) At the fact hearing, however, Mrs. Prokopeas recalled these symptoms as being less severe. (*See* Tr. 28-31.) In this regard, she averred that once C.A.P.'s thrush resolved after his sick visit of August 13, 2002, C.A.P. started nursing again, was not as fussy, was "sleeping a little better," and that "[t]hings looked like he was getting a little better." (Tr. 31.)

d. C.A.P.'s vaccination of September 24, 2002, and alleged ensuing symptoms

Mrs. Prokopeas stated that after C.A.P.'s Hepatitis B vaccination of September 24, 2002, C.A.P. experienced symptoms "almost identical" to those that he had experienced after his prior rounds of vaccinations. (Tr. 32-33; Ex. 58, p. 2.) She alleged that immediately after that vaccination, C.A.P. started crying, was screaming, was "very upset," rejected nursing, was unhappy, and slept for "many hours." (*Id.*) She further testified that those symptoms continued for a week, and she noticed him "getting worse," prompting her to take C.A.P. to the pediatrician on September 30, 2002. (Tr. 34; Ex. 58, p. 2.) Mrs. Prokopeas recalled reporting to the pediatrician that C.A.P. was "just very, very sick," additionally reporting the following symptoms: "congestion"; "runny nose"; "coughing"; "not nursing"; "screaming"; wanting to be held; and having diarrhea. (Tr. 34.) She additionally stated that at his sick visit of September 30, 2002, C.A.P.'s pediatrician assessed him with having a cold, and assured her that C.A.P.'s symptoms would pass. (Ex. 58, p. 2.)

e. C.A.P.'s care from November of 2002

Mrs. Prokopeas stated that, due to C.A.P.'s alleged symptoms after his previously administered vaccinations, she decided to postpone his future vaccinations. (Ex. 58, p. 2.) Additionally, she stated that because of her decision not to administer further vaccinations to C.A.P., Dr. Porter -- C.A.P.'s pediatrician at that time -- refused to provide further care. (*Id.*) She acknowledged that there are "no medical records for C.A.P. from 11 months to 20 months of age" (*i.e.*, from November of 2002 to August of 2003) (Ex. 91, ¶ 3), although in a later statement she indicated that a family friend, Dr. Kotsanis, provided some care to C.A.P. during this period (Ex. 101, ¶ 4; *see also* Ex. 58, p. 2). In this regard, she further asserted that during that time period, she "accepted [C.A.P.'s] behavior as being a difficult child," but that she "never thought we had a problem until he was 21 months old and still was not speaking." (Ex. 58, p. 2)

f. C.A.P.'s alleged developmental progress from seven months of age to twenty-four months of age

At the fact hearing, Mrs. Prokopeas provided a narrative of C.A.P.'s developmental milestones from when he was seven months of age until he was twenty-four months of age. (Tr. 35-39.) Specifically, she referred to a chart in his medical records (entitled "developmental

screening checklist") -- a chart that was used by the Pediatric Associates of Dallas to track C.A.P.'s development through the first seven months of his life. (Tr. 35-36; Ex. 34-1, pp. 15-17.)[27]

At the fact hearing, Mrs. Prokopeas attempted to complete that developmental screening chart, commenting on C.A.P.'s developmental milestones starting from when he was seven months of age.[28] (Tr. 36-39.) I list below, the "yes" or "no" answers given by Mrs. Prokopeas to the age-appropriate questions from that developmental checklist chart.[29]

i. C.A.P.'s developmental parameters at seven months of age

Mrs. Prokopeas answered "yes" to both of the developmental checklist questions listed at seven months of age: "lift hands when sitting," and "transfers objects from 1 hand to other." (Tr. 36; *compare* Ex. 34-1, p. 15.)

ii. C.A.P.'s developmental parameters at eight months of age

Mrs. Prokopeas answered "yes" to the question of whether C.A.P. "stays briefly on all fours when placed." (Tr. 37; *compare* Ex. 34-1, p. 16.) She answered "no" to the following questions: "catches self to sides in sitting"; "sits at least five minutes"; and "rocks on all fours." (*Id.*)

iii. C.A.P.'s developmental parameters at nine months of age

Mrs. Prokopeas answered "yes" to the developmental parameter question of whether C.A.P. "gets in and out of sitting independently." (Tr. 37; *compare* Ex. 34-1, p. 16.) However, she answered "no" to the following questions: "crawls on hands and knees"; "stands holding on when placed"; "understands simple words"; "Shakes toys"; "Drops things and looks for them"; "Says MaMa, DaDa." (*Id.*)

iv. C.A.P.'s developmental parameters at ten and eleven months of age

For the chart's developmental questions at ten months of age, she answered "no" to: "pulls up to standing," and "plays Peek-A-Boo." (Tr. 37; *compare* Ex. 34-1, p. 16.) She also answered a "no" to all of the following developmental questions listed at eleven months of age: "cruises"; "walks holding on to the furniture"; "practices different standing positions while

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[27] Specifically, that checklist documented C.A.P.'s developmental progress at his various medical visits to that pediatric practice. (Ex. 34-1, pp. 15-17.) Petitioners' counsel asserted at the fact hearing that C.A.P.'s developmental milestones chart was *not updated* after C.A.P. switched to a different pediatrician at seven months of age. (Tr. 36.)

[28] Mrs. Prokopeas attempted to complete the developmental checklist chart contained on pages 15 through 17 of Exhibit 34-1. (Ex. 34-1, pp. 15-17.)

[29] Petitioners' counsel asked Mrs. Prokopeas to give "yes" or "no" answers to the listed age-appropriate questions from the developmental checklist chart reflected on Exhibit 34-1, pages 15 through 17. (Tr. 36-39.)

holding on"; "lowers to sitting from standing"; "points/pokes with finger"; and "picks up small objects with thumb and forefinger." (*Id.*)

v. C.A.P.'s developmental parameters at twelve months of age

Mrs. Prokopeas answered "yes" to the following developmental parameter questions concerning C.A.P. at twelve months of age: "waves bye-bye"; and "gives and takes toys in play." (Tr. 37; *compare* Ex. 34-1, p. 16.) She replied "no," however, to the following developmental checklist questions: "prefers standing to sitting"; "walks with 1 hand held"; "has 3-10 word vocabulary"; "repeats performance if laughed at"; "puts things in containers"; and "drinks from cup." (*Id.*)

vi. C.A.P.'s developmental parameters at fifteen months of age

Mrs. Prokopeas answered "yes" to the checklist question of whether he "hugs and kisses." (Tr. 37; *compare* Ex. 34-1, p. 16.) She replied "no" to the following questions: "walks independently"; "stands alone"; "indicates wants by gesturing/grunting"; and "builds tower of 3 blocks." (*Id.*)

vii. C.A.P.'s developmental parameters at eighteen months of age

Mrs. Prokopeas answered "yes" for the following developmental parameters at eighteen months of age: "climbs into chair"; "finger feeds"; and "points to 2-3 body parts." (Tr. 38; *compare* Ex. 34-1, p. 16.) She replied "no" to the following questions: "walks backwards"; "takes clothes off"; "says 15-20 words"; "follows requests (*i.e.*, get the ball)"; and "scribbles." (*Id.*)

viii. C.A.P.'s developmental parameters at twenty-four months of age

Mrs. Prokopeas answered "yes" to the following questions: "runs"; "carries toys walking"; and "pulls toys." (Tr. 37; c*ompare* Ex. 34-1, p. 16.) She replied "no," however, to the following questions: "squats"; "kicks a ball"; "rides bike-no pedals"; "walks up and down stands holding rail"; "has 200 word vocabulary"; "uses 2 word sentences (*i.e.*, 'More Cookie')"; "asks questions (*i.e.*, 'Where's kitty?, 'What's that')"; "asks for food or drink"; "names some pictures"; "builds tower of 6 blocks"; and "stays with one activity 6-7 minutes." (*Id.*)

ix. C.A.P.'s developmental parameters at two and a half years of age

For his developmental checklist parameters at two and a half years of age, Mrs. Prokopeas answered a "no" to all of the following questions: "jumps with 2 feet off ground"; "knows full name"; "builds tower of 7+ blocks"; "point to body parts"; and "copies." (Tr. 38; c*ompare* Ex. 34-1, p. 17.)

2. Nick Chrissikos

Nick Chrissikos submitted an affidavit on June 13, 2016, but did not testify at the fact hearing. (ECF No. 125, Ex. 100.) Mr. Chrissikos stated that he is a "very close family friend" of the Petitioners, and, in this capacity, he was able to report on C.A.P.'s alleged symptomatology after receiving each set of vaccinations in his first year of life. (Ex. 100, p. 1.)

Mr. Chrissikos stated that, after receiving his first set of vaccinations on February 5, 2002, C.A.P. had diarrhea, and was "running a fever." (*Id.*) Similarly, Mr. Chrissikos reported seeing C.A.P. the day after he received his second set of vaccinations on April 9, 2002, alleging that at that time, C.A.P. suffered from "a rash all over his body," "a fever of over 101" degrees Fahrenheit, being "fussy," and crying excessively. (*Id.*)

Mr. Chrissikos also asserted that he observed C.A.P. soon after the vaccinations of July 22, 2002. (Ex. 100, p. 1.) He recalled that C.A.P. had developed a fever of 103 degrees Fahrenheit, was "not nursing," was "sleeping all day," and was "screaming for no apparent reason while appearing lifeless." (*Id.*) He further alleged that these symptoms were "getting worse" by July 25, 2002, and observed that these symptoms continued throughout August of 2002. (Ex. 100, p. 2.) Mr. Chrissikos also stated that in August of 2002 C.A.P. was "still sick," with a "high fever" and "vomiting" symptoms. (*Id.*) Notably, he claimed that C.A.P. had a "high fever" as late as September of 2002. (*Id.*)

Moreover, Mr. Chrissikos stated that he observed C.A.P. after he was hospitalized in October of 2002,[30] alleging that he "looked tired," would not smile, and would not come to him when called. (Ex. 100, p. 2.) He also alleged that he observed C.A.P. on December 25, 2002, crying for no apparent reason, and refusing to sit still. (*Id.*, ¶ 5.)

Overall, Mr. Chrissikos alleged that "every time" he observed C.A.P., he was "fussy," "did not look well," "always had dark circles under his eyes," and "seemed to have a fever all the time." (Ex. 100, p. 2.) Similarly, Mr. Chrissikos stated that:

> [l]ooking back, I can clearly see on the days he was vaccinated, within a few hours, C.A.P. developed a high fever, screamed uncontrollably with a high pitch, and was lethargic and irritable.

(Ex. 100, p. 3.)

3. Naomi de la Torre

Naomi de la Torre submitted an affidavit on June 13, 2016, but did not testify at the fact hearing. (Ex. 102.) Ms. de la Torre alleged that she was "very close" to Mrs. Prokopeas, and thus was able to observe C.A.P.'s condition from his early years of life. (Ex. 102, p. 1.)

Ms. de la Torre alleged that she observed C.A.P. on March 20, 2002 -- *i.e.*, several weeks after his first set of vaccinations of February 5, 2002. (Ex. 102, p. 1.) She described C.A.P. as being "extremely sick" at that time, asserting that C.A.P. was fussy, had a runny nose, was "running a fever," and slept a majority of the day. (*Id.*) Similarly, she observed C.A.P. on July 23, 2002 (*i.e.*, the day after his vaccinations of July 22, 2002), describing him as having a fever, as being unable to sit still, and as crying uncontrollably. (*Id.*) Thereafter, Ms. de la Torre alleged that she observed C.A.P. on July 25, 2002, describing C.A.P. at that time, as having "a rash all over his body," crying uncontrollably, being "very upset," and "burning up with a fever of

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[30] Mr. Chrissikos was perhaps referring to C.A.P.'s emergency room visit of October 13, 2002. (*Compare* Ex. 35, pp. 16-19; *see also* pp. 14-15, above.)

103.9” degrees Fahrenheit. (Ex. 102, p. 1.) She alleged that C.A.P.’s high fever at that time lasted several days. (*Id.*)

Overall, Ms. de la Torre alleged that C.A.P. had ongoing symptoms of “rash,” “irritability,” “crankiness,” “inconsolability,” and “fever,” stating that she observed these symptoms “within a day of his vaccinations.” (Ex. 102, p. 2.) Moreover, she described C.A.P.’s condition after his twelve-month well-visit, alleging that he “appeared to be getting worse,” since he was not developing, not making eye contact, and perpetually fussy. (*Id.*, ¶ 6.) She further alleged that, over time, C.A.P. generally had “no expression on his face,” stopped laughing, and stopped smiling. (*Id.*, p. 3.)

V

SUMMARY OF PETITIONERS’[31] EXPERT WITNESSES’ QUALIFICATIONS AND OPINIONS

In this case, Petitioners relied upon expert reports of two medical experts for the proposition that vaccinations harmed C.A.P. -- Joseph Bellanti, M.D. (Exs. 87 and 89), and Jean-Ronel Corbier, M.D. (Exs. 98-99).[32] These two experts, Drs. Bellanti and Corbier, each relied on multiple factual assumptions about C.A.P.’s medical history that are *at variance* with his medical records. Thus, at this point, I will briefly summarize both the qualifications and opinions of these two expert witnesses, as they relate to the present “fact ruling.”

A. Petitioners’ expert Dr. Joseph Bellanti

1. Qualifications

Joseph Bellanti, M.D., earned his medical degree from the University of Buffalo School of Medicine in 1958. (Ex. 88, p. 3.) He subsequently completed his internship at Millard Fillmore Hospital in 1959, and his residency in pediatrics at Children’s Hospital of Buffalo in 1961. (*Id.*) From 1961 to 1962, he was a special National Institute of Health (NIH) trainee in Immunology at the University of Florida, subsequently working as a research virologist at Walter Reed Army Institute of Research, from 1962 to 1964. (*Id.*)

Dr. Bellanti has held a faculty position at Georgetown University School of Medicine since 1963, rising to the position of Professor of Pediatrics and Microbiology-Immunology in

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[31] Respondent has also filed the expert reports of two highly qualified expert witnesses, but I have not summarized those reports in this Ruling, since they are for the most part not relevant to the factual rulings that I am making in this Ruling. However, I do note that, unlike the Petitioners’ two primary causation experts, Respondent’s experts relied upon the facts contained in the medical records, rather than upon the additional representations in the Petitioners’ joint affidavit filed as Ex. 58.

[32] Petitioners also submitted an expert report of Brett Abrahams, Ph.D., but that report only disputes a point in the report of Respondent’s expert. Dr. Abrahams does *not* opine that vaccinations harmed C.A.P. (*See generally* Ex. 96.)

1970. (Ex. 88, p. 3.) Since 1975, Dr. Bellanti has concurrently served as the Director of the International Center for Interdisciplinary Studies of Immunology at Georgetown University. (*Id.*) Since 1980, he has also served as the Director of the Division of Immunology and Virology in the Department of Laboratory Medicine at Georgetown University. (*Id.*) Additionally, he holds an academic staff position in pediatrics at the Children's Hospital National Medical Center, concurrently holding clinical positions in the pediatrics departments of Arlington Hospital and INOVA Fairfax Hospital. (*Id.*, p. 1.)

Dr. Bellanti is certified by the American Board of Pediatrics, and holds the accreditation of a "Diplomate" from the American Board of Allergy and Immunology, and from the National Board of Medical Examiners. (Ex. 88, p. 4.)

Dr. Bellanti lists numerous accomplishments in his *curriculum vitae*. (*See generally* Ex. 88.) He has held over a dozen leadership positions in various scientific societies, and presently serves on the editorial board of five scientific publications. (*Id.*, pp. 5-6.) He has co-authored more than 200 research articles and more than 150 abstracts in peer-reviewed journals. (*Id.*, pp. 9-38.) He has also co-authored over 50 medical texts/book chapters (*id.*, pp. 38-39), and has been invited to give numerous presentations internationally (*id.*, pp. 9-11).

2. Summary of Dr. Bellanti's opinion

Dr. Bellanti opined that a "causal relationship" existed between the vaccines administered to C.A.P. in his first year of life, and his current "neurologic and developmental abnormalities." (Ex. 89, p. 2 of 3.) Specifically, he asserted that C.A.P.'s current developmental abnormalities are due to brain injuries caused by "repeated allergic (immune mediated) reactions to his vaccines received in 2002." (Ex. 87, p. 3 of 5, parenthetical in original.)

Notably, Dr. Bellanti based his opinion on *parental testimony*, describing symptoms allegedly suffered by C.A.P. immediately after he was administered each set of vaccinations during his first year of life. (Ex. 87, pp. 1-2 of 5.) In this regard, Dr. Bellanti asserted that C.A.P. "reacted similarly to each of his sets of vaccinations," including the "final Hepatitis B vaccination." (*Id.*, p. 3 of 5.) He opined that C.A.P.'s alleged post-vaccination symptoms after receiving each set of vaccinations, were, in fact, "reactions" to his administered vaccinations, deeming those "reactions" as "clearly" demonstrating that C.A.P. "was allergic to some components of the vaccines." (*Id.*)

Moreover, as to *how* C.A.P.'s particular condition was caused by the vaccinations administered to him in his first year of life, Dr. Bellanti seemed to simply rely on a *temporal association*. (Ex. 89, p. 3 of 3, ¶¶ 2 and 3.) In describing that alleged temporal association, Dr. Bellanti opined that C.A.P.'s case reflected "the striking history of a well child" who allegedly sustained "fever," "high pitched cry," and "developmental abnormalities" after his vaccinations. (*Id.*)

B. Petitioners' expert, Dr. Jean-Ronel Corbier

1. Qualifications

Jean-Ronel Corbier, M.D., earned his medical degree from Michigan State University, College of Human Medicine, in 1995. (Ex. 99, p. 6 of 10.) He completed his residency in pediatrics at Hurley Medical Center in 1997, later completing training in adult neurology at the University of Cincinnati in 1998. (*Id.*) In 2000, he completed a fellowship in pediatric neurology from the Children's Hospital Medical Center in Cincinnati, Ohio. (*Id.*) Since 2000, Dr. Corbier has been in private practice as a pediatric neurologist. (*Id.*, p. 8 of 10.) He is a member of several medical organizations, including the Child Neurology Society, American Academy of Neurology, the Medical Association of the State of North Carolina, and the American Board of Medical Specialists. (*Id.*) Dr. Corbier's *curriculum vitae* reflects that he has authored three books, in addition to co-authoring one research article, and has one research publication pending.[33] (*Id.*, p. 9 of 10.) He has also been invited to give several presentations in his medical specialty. (*Id.*)

2. Summary of Dr. Corbier's opinion

Dr. Corbier opined that "it is more likely than not" that C.A.P. "was vaccine injured," and that his "immunizations led to a chronic brain disorder" -- a brain disorder he varyingly termed as "static encephalopathy" or "chronic encephalopathy." (Ex. 98, p. 3 of 3; Ex. 99, pp. 4-5 of 10.) Regarding C.A.P.'s alleged "static encephalopathy," Dr. Corbier asserted that "[a]ll of [C.A.P.]'s problems" were essentially "the expression of his static encephalopathy" that "manifested within a day of his vaccinations." (Ex. 99, p. 5 of 10.) At another point in his reports, Dr. Corbier termed C.A.P.'s alleged brain disorder as "Vaccine Induced Encephalitis," defining that term as "an inflammation of the brain caused by vaccines." (Ex. 98, p. 4.)

Dr. Corbier's reports, however, were unclear as to exactly *what vaccinations* allegedly caused C.A.P.'s encephalopathy. In his first expert report, Dr. Corbier seemed to point exclusively to C.A.P.'s vaccinations of July 22, 2002, asserting that the "records show a significant vaccine reaction" at that time, and opining that that alleged "vaccine reaction" caused C.A.P. to "become lethargic," "lifeless," and "febrile" within 72 hours of his vaccinations. (Ex. 98, pp. 2 and 3 of 3.) In this regard, Dr. Corbier opined that after C.A.P.'s vaccinations of July 22, 2002, at age "7-months," C.A.P. suffered from a "series of neurological and immune problems," which, by "15-18 months" of age, led to C.A.P. developing "clear regressive symptoms," and becoming "encephalopathic." (*Id.*, p. 3 of 3.)

In his supplemental expert report, however, Dr. Corbier instead seemed to substantially change his causation opinion. Instead of pointing to *all* of C.A.P.'s vaccinations of *July 22*, 2002, he now pointed to the *pertussis* vaccinations (as part of the DTaP vaccinations) administered to C.A.P. on *several occasions* during his first year of life. (Ex. 99, pp. 3, 4 of 10.) In this regard, Dr. Corbier opined that the pertussis vaccinations caused C.A.P. to experience numerous symptoms, such as -- "irritability," "high fever," "lethargic state," "decreased responsiveness," "rash," "fussiness," and "decreased consciousness." (Ex. 99, p. 4 of 10.)

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[33] Dr. Corbier's research article appears to have been pending as of December 4, 2015, the date on which his *curriculum vitae* was submitted in this case.

Moreover, he deemed those alleged symptoms to be "evidence" of an "acute encephalopathy," which, according to Dr. Corbier, occurred on the "same day" as C.A.P.'s administered DTaP vaccinations of "2/5/2002, 4/9/2002, 7/22/2002 and 9/24/2002." (*Id.*)

Dr. Corbier further opined that C.A.P.'s "acute encephalopathy" eventually progressed to a "chronic encephalopathy," defining C.A.P.'s "chronic encephalopathy" to be "characterized by dysfunction in his cognitive and social skills." (Ex. 99, p. 3 of 10.) Moreover, he alleged that certain of C.A.P.'s alleged symptoms -- "fever," "irritability," "decreased responsiveness," and "rash" -- were observed within the "time period after immunization" during which children experience an "increased risk of encephalopathy." (*Id.*) Thus, he ultimately opined that C.A.P.'s "chronic encephalopathy resulted from his pertussis vaccination." (*Id.*)

Dr. Corbier acknowledged, however, that C.A.P.'s "medical records did not document" "certain symptoms" that allegedly were suffered by C.A.P. (Ex. 98, p. 3 of 3.) Thus, Dr. Corbier admitted to relying on *parental assertions* of C.A.P.'s alleged medical history, in order to formulate certain factual assumptions upon which his expert opinion is based in this case. (Ex. 98, p. 3 of 3; Ex. 99, p. 3 of 10.)

VI

SCOPE OF RULING AND FACTUAL ISSUES TO BE DECIDED

The record in this case includes, as relevant to this Ruling, a large volume of medical records, affidavits of Petitioners and their family friends, Mrs. Prokopeas' testimony at the fact hearing, and the reports of two experts for the Petitioners. Petitioners' two experts both base their causation opinions not primarily upon the medical records, but most heavily upon the *additional symptoms* allegedly displayed by C.A.P. during his first years of life, as set forth in the affidavits of the Petitioners and their friends, plus Mrs. Prokopeas' hearing testimony. Petitioners, thus, at this time seek my ruling concerning the facts of C.A.P.'s early years of life. Specifically, I am asked to rule whether the *additional facts* alleged by C.A.P.'s parents and their friends concerning C.A.P. -- *i.e.*, those facts that *do not* appear in C.A.P.'s *contemporaneous* medical records -- are accurate descriptions of C.A.P.'s medical history. Because of the absence from the medical records of most of the symptoms alleged by the parents and family friends, Petitioners' counsel requested that I conduct a fact hearing, and rule upon whether the parental and friend accounts can be credited. (ECF No. 116.)

To summarize my factual finding below, I *do not* find, to be reliable, the written and oral testimony offered by C.A.P.'s parents and family friends, alleging that C.A.P. suffered additional post-vaccination symptoms after each set of vaccinations administered to C.A.P. in his first year of life -- *i.e.*, alleged symptoms that are not already reflected in his contemporaneous medical records. I emphasize that I am not questioning the sincerity or honesty of the Petitioners, or the other affiants. I simply find the *contemporaneous medical records*, reflecting C.A.P.'s condition at the time his parents sought medical care during his first year of life, to be more reliable.

To summarize my discussion below, I first set forth, in Section VII, my general reasons for relying on the contemporaneous medical records from C.A.P.'s first year of life over the

written and oral testimony of the Petitioners and additional affiants, alleging that C.A.P. suffered additional post-vaccination symptoms after each set of vaccinations. Thereafter, in Section VIII, I set forth my reasons as to why I find two specific parental narratives of C.A.P.'s medical history, as relayed to C.A.P.'s medical care providers at Ex. 5, pp. 2-3, and Ex. 69, pp. 4-5, to be *inconsistent* with C.A.P.'s earlier *contemporaneous* medical records, and thus, I find them to be unreliable. Next, in Section IX, in order to provide clarity, I list some of the critical assertions of the Petitioners and their close family friends that I *specifically reject*. Thereafter, in Section X, I list the incorrect assumptions of fact found in Petitioners' expert reports from Drs. Bellanti and Corbier. Finally, in Section XI, I issue a *warning to Petitioners' counsel* to carefully assess the reasonableness of moving forward with this case.

VII

GENERAL REASONS FOR MY FINDING THAT C.A.P.'S MEDICAL RECORDS FROM HIS FIRST YEAR OF LIFE ARE <u>*MORE RELIABLE*</u> THAN LATER PARENTAL AND FRIEND STATEMENTS ALLEGING ADDITIONAL SYMPTOMS <u>*NOT REFLECTED*</u> IN THOSE MEDICAL RECORDS

In the discussion below, I highlight several reasons as to why I find C.A.P.'s medical records from his first year of life, reflecting C.A.P.'s symptoms as *contemporaneously* reported by his parents to his medical care providers, to be much more reliable than the parental and friend narratives, made later in time, concerning his alleged post-vaccination symptomatology. Specifically, I *reject* the statements made by Petitioners and their friends in the course of this litigation, alleging *additional symptoms* purportedly suffered by C.A.P. after each set of vaccinations administered to him in his first year of life -- *i.e.*, alleged symptoms that are *not reflected* in his contemporaneous medical records.

A. The stark contrast between the contemporaneous medical records and the affidavits and fact hearing testimony of Petitioners and friends

The chief reason why I must credit the *contemporaneous* medical records over the proffered affidavits and the fact hearing testimony of Mrs. Prokopeas is simply that there was such a *stark contrast* between the contemporaneous medical records and the affidavits/fact hearing testimony. The affidavits and fact hearing testimony allege that C.A.P. suffered a number of *very dramatic and serious symptoms*, in close proximity to each of his 2002 vaccinations. Yet those serious or dramatic symptoms were *not recorded at all* in the *contemporaneous* medical records. This stark contrast simply makes the parents' and friends' later recollections seem unbelievable. That is, if in fact C.A.P.'s symptoms took place as the parents and friends later alleged, then his parents, as concerned, caring parents, would *certainly* have reported those symptoms during their many contacts with C.A.P.'s medical care providers throughout his first year of life. The absence of those symptoms in the contemporaneous medical records indicates that the parents and friends are *not* remembering C.A.P.'s symptoms *accurately*. Some examples of this stark contrast are detailed below.

1. Example one: Alleged symptoms after vaccinations of February 5, 2002

As the first example, Mrs. Prokopeas testified that "within a few minutes" of C.A.P.'s first set of vaccinations, on February 5, 2002, he began to scream and cry uncontrollably, followed by a "deep sleep for many hours." (Ex. 58, p. 1; Tr. 11-14.) She alleged that even after C.A.P. woke up he was screaming and crying, rejected nursing, had lost his appetite, appeared "very weak," and ran a fever of 103.9 degrees Fahrenheit overnight. (Tr. 14-15.) Mrs. Prokopeas added that she called C.A.P.'s pediatrician the next morning (*i.e.*, on February 6, 2002), to report those symptoms. (Tr. 15.) Additionally, Mrs. Prokopeas alleged that C.A.P. *rejected nursing for five days* after February 5. (Ex. 58, p. 1, ¶ 4.)

The contemporaneous medical records, however, present an entirely different story. The record of the visit of February 5 indicates that several vaccinations were given, but does not indicate *any reaction at all* to them. (Ex. 34, p. 34 of 39.) Further, while other phone calls on other days by C.A.P.'s parents to his pediatricians were explicitly recorded in the pediatrician's records (*e.g.*, Ex. 34-2, pp. 31, 36, 37; Ex. 10, p. 4 of 15), there is *no mention* in the medical records of any call on February 6, 2002. (Ex. 34-2, pp. 34-35.) Finally, during C.A.P.'s next regular visit on April 9, 2002, no mention is made of any unusual behavior by C.A.P. after the February 5 vaccinations. (Ex. 34-2, p. 35.)

Thus, if after the February 5 vaccinations, C.A.P. really had screamed uncontrollably, run a fever of 103.9 degrees, and stopped nursing for *five days*, it seems *extremely likely* to me that C.A.P. would have been taken back to the pediatrician, and such symptoms would have been *recorded in the medical records*.

2. Example two: Alleged symptoms after vaccinations of April 9, 2002

Mrs. Prokopeas also asserted that after receiving his vaccinations of April 9, 2002, C.A.P. experienced symptoms "very similar" to those that he had after his first set of vaccinations (*i.e.*, screaming, uncontrollable crying, rejecting nursing, falling into a deep sleep, and developing a fever). (Tr. 16-17; Ex. 58, p. 1, ¶ 5.) She stated that she called C.A.P.'s pediatrician after that incident, but was assured that C.A.P.'s symptoms were normal. (Ex. 58, p. 1, ¶ 5.)

However, again the contemporaneous records of C.A.P.'s pediatrician *contradict* Mrs. Prokopeas' testimony. The record of April 9, 2002, does not indicate any immediate reaction by C.A.P. to his vaccinations (Ex. 34-2, p. 35 of 39), and there is no mention anywhere in the contemporaneous medical records of *any* symptoms in C.A.P. around this time period, or of any phone call or visit by C.A.P.'s parents to the practice on or soon after April 9. Further, on the same page as the record of the pediatric visit of April 9, 2002, there is a note concerning another pediatric visit later that month. (Ex. 34-2, p. 35 of 39.) The date of that visit was miswritten on the medical chart, recorded as "04/300/2." But it seems clear that the actual visit date was April 30, 2002, with the second "slash" having been accidentally misplaced -- the apparent intent was to write "04/30/02." And that record of April 30, 2002, makes no mention of *any* symptoms by C.A.P. in the several days after the vaccinations on April 9, 2002, much less the serious, dramatic symptoms reported by Petitioners in this litigation. The April 30 notation states only that C.A.P. had suffered from a cough, a runny nose, and a "rash throughout body," for one week prior to the April 30 visit, or since April 23, 2002.

3. Example three: Alleged symptoms after vaccinations of July 22, 2002

Describing C.A.P.'s alleged symptomatology after his vaccinations of July 22, 2002, Mrs. Prokopeas indicated that his third set of vaccinations "seemed to do the most harm so far." (Ex. 58, p. 1, ¶ 6.) She stated that C.A.P. had "[v]ery much the same symptoms" as he had after his first two rounds of vaccinations (*i.e.*, screaming, uncontrollable crying, rejecting nursing, falling into a deep sleep, and developing a fever). (Tr. 20; Ex. 58, pp. 1-2.) She testified that C.A.P. had a fever of 103.9 degrees Fahrenheit on the night of July 22 -- a temperature that she alleged lasted "for days." (Ex. 58, pp. 1-2; Tr. 20-21.)

Mrs. Prokopeas testified that she called C.A.P.'s pediatrician's office on July 23, 2002, and spoke with a nurse, reporting that C.A.P. had a fever, was miserable, could not open his eyes, rejected nursing, seemed to be "very weak," and "appeared lifeless." (Tr. 21-22.) She further testified that when C.A.P.'s pediatrician called her back later that same day, she told the pediatrician that C.A.P. had the "same symptoms" as earlier that day. (*Id.*)

However, again the contemporaneous records paint quite a different picture. Those records indicate a call from Mrs. Prokopeas on July 23, 2002, reporting a fever of 102-103 degrees, and that C.A.P. had been "fussy," but that he was feeling better after taking Motrin, and was "eating ok." (Ex. 34-2, p. 36 of 39.) The records indicate a second phone call that day between Mr. Prokopeas and the office, recording that C.A.P. still had a fever of 102-103 degrees, but that he was also "playful," and had *no other symptoms* beside the fever. (*Id.*, p. 37.) The records further reflect that C.A.P. was taken back to his pediatrician on July 24, with a fever of up to 103 degrees, with his parents then describing him as "not himself." (*Id.*) C.A.P. was also taken to another pediatrician, Dr. Porter, on July 25, with a brief history of fever, vomiting, and diarrhea; but at that visit C.A.P. was also reported to have breastfed three times that day with no further diarrhea, and Dr. Porter observed C.A.P. to be "happy" and "playful." (Ex. 10, p. 4 of 15.)

In other words, the medical records tell a distinctly different story from that told by Petitioners' proffered affidavits and testimony, concerning the time period immediately after the vaccinations of July 22, 2002. There was no mention whatsoever in the medical records of the screaming, uncontrollable crying, or an extended refusal to nurse, as alleged by Petitioners in this Program proceeding. Instead, in the phone call records of July 23, C.A.P. is described as "eating ok," and as having *no other symptoms* except for fever. (Ex. 34-2, p. 36 of 39.) And in the records of July 24 and 25, C.A.P. is described not as miserable, but as "playful" (Ex. 34-2, p. 37 of 39; Ex. 10, p. 4) and "happy" (Ex. 10, p. 4).

4. Example four: Symptoms after vaccination of September 24, 2002

Mrs. Prokopeas stated that after C.A.P.'s Hepatitis B vaccination of September 24, 2002, C.A.P. experienced symptoms "almost identical" to those that he had experienced after his prior rounds of vaccinations. (Tr. 32-34; Ex. 58, p. 2.) She alleged that immediately after that vaccination, C.A.P. started crying, was screaming, was "very upset," rejected nursing, was unhappy, and slept for "many hours." (*Id.*) She further testified that those symptoms continued for a *week*, and she noticed him "getting worse," prompting her to take C.A.P. to the pediatrician on September 30, 2002. (Tr. 34; Ex. 58, p. 2.) Mrs. Prokopeas recalled reporting to the

pediatrician that C.A.P. was "just very, very sick," additionally reporting that he was not nursing and was screaming. (Tr. 34.)

However, the actual record of the visit on September 30 states *only* that C.A.P. had congestion and a runny nose for three days, plus sneezing, vomiting, teething, and poor sleep. (Ex. 10, p. 3 of 15.) No mention was made of screaming, uncontrollable crying, or fever. (*Id.*)

5. Summary concerning this "stark contrast"

As these four examples demonstrate, the very stark contrast between (1) the allegations of the Petitioners' proffered affidavits and testimony, and (2) the actual contemporaneous medical records, are a strong reason why I find the *contemporaneous medical records* to be much more reliable than the allegations of the parents and friends made in this litigation.

6. Additional reason for finding the stark contrast to be problematic

This is especially true since the medical records, taken as a whole, indicate that C.A.P.'s parents were *not shy* about communicating with C.A.P.'s health care providers by telephone, or through office visits, during C.A.P.'s first year of life. *See* "patient phone call records" of: December 27, 2001 (Ex. 34-2, p. 31); July 23, 2002 (Ex. 34-2, p. 36); July 23, 2002 (Ex. 34-2, p. 37.); and August 13, 2002 (Ex. 10, p. 4 of 15). *See also* C.A.P.'s office visits of: December 11, 2001 (Ex. 34-2, p. 30); December 20, 2001 (*id.*, p. 32); December 27, 2001 (*id.*, pp. 31-32); January 8, 2002 (*id.*, p. 33); February 5, 2002 (*id.*, p. 34); April 9, 2002 (*id.*, p. 35); April 30, 2002 (*id.*, p. 35); July 22, 2002 (*id.*, p. 36); July 24, 2002 (*id.*, p. 37); July 25, 2002 (Ex. 10, p. 4 of 15); August 14, 2002 (*id.*); September 24, 2002 (*id.*, p. 3 of 15); and September 30, 2002 (*id.*). Therefore, since C.A.P.'s parents were quick to report by phone relatively minor symptoms of C.A.P., and to bring him in to the doctor with relatively minor ailments, it seems *extremely unlikely* that they would have failed to bring C.A.P. in, or even to report the symptoms during C.A.P.'s next visit, if in fact C.A.P. actually displayed the dramatic and serious symptoms reported in the affidavits and testimony of the parents and friends.

B. Other reasons for rejecting the Petitioners' and friends' allegations of symptoms that are not reported in the contemporaneous medical records

1. Mrs. Prokopeas' fact hearing testimony suffered from several flaws, and was unpersuasive overall.

As part of my reasons for my general conclusion set forth in this Section VII, I note specifically that I cannot credit the fact hearing testimony, of Mrs. Prokopeas, for additional reasons as well. Her testimony suffered from extensive flaws, rendering her entire testimony to be unpersuasive overall. Specifically, Mrs. Prokopeas' testimony (1) appeared to be mainly a recitation of her written notes, and (2) was compromised by Petitioners' counsel's strategy of asking leading questions throughout the fact hearing -- both of which led me to question whether Mrs. Prokopeas, by the time of hearing (14 years after the vaccinations in question), had an accurate, independent recollection of C.A.P.'s early months of life.

a. *Mrs. Prokopeas' fact hearing testimony appeared to be a recitation of her written notes.*

I highlight that for the majority of her fact hearing testimony, Mrs. Prokopeas appeared to be reading from prepared written notes that she had with her on the witness stand. Hence, instead of relying on *her memory* to offer an accounting of C.A.P.'s alleged post-vaccination symptoms, Mrs. Prokopeas' oral testimony was, in essence, a *reading of her prepared notes*. (*E.g.*, Tr. 11-12 (reading from a "piece of paper"); Tr. 14 (Mrs. Prokopeas stating that "looking at my records," C.A.P. had a fever of "103.9" degrees Fahrenheit after his vaccinations of February 5, 2002); Tr. 17 (after Mrs. Prokopeas stated that she was "looking at my notes," she proceeded to testify about C.A.P.'s symptoms after his vaccinations of April 9, 2002); Tr. 26-27 (Mrs. Prokopeas appeared to be reading from her notes while testifying about C.A.P.'s symptoms after his vaccinations of July 22, 2002); Tr. 28-29 (Mrs. Prokopeas appeared to be reading from her notes while testifying about C.A.P.'s alleged lack of eye contact after his vaccinations of July 22, 2002); Tr. 33-34 (Mrs. Prokopeas appeared to be reading from her prepared notes while testifying about C.A.P.'s symptoms after his vaccination of September 24, 2002).)

I further note that at the fact hearing, Petitioners' counsel acknowledged that at least one of those prepared records relied upon by Mrs. Prokopeas during her testimony was Exhibit 58 -- *i.e.*, Petitioners' joint affidavit. (Tr. 26-27.) Moreover, I then requested that Mrs. Prokopeas discontinue reading from that affidavit, encouraging her to rely instead upon *her memory* to testify about C.A.P.'s post-vaccination symptoms during his first year of life. (Tr. 26-27.) However, even after I made several requests that she discontinue reading from her prepared notes (*e.g.*, Tr. 27-29), Mrs. Prokopeas failed to comply, and continued reading from those notes (Tr. 33-34). Thus, for that reason alone, I found Mrs. Prokopeas' testimony at the fact hearing to be unpersuasive, and I cannot give it any substantial weight.[34]

b. *Petitioners' counsel asked leading questions throughout the fact hearing.*

Another reason why I afford little weight to Mrs. Prokopeas' testimony during the fact hearing is that Petitioners' counsel used a strategy of asking leading questions throughout that hearing. In this regard, Petitioners' counsel was blatantly obvious in asking leading questions in order to elicit certain testimony to substantiate critical factual assumptions relied upon in the Petitioners' expert reports submitted in this case. I highlight two examples below.

In one such instance, Petitioners' counsel asked repeated leading questions. (Tr. 18-19.) Specifically, Petitioners' counsel asked the following leading questions while questioning Mrs. Prokopeas about C.A.P.'s visit to the pediatrician in April of 2002:

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[34] I am sympathetic to the fact that fourteen years after the events in question, Mrs. Prokopeas could not reasonably be expected to remember all details of the events in question. But since the *entire purpose* of the fact hearing was to *buttress*, by oral testimony, the previously-filed affidavits, then it seemed pointless to me *for Petitioners' counsel* to simply have the witness read from the very affidavit that her testimony was intended to support. (Of course, I fault Petitioners' counsel, not Mrs. Prokopeas, for this flawed trial strategy.)

Q: Okay. *And that's your recollection, that you took him in because he was having these symptoms after the vaccinations, is that correct*?

A: Well, I took him in because he still had the same symptoms. He was coughing; he had a runny nose. It had been close to a week now. He didn't have a fever, but he did have the rash throughout his body.
Q: And that was – *that rash had started shortly after the vaccinations; is that correct?*

A: Yes. All of this has been going on since Tuesday. Since the day he was vaccinated.

(Tr. 18-19, emphasis added.)

Similarly, Petitioners' counsel asked another clearly leading question in an attempt to elicit testimony by Mrs. Prokopeas, specifically regarding C.A.P.'s alleged loss of eye contact after his vaccinations of July 22, 2002 -- *i.e.*, a critical alleged fact *at variance* with C.A.P.'s contemporaneous medical records from his first year of life. In this regard, Petitioners' counsel attempted to elicit an answer from Mrs. Prokopeas to the following question at the fact hearing:

Q: *Did you notice anything after those vaccines with regard to his eye contact and his responding to you?*

(Tr. 28, emphasis added.) At that point, I *explicitly* asked Petitioners' counsel to *discontinue* asking leading questions critical to substantiating Petitioners' expert reports submitted in this case. (Tr. 28-29.) However, Petitioners' counsel continued to ask such leading questions to elicit answers from Mrs. Prokopeas. (*E.g.*, Tr. 33.)

Thus, this behavior -- *i.e.*, Petitioners' counsel's repeated leading questioning at the fact hearing -- added another reason for me to discount the accuracy of the testimony of Mrs. Prokopeas at the fact hearing.

c. Phone log of C.A.P.'s pediatrician

Moreover, I highlight that Mrs. Prokopeas alleged that she made a telephone call to C.A.P.'s pediatrician on February 6, 2002, to complain of C.A.P.'s symptoms after his vaccinations of February 5, 2002. (Tr. 15.) Similarly, she also testified to making a telephone call to the pediatrician on April 9, 2002, to complain of C.A.P.'s symptoms after his vaccinations earlier that day. (Ex. 58, p. 1, ¶ 5.) However, the records from C.A.P.'s pediatrician at the time -- *i.e.*, Pediatric Associates of Dallas -- *do not* reflect that his parents made contact with the office on those dates. (*See* Ex. 34-2 generally.) In this regard, I note that the records from Pediatric Associates of Dallas reflect that that pediatrician's office kept relatively detailed records of parental phone calls, prior to and after the dates upon which C.A.P.'s parents alleged they called the pediatrician's office. (*See* "patient phone call records" of December 27, 2001 (Ex. 34-2, p. 31)); July 23, 2002 (Ex. 34-2, pp. 36-37) (two separate call notes); and August 13, 2002 (Ex. 10, p. 4 of 15). Thus, I find that it would be *unlikely* that a staff member from that pediatrician's office would not have documented the alleged phone calls on February 6 and April 9, 2002, if in fact Mrs. Prokopeas had made those calls.

d. Inconsistencies between affidavits and fact hearing testimony

I additionally note that were several *internal inconsistencies* between Mrs. Prokopeas' written statements in the joint affidavit (Ex. 58) and her fact hearing testimony. I discuss a few of those instances below.

i. C.A.P.'s alleged high fever after his vaccinations of February 5, 2002, and allegations of a phone call made to his pediatrician on February 6, 2002

At the fact hearing, Mrs. Prokopeas asserted that after C.A.P.'s vaccinations of February 5, 2002, (1) C.A.P. ran a fever of 103.9 degrees that night, and (2) she called C.A.P.'s pediatrician the morning of February 6, 2002, to report his fever symptoms. (Tr. 14-15.) I note, however, that that oral testimony was *inconsistent* with written testimony provided by Mrs. Prokopeas in her previously-filed affidavits.

For example, *none* of the affidavits submitted by Mrs. Prokopeas previously alleged that C.A.P. had any type of *high* fever, much less a temperature of 103.9 degrees, after his vaccinations of February 5, 2002. (*See* Ex. 58, p. 1 of 5 (discussing C.A.P.'s condition after his vaccinations of February 5, 2002).) Additionally, another of her allegations at the fact hearing, that she phoned the pediatrician's office on February 6, 2002, was never mentioned in any of her previous affidavits. (*See generally* Exs. 58, 91, and 101.)

ii. Allegations regarding the severity of certain of C.A.P.'s symptoms after his vaccinations of July 22, 2002

In one of her affidavits, Mrs. Prokopeas asserted that C.A.P. experienced numerous symptoms after his vaccinations of July 22, 2002. (Ex. 58, p. 2.) Specifically commenting on some of those symptoms -- vomiting, fever, failure to nurse, and diarrhea -- Mrs. Prokopeas stated that those symptoms were "still going on even *three weeks later*" (*i.e.*, three weeks after his vaccinations of July 22, 2002). (*Id.*, emphasis added.) Moreover, Mrs. Prokopeas also described additional symptoms as occurring in late July or August, including crying, being miserable, only sleeping two hours per night, having intermittent "high fevers," being difficult and demanding, having a "lack of eye contact," and developing "random outbursts" for no apparent reason. (*Id.*)

At the fact hearing, however, Mrs. Prokopeas' described C.A.P.'s symptoms after his vaccinations of July 22, 2002, as being *far less* severe than those stated in her affidavit. (*See* Tr. 20-31 generally.) Notably, at the hearing, Mrs. Prokopeas did not describe C.A.P. having a lack of eye contact,[35] or having random outbursts in the period following his vaccinations of July 22, 2002. (*Id.*) Moreover, regarding C.A.P.'s symptoms of vomiting, inability to nurse, and diarrhea, Mrs. Prokopeas did not state at the fact hearing that those symptoms were *continuously* ongoing

[35] At this point in the fact hearing, I admonished Petitioners' counsel for attempting to ask a leading question, regarding C.A.P.'s alleged lack of eye contact immediately after his vaccinations of July 22, 2002, in an attempt to elicit testimony from Mrs. Prokopeas concerning that critical allegation of fact in this case. (Tr. 28-29.) However, Mrs. Prokopeas did not give an answer to that leading question. (*Id.*)

for *three consecutive weeks* after his vaccinations of July 22, 2002, as the Petitioners had alleged in their joint affidavit. (Tr. 29-30; *compare* Ex. 58, p. 2.) In this regard, although Mrs. Prokopeas testified about C.A.P. having symptoms on or about July 25, 2002, she also testified that, after his sick visit on July 25, C.A.P. "seemed to have been getting better" (Tr. 29-30) (although apparently he did "have some" symptoms again in the days prior to August 13, 2002 (Ex. 10, p. 4 of 15).)

C. Summary of Section VII

For all of the reasons outlined above in this Section VII, I find that C.A.P.'s medical records from his first year of life, reflecting C.A.P.'s symptoms as contemporaneously reported by his parents to his medical care providers for the purposes of seeking treatment, to be *far more reliable* than the parental and friend narratives of his alleged post-vaccination symptomatology made later in time, for the purposes of advancing this litigation. In this regard, I *do not* find sufficient indicia of reliability in the written and oral testimony of Mr. and Mrs. Prokopeas, and their friends, to credit their testimony over the evidence found in the contemporaneous records. Thus, I *generally reject* allegations made by Petitioners and their close family friends of *additional post-vaccination symptoms* purportedly suffered by C.A.P. after each set of vaccinations -- *i.e.*, alleged symptoms that are not reflected in C.A.P.'s contemporaneous medical records from his first year of life.

VIII

I *REJECT* TWO SPECIFIC *RETROSPECTIVE* PARENTAL NARRATIVES GIVEN TO C.A.P.'S MEDICAL CARE PROVIDERS CONCERNING HIS PURPORTED MEDICAL HISTORY IN HIS EARLY MONTHS OF LIFE

In regard to the issue of determining an accurate medical history of C.A.P.'s first months of life, I add that while I credit the *contemporaneous* medical records, I do *not* credit *two specific parental narratives* given *much later* to C.A.P.'s medical care providers, concerning his medical history from his early months of life. Those two unacceptable narratives are: (1) the medical history reported by the Petitioners to Dr. Kotsanis during C.A.P.'s telephonic phone consultation of January 6, 2004 (Ex. 5, pp. 2-4); and (2) the medical history reported by Mr. Prokopeas to Dr. Brasted during C.A.P.'s psychological evaluation of October 11, 2004 (Ex. 69, pp. 4-5).

At the outset, I point out that in this case, as in most Program cases, I generally afford the most weight to those medical histories that represent the *contemporaneous* recitation of symptoms *then taking place*. In this case, however, the two particular medical histories listed above do *not* contemporaneously describe symptoms then happening, or that happened in the previous several days, but instead describe symptoms that allegedly happened *more than a year* beforehand.[36] And those two histories are so *drastically inconsistent* with the *contemporaneous* medical records, as well as with the majority of the other medical histories contained in C.A.P.'s medical records, that I cannot rely upon those two histories as accurate. In the discussion below,

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[36] Respondent's expert, Dr. Judith Miller, also seemed skeptical of Dr. Kotsanis' report, for the same reason. (Ex. H, pp. 7-8 of 9.)

I highlight the specific problems I have with each of those two purported medical histories, and why I ultimately find them to be unreliable.

A. Parental narrative of C.A.P.'s medical history relayed to Dr. Kotsanis in the phone consultation of January 6, 2004

1. The parental narrative of C.A.P.'s medical history, provided by Petitioners to Dr. Kotsanis in January of 2004, is drastically at variance with the contemporaneous accounts of C.A.P.'s symptomatology, given by Petitioners to his medical care providers during his first year of life.

After carefully comparing the parental narrative of C.A.P.'s medical history given to Dr. Kotsanis[37] in January of 2004 with their *other histories* made to C.A.P.'s medical care providers during his early years of life, I find that the medical history reported by the parents to Dr. Kotsanis in January of 2004 is drastically *at variance* with the large majority of the medical histories contained *throughout* C.A.P.'s medical records, as well as with all the medical records made during C.A.P.'s first year of life.

In January of 2004, Petitioners recounted to Dr. Kotsanis a history of C.A.P.'s developmental milestones, reporting that "C.A.P. had met all his developmental milestones until *July 2002*, but that they started noticing problems *after his vaccinations administered that month*." (Ex. 5, pp. 2-3, emphasis added.) Thus, in January of 2004, C.A.P.'s parents reported that they *first noticed* issues with C.A.P.'s development as early as *July of 2002* (*i.e.*, when C.A.P. was approximately seven months of age). However, that accounting of the approximate timeframe of when the Petitioners started noticing C.A.P.'s developmental problems is *inconsistent with prior and subsequent accounts* given by the Petitioners to various other medical care providers.

First, in statements made by Petitioners to C.A.P.'s various medical care providers *prior to January of 2004* -- *i.e*, from October 2003 to December 2003 -- the parents reported that they started noticing problems with C.A.P.'s development (specifically with his verbalization skills), *after C.A.P.'s head injury in September or October of 2003*. (*E.g.*, Ex. 67, p. 3; Ex. 54-1, p. 3; Ex. 54-1, p. 4; Ex. 54-2, pp. 43-44.)

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[37] I once again highlight that Dr. Kotsanis' role in providing care for C.A.P. is unclear in this case. Moreover, Ex. 25, p. 52 reveals that Dr. Kotsanis is a founding member of Defeat Autism Now ("DAN"), an organization that promotes "alternative" theories concerning autism. (Ex. 25, p. 52.) In this regard, I note that in his phone consultation note of January 6, 2004, Dr. Kotsanis recorded that "[i]n the summer/fall of 2002," C.A.P.'s parents attended one of Dr. Kotsanis' "public lectures" during which he advised them to "do a comprehensive pediatric evaluation with a pediatrician that is aware of possible postvaccination injury." (Ex. 5, p. 3.) Thus, at the very least, it seems that as early as 2002, Dr. Kotsanis was actively advocating for Petitioners to seek out pediatricians who believed in the idea of "possible postvaccination injury" in relation to *autistic* children, and may have played some role in the parents' decisions to withhold future vaccinations. (*Id.*)

Second, in several accounts given by C.A.P.'s parents *after January of 2004*, they once again reported that they started noticing problems with C.A.P.'s development *after his head injury in September or October of 2003*. (*E.g.*, Ex. 16, p. 1; Ex. 9, p. 1.) For instance, in an audiological evaluation of February 2004, Mrs. Prokopeas reported that her concerns about C.A.P.'s development had "began in *October of 2003*, when [C.A.P.] had an injury to his forehead." (Ex. 16, p. 1, emphasis added.) Similarly, in a psychological evaluation of July of 2004, Mrs. Prokopeas gave the following accounting of C.A.P.'s developmental history:

> This past *November [of 2003]* [C.A.P.]'s parents noted a *substantial change* in his behavior. He began fussing and crying much more than previously had been the case, his eye contact, reported as previously typical, became briefer and less consistent, he responded less consistently to people speaking to him, and his attention span shortened considerably, as well as he became more insistent upon things and activities being as he preferred.

(Ex. 9, p. 1, emphasis added.)

Thus, in the time period surrounding the phone consultation of January 6, 2004, I can point to *six separate instances* during which the Petitioners relayed to C.A.P.'s various medical care providers that they *first* started noticing problems with C.A.P.'s development *after his head injury in September or October of 2003*. (*E.g.*, Ex. 67, p. 3; Ex. 54-1, p. 3; Ex. 54-1, p. 4; Ex. 54-2, pp. 43-44; Ex. 16, p. 1; Ex. 9, p. 1.) In this regard, I highlight that the approximate timeline provided by Petitioners to Dr. Kotsanis in January of 2004, specifically regarding when the parents *first* started noticing C.A.P.'s developmental problems, is *drastically inconsistent and at variance* with the majority of such timelines provided to other of C.A.P.'s medical care providers.

Thus, for the reasons stated above, I find Petitioners' observations to Dr. Kotsanis in January of 2004, concerning C.A.P.'s developmental history, to be so inconsistent with the majority of the other medical histories relayed by them, that I do not rely on the medical history found on Ex. 5, pages 2-3.

B. C.A.P.'s purported medical history reported by Mr. Prokopeas during C.A.P.'s psychological evaluation in October of 2004

I additionally note that the medical history provided by Mr. Prokopeas during C.A.P.'s psychological evaluation of October 2004, was also *substantially different* from the majority of the medical histories contained in the record of this case. Specifically, on October 11, 2004, C.A.P. underwent a psychological evaluation by William Brasted, Ph.D. (Ex. 69.) At that time, Mr. Prokopeas reported an oral history of C.A.P.'s development to Dr. Brasted. In relevant part, Dr. Brasted recorded the following about C.A.P.'s developmental history:

> At 9-12 months, the family noticed that [C.A.P.] was not achieving developmental milestones within normal limits. He [sic] speech appeared delayed. At 9 months of age, [C.A.P.] appeared to have a reaction to his immunization shots. He began having *temper tantrums* and *banging his head at 12 to 14 months of age* and was easily irritated.

(Ex. 69, p. 4 of 5, emphasis added.) In other words, in October of 2004, Mr. Prokopeas relayed to Dr. Brasted that the parents noticed C.A.P.'s developmental problems *as early as September of 2002* -- a time frame which is *drastically inconsistent* with the majority of the observations provided to other of C.A.P.'s medical care providers. In fact, the large majority of the medical histories given by Petitioners in the medical records submitted in this case reflect that the parents started noticing problems with C.A.P.'s development after his *head injury in September or October of 2003*. (*E.g.*, Ex. 67, p. 3; Ex. 54-1, p. 3; Ex. 54-1, p. 4; Ex. 54-2, pp. 43-44; Ex. 16, p. 1; Ex. 9, p. 1.)

Moreover, as alleged in Dr. Brasted's evaluation of October 2004, Mr. Prokopeas' report that C.A.P.'s alleged temper tantrums and head-banging started as early as when C.A.P. was "12 to 14 months" of age, is *greatly at variance* with other medical histories provided of C.A.P. (Ex. 69, pp. 4-5.) In fact, in numerous medical histories provided to C.A.P.'s medical care providers *prior to* C.A.P.'s evaluation in October of 2004, C.A.P.'s parents make *no mention* of his temper tantrums and head-banging symptoms as having started as early as when he was twelve months of age. (*E.g.*, Ex. 67, p. 3; Ex. 54-1, p. 3; Ex. 54-1, p. 4; Ex. 54-1, pp. 29-31; Ex. 54-2, pp. 43-44; Ex. 16, p. 1; Ex. 9, p. 1; Ex. 18, p. 7.)

Similarly, in medical histories contained in C.A.P.'s medical records *subsequent to* his evaluation of October 2004, his parents again reported a version of C.A.P.'s medical history that *contradicts* Mr. Prokopeas' statements in October of 2004. For instance, on November 8, 2004, C.A.P. was examined by Dr. Tardo for a possible autism diagnosis. (Ex. 75, p. 2.) At that time, Dr. Tardo recorded an oral history of C.A.P.'s development, as reported to her by Mrs. Prokopeas. (*Id.*) In that history, Mrs. Prokopeas made *no mention* of C.A.P.'s head-banging symptoms. (*Id.*) Moreover, during Dr. Tardo's evaluation of November 8, 2004, Mrs. Prokopeas reported that she became concerned about C.A.P.'s development "when he was approximately *20 months of age*," but that she initially thought that C.A.P. was "just a late talker." (*Id.*, emphasis added.)

Because of the inconsistencies mentioned above, I find Mr. Prokopeas' observations to Dr. Brasted in October of 2004, concerning C.A.P.'s neurodevelopmental medical history, to be *drastically inconsistent* with the majority of the other medical histories relayed by the Petitioners in the medical records submitted in this case. Thus, I do not rely on the medical history found on Ex. 69, pages 4-5 of 5.

C. Summary of Section VIII

As highlighted above, upon my close examination of C.A.P.'s medical records, I do not credit *two specific medical histories* reported to C.A.P.'s medical care providers concerning C.A.P's medical history concerning his early months of life. I find Petitioners' observations (1) to Dr. Kotsanis in January of 2004, as reflected in Ex. 5, pp. 2-3, and (2) to Dr. Brasted in October of 2004, as reflected in Ex. 69, pp. 4-5 of 5, to be *drastically inconsistent* with the majority of the other medical histories reported by them in the medical records submitted in this case. Hence, I do not find those two medical histories to be reliable.

IX

SPECIFIC FACT FINDINGS

In this section, for the purpose of providing clarity to the record of this case, I summarize some of the critical allegations made by C.A.P.'s parents that I *specifically reject* in this ruling on the facts, for reasons explained above in Sections VII and VIII of this Ruling.

A. C.A.P.'s alleged additional symptoms after his vaccinations of February 5, 2002

Specifically, I do *not* find that on February 5, 2002, C.A.P. screamed and cried uncontrollably, followed by a deep sleep. I also do *not* find that C.A.P.'s parents contacted his pediatrician's office on February 6, 2002, as later alleged by the Petitioners.

B. C.A.P.'s alleged additional symptoms after his vaccinations of April 9, 2002

I *reject* the Petitioners' allegations that soon after his vaccinations of April 9, 2002, C.A.P. suffered symptoms similar to those he allegedly experienced after his February 5 vaccinations, such as screaming and crying uncontrollably, and rejecting nursing. I *reject* Mrs. Prokopeas' testimony that the date of C.A.P.'s second visit to the pediatrician in April of 2002, was on *April 13* -- I find that it was April 30.

C. C.A.P.'s alleged additional symptoms after his vaccinations of July 22, 2002.

I *reject* the Petitioners' allegation that shortly after his vaccinations of July 22, 2002, C.A.P. had uncontrollable screaming and crying, and failed to nurse. I *reject* that C.A.P.'s sleeping difficulties began soon after his vaccinations of July 22, 2002. I also *reject* Petitioners' allegations that C.A.P.'s lack of eye contact began in the time period immediately after his vaccinations of July 22, 2002. Further, I credit the notation in the record of the second phone call of July 23, 2002, that C.A.P. was "playful," and that he *had no additional symptoms* at that time other than his fever.

D. Symptoms allegedly occurring after vaccination of September 24, 2002

I *reject* the Petitioners' contention that after the vaccination of September 24, 2002, C.A.P. had any symptoms other than the minor symptoms reported in the record of the visit of September 30, 2002.

E. C.A.P.'s parents' developmental concerns

I *reject* Petitioners' allegations that they first noticed developmental problems with C.A.P. at any time prior to his head injury *in September or October of 2003*.

F. The medical history recorded by Dr. Kotsanis during his telephone consultation of January 6, 2004

I reject, as inaccurate, the medical history recorded by Dr. Kotsanis in January of 2004, as contained in Ex. 5, pp. 2-3.

G. C.A.P.'s psychological evaluation of October 11, 2004

I specifically *reject* the medical history recorded by Dr. Brasted in October of 2004, as contained in Ex. 69, pp. 4-5 of 5.

X

PETITIONERS' EXPERTS RELIED ON NUMEROUS *MISASSUMPTIONS OF FACT* IN FORMULATING THEIR RESPECTIVE EXPERT OPINIONS

Based on my factual findings above, I necessarily also find that Petitioners' experts relied on *numerous misassumptions of fact* in formulating their respective expert reports. I detail each experts' critical misassumptions of fact below.

A. Dr. Bellanti's misassumptions of fact

In his expert report of July 8, 2013, Dr. Bellanti set forth the factual assumptions upon which he based his expert opinion in this case. (Ex. 87, pp. 1-3) Specifically, Dr. Bellanti heavily relied on the joint affidavit of Mr. and Mrs. Prokopeas, filed as Exhibit 58, to assume certain facts concerning C.A.P.'s condition after each set of vaccinations administered to C.A.P. during his first year of life. (*E.g.*, Ex. 87, p. 1, ¶¶ 2, 4; Ex. 87, p. 2, ¶¶ 1, 3-7.)[38]

Additionally, in his expert report of July 8, 2013, Dr. Bellanti relied upon Dr. Kotsanis' recorded medical history contained in Exhibit 5, deeming that recorded medical history as being "an excellent history of what was going on at that time." (Ex. 87, p. 2, ¶ 8.) Moreover, Dr. Bellanti stated the following regarding the medical history recorded by Dr. Kotsanis in January of 2004:

> The history he recorded (Ex. 5, at 1-3) is entirely consistent with the narrative of [C.A.P.]'s parents.

(Ex. 87, p. 3, parenthesis in the original.)

As discussed in Section VII above, however, I specifically *reject* Petitioners' written and oral statements in this case, testifying to additional post-vaccination symptoms allegedly suffered by C.A.P. -- alleged symptoms that are not reflected in C.A.P.'s contemporaneous medical records -- during his first year of life. Moreover, as also discussed above, I also specifically

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[38] *See* Ex. 87, p. 1, ¶ 4 (assuming as fact parental assertions of C.A.P.'s condition after his vaccinations of February 5, 2002); Ex. 87, p. 2, ¶ 1 (assuming as fact parental assertions of C.A.P.'s condition after his vaccinations of April 9, 2002); Ex. 87, p. 2, ¶¶ 3-4 (assuming as fact parental assertions of C.A.P.'s condition immediately following his vaccinations of July 22, 2002); Ex. 87, p. 2, ¶ 5 (assuming as fact parental assertions as to the start of certain of C.A.P.'s symptoms, including his lack of eye contact, following his vaccinations of July 22, 2002); Ex. 87, p. 2, ¶ 6 (assuming as fact parental assertions of C.A.P.'s condition after his vaccination of September 24, 2002).

reject the medical history recorded by Dr. Kotsanis in January of 2004, as contained in Ex. 5, pp. 2-3.

Thus, I emphasize that the majority of the factual assumptions reflected in both of the expert reports of Dr. Bellanti submitted in this case (Exs. 87 and 89) are *clearly erroneous*.[39]

B. Dr. Corbier's misassumptions of fact

Dr. Corbier relied on the assumptions that shortly after his vaccinations of February 5, 2002, C.A.P. "lost his appetite and slept for long hours at a time" (Ex. 98, p. 2 of 3), and that soon after his vaccinations of July 22, 2002, C.A.P. became "lifeless" and "lethargic," and was "crying inconsolably" (Ex. 98, pp. 2-3 of 3). Dr. Corbier also assumed that C.A.P. had "irritability" and a "lethargic state" after *each* of his vaccination sets on February 5, April 9, and July 22. (Ex. 99, p. 3 of 10.)

However, as I have set forth above, I find that those were *erroneous* assumptions of fact, upon which Dr. Corbier based his opinion.

C. Summary of my conclusions concerning Dr. Bellanti's and Dr. Corbier's expert opinions

For the reasons described in detail above, I find that the expert opinions of Drs. Bellanti and Corbier in this case are based upon numerous flawed assumptions, with those erroneous assumptions being *strongly contradicted* by C.A.P.'s medical records. Hence, I find that the expert opinions of both Drs. Bellanti and Corbier[40] are *fatally flawed*, and thus, *wholly unreliable*.[41]

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[39] I note that, in serving as an expert witness for petitioners in prior Vaccine Act cases, Dr. Bellanti has a history of basing his causation opinion on *clearly faulty* factual assumptions. In a prior case before me in which Dr. Bellanti served as Petitioners' expert witness, *Brook v. HHS*, No. 04-405V, 2015 WL 3799646 (Fed. Cl. Spec. Mstr. May 14, 2015), I found that Dr. Bellanti's causation opinion in that case was "premised on assumptions that run *contrary* to the clinical history presented by the medical records." 2015 WL 3799646 at *11, emphasis in original.

[40] Dr. Corbier also opined that C.A.P. suffered a "Table Injury encephalopathy" after his vaccinations of July 22, 2002. (Ex. 99, p. 4 of 10.) However, after studying the medical records of July 23, 24, and 25, 2002, it is absolutely clear that C.A.P. did *not* suffer such a Table Injury. (That conclusion by Dr. Corbier, indeed, was, in my view, quite absurd.)

[41] "To the extent that it relies on the testimony of the petitioners' witnesses as to the occurrence and timing of events, [expert medical opinion] must stand or fall with the fact testimony." (*Murphy v. HHS*, 90-882V, 1991 WL 74931, at *3 (Fed. Cl. Spec. Mstr. April 25, 1991) (*aff'd,* 23 Cl. Ct. 726 (1991), *aff'd,* 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 113 S. Ct. 463 (1992).) Thus, because I decline to credit Petitioners' testimony with regard to C.A.P. allegedly suffering from additional post-vaccination symptoms after each set of vaccinations, including allegations that some of those post-vaccination symptoms constituted severe reactions to his vaccinations in the immediate time period following his vaccinations, I likewise decline to accept Drs. Bellanti's and Corbier's opinions based upon that testimony.

XI

WARNING TO PETITIONERS' COUNSEL CONCERNING "REASONABLE BASIS"

In several cases before myself and other special masters hearing cases involving children with diagnoses on the autism spectrum, petitioners' experts have relied upon parental testimony, as opposed to the minor child's medical records, in formulating factual assumptions upon which they based their expert opinions. In many of those cases, parental testimony offered in the course of litigation, alleging that the child suffered certain severe post-vaccination symptoms not reflected in his/her medical records, is the exclusive or predominant evidence supporting the factual assumptions of the petitioners' experts. But in many of those cases, as in this case, a careful examination of the record of the case has revealed that the child's medical records *strongly contradicted* the petitioners' assertions that their child suffered any kind of serious symptoms soon after his/her vaccinations in question. *See*, *e.g.*, *Hardy v. HHS*, *supra*; *Brook v. HHS*, *supra*; *Hooker v. HHS*, *supra; Dempsey v. HHS, supra; Hashi v. HHS*, No. 08-307V, 2015 WL 4626089 (Fed. Cl. Spec. Mstr. June 1, 2015). In certain of those cases, I have found that petitioners' proffered expert opinions were so divorced from the actual facts contained in the child's medical records, that in effect petitioners' case, as presented, was simply *frivolous*. *See*, *e.g.*, *Hardy v. HHS*, *supra*; *Hooker v. HHS*, *supra*.

This case clearly fits such a fact pattern, as explained above. Therefore, I hereby notify Petitioners' counsel in *this* case, that if Petitioners choose to continue to pursue any further proceedings in this case, after this point in time, I would be unlikely to conclude that there was a "reasonable basis" for such further proceedings, and therefore would be unlikely to compensate Petitioners for any further attorneys' fees and/or costs incurred concerning this petition. (I think it likely that *any* special master that might succeed me in this case would probably reach the same conclusion.)

Further, I strongly advise petitioners' counsel in *all* pending Vaccine Act cases that such counsel should *carefully scrutinize*, for *credibility*, any cases in which an expert witness, opining that vaccines caused or aggravated a minor child's ASD or other neurologic disorder, bases an expert opinion in a case in substantial part on parental allegations of the child undergoing certain severe post-vaccination symptoms; if, as in this case, such alleged symptoms *are not reflected* in the *contemporaneous medical records* of the child, I (or any special master) *will be unlikely to find that the use of such expert was reasonable*, and thus compensable.

XII

CONCLUSION

Petitioners' counsel is hereby ordered to carefully study these findings of fact. Expert opinion inconsistent with these findings of fact is not likely to be persuasive. *See Burns v. HHS*, 3 F.3d 415, 417 (1993) (holding that the special master did not abuse his discretion in refraining from conducting a hearing when the petitioner's expert "based his opinion on facts not

substantiated by the record"); *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict."); *Perreira v. HHS.*, 33 F.3d 1375, 1376 n.6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it."); *see also Bradley v. HHS*, 991 F.2d 1570, 1574 (Fed. Cir. 1993) (the assumption of an expert about the accuracy of a fact witness's testimony does not "substantiate" the fact witness's testimony).

Moreover, I also strongly urge Petitioners' counsel to comprehensively study C.A.P.'s medical records, and this ruling on the facts, as discussed in Section X of this Decision above, prior to proceeding further with this case.

IT IS SO ORDERED.

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master