

OFFICE OF SPECIAL MASTERS

(Filed: May 22, 2006)

No. 04-1771V

PUBLISHED

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DARLA MEYERS, Guardian ad Litem for)	
MATTHEW MEYERS, a Minor Petitioner, ¹)	
)	
	Petitioner,)	Motion for Judgment on the
)	Record; Failure to Offer either a
)	Reliable or Relevant Medical
v.)	or Scientific Explanation
)	
)	
SECRETARY OF THE DEPARTMENT OF)	
HEALTH AND HUMAN SERVICES,)	
)	
	Respondent.)	
)	
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Thomas P. Gallagher, Gallagher & Gallagher, Somers Point, NJ, for Petitioner.

Glenn A. Macleod, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION²

¹ The case caption as filed lists the minor petitioner as “Matthews Meyers.” However, the records indicate that the correct spelling of the minor petitioner’s name is “Matthew Meyers.”

²Vaccine Rule 18(b) states that all of the decisions of the special masters will be made available to the public unless the decisions contain trade secrets or commercial or financial information that is privileged or confidential, or the decisions contain medical or similar information the disclosure of which clearly would constitute an unwarranted invasion of privacy. Within 14 days of the filing of a decision or substantive order with the Clerk of the Court, a party may identify and move for the redaction of privileged or confidential information before the document’s public disclosure.

On December 14, 2004, petitioner, Darla Meyers, as Guardian ad Litem for Matthew Meyers (Matthew), a minor, filed a petition pursuant to the National Vaccine Injury Compensation Program³ (the Act or the Program). The petition alleges that Matthew developed diabetes as a result of four DTP vaccinations administered on October 31, 1997, December 12, 1997, February 28, 1998 and February 15, 1999. Petition (Petn.) at 1. Petitioner further alleges that the April 17, 2002 DPT vaccination significantly aggravated Matthew's diabetes. Id.

_____ In support of the petition, petitioner filed voluminous medical records; the Affidavit of Darla Meyers; and the Expert Report and curriculum vitae of Harold E. Buttram, M.D., with accompanying medical literature.

On November 29, 2005, respondent filed the Rule 4 Report (R. Report) pursuant to Vaccine Rule 4(c), recommending that compensation be denied in this case as petitioner has not met her burden of demonstrating actual causation. R. Report at 4-5. Specifically, respondent argues that petitioner "has not provided a reliable medical or scientific explanation supporting the assertion that any of the DTaP immunizations Matthew received can cause Type I diabetes mellitus, nor that they did so in this case."⁴ Id. at 4.

_____ On March 1, 2006, respondent filed the Expert Report and curriculum vitae of Neal A. Halsey, M.D., who rebutted the assertions made by Dr. Buttram in his expert report and concluded that the "[i]nformation submitted with this petition does not provide evidence of a causal relationship between any vaccine and diabetes in general, or in Matthew Meyers [in particular]." Respondent's Exhibit (R. Ex.) A at 3.

_____ On March 8, 2006, the undersigned conducted a telephonic status conference. During this conference, petitioner's counsel reported that he had discussed Dr. Buttram's expert report with petitioner, who had given her consent for counsel to request that the special master issue a ruling on the record as filed. Petitioner's counsel stated that all of the evidence that petitioner plans to introduce is now before the court, and the record is

³ The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. § 300aa-10-§ 300aa-34 (West 1991 & Supp. 2002) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

⁴ Respondent notes and the medical records reflect that the vaccinations Matthew received were actually DTaP vaccinations rather than DTP vaccines as alleged in the petition. R. Report at 2 n.3.

complete. The undersigned set a briefing schedule for petitioner's motion for judgment on the record. Petitioner's counsel declined the opportunity to file a Reply brief to respondent's Response to petitioner's Motion.

_____ On March 20, 2006, petitioner's counsel filed a Motion for Judgment on the Record. In the one sentence Motion, petitioner's counsel represents, "Petitioner, through her attorney, seeks a Motion for Judgment on the Record supported by submissions previously filed with the Court and Counsel's Certification." Petitioner's Certification of Counsel provides a list of 11 statements by counsel. Among other things, counsel states that "[a]ll relevant medical records have been filed with the Court in this matter." Certification of Counsel at 1. Further, counsel reports that petitioner has filed the report of Harold Buttram, M.D., to support petitioner's causation theory. *Id.* Counsel indicates that he spoke with petitioner, Darla Meyers, on several occasions, and most recently on March 16, 2006, concerning the issues presented in this case. *Id.* at 2. Counsel states that Ms. Meyers requested that he file a Motion for Judgment on the Record. *Id.* at 2.

On April 5, 2006, respondent filed Respondent's Response to Petitioner's Motion for Judgment on the Record, arguing that "compensation should be denied because petitioner has not satisfied the criteria for receiving such compensation under the terms and conditions of the National Vaccine Injury Compensation Program.

Petitioner's motion for judgment on the record is now ripe for decision.

I. Facts

_____ Matthew was born on August 25, 1997. Petitioner's Exhibit (Pet. Ex.) 1 at 5. On October 31, 1997, December 12, 1997, February 28, 1998 and February 15, 1999, Matthew received the Diphtheria-Tetanus-acellular Pertussis (DTaP) vaccination.⁵ *Id.* at 26. Matthew was in good health until December 2001, at which time he developed signs and symptoms of diabetes mellitus. *Id.* at 31. During an examination approximately 10 days later, Matthew's primary care physician confirmed the diagnosis of diabetes, *id.*, and ordered Matthew's hospitalization to begin insulin therapy, *id.* at 39. Matthew received another DTaP vaccination on April 17, 2002. *Id.* at 26, 30.

II. Discussion

⁵The DTaP vaccine is "a combination of diphtheria toxoid, tetanus toxoid, and pertussis vaccine; administered intramuscularly for simultaneous immunization against diphtheria, tetanus, and pertussis." Dorland's Illustrated Medical Dictionary 1998 (30th ed. 2003).

_____ Before the court is a petition for compensation under the Vaccine Act alleging that Matthew developed diabetes as a result of four administered DTaP vaccines and that the fifth administered DTaP vaccine significantly aggravated his diabetic condition. For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. 42 U.S.C. §300aa-14(a). Diabetes is not an injury listed on the Vaccine Injury Table and thus does not benefit from the Act’s presumed causation. Id. Accordingly, petitioner must prove that the administered vaccines in fact caused Matthew’s injury in this “off-Table” case.

_____ To establish entitlement to compensation in an “off-Table” case, petitioner must demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See, e.g., Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Secretary of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Secretary of HHS, 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and (II). To meet this preponderance of the evidence standard, “[petitioner must] show a medical theory causally connecting the vaccination and the injury.” Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Secretary of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999). A petitioner satisfies this requirement by offering “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Secretary of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges v. Secretary of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993); Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, a petitioner must support the logical sequence of cause and effect with “[a] reputable medical or scientific explanation” which may include “evidence in the form of scientific studies or expert medical testimony.”⁶ Grant, 956 F.2d at 1148; Jay, 998 F.2d at

⁶ General acceptance of a theory within the scientific community may militate in favor of finding the theory to be reliable while a theory that has attracted only minimal support in the scientific community may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that “Daubert is useful in providing a framework for evaluating the reliability of scientific evidence.” Terran v. Secretary of HHS, 41 Fed. Cl. 330, 336 (1998), aff’d, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, Terran v. Shalala, 531 U.S. 812 (2000). In Daubert, the Supreme Court noted that scientific knowledge “connotes more than subjective belief or unsupported speculation.” Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert’s opinion. Id. In other words, the “testimony must be supported by appropriate validation – i.e., ‘good grounds,’ based on what is known.” Id. Factors relevant to that determination may include, but are not limited to:

984; Hodges, 9 F.3d at 960. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344.

While petitioner need not show that the vaccine was the sole or even predominant cause of the injury, petitioner bears the burden of establishing “that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface, 165 F.3d at 1352-53. A petitioner does not meet her affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6344. Nor does petitioner satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating “inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation.”)); Hodges, 9 F.3d at 960. Finally, petitioner does not

Whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it’s been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand, 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

However, the court also offered a warning against rejecting novel scientific theories that have not yet been subjected to peer review and/or publication. The court pointed out that the publication “does *not* necessarily correlate with reliability,” because “in some instances well-grounded but innovative theories will not have been published.” Daubert, 509 U.S. at 594. The Supreme Court’s limited guidance to lower courts in assessing the reliability of a novel proposition is that

. . . submission to the scrutiny of the scientific community is a component of “good science,” in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised.

Id. at 593-94; see Gall v. Secretary of HHS, No. 91-1642V, 1999 WL 1179611, at *8 (Fed. Cl. Spec. Mstr. Oct. 31, 1999).

demonstrate actual causation solely by eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

_____ Recently, the United States Court of Appeals for the Federal Circuit reiterated that petitioner’s burden is to produce “preponderant evidence” demonstrating: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury.” Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (Althen III). The Federal Circuit stated further that “requiring that the claimant provide proof of medical plausibility, a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes – is merely a recitation of this court’s well established precedent.” Id. at 1281. The Federal Circuit concluded that to support petitioner’s theory of causation, there is no requirement in the Vaccine Act’s preponderant evidence standard that petitioner submit “objective confirmation” such as medical literature. Id. at 1279. The Federal Circuit explained that requiring medical literature “prevents the use of circumstantial evidence envisioned by the preponderance standard and negates the system created by Congress, in which close calls regarding causation are resolved in favor of the injured claimants.” Id. at 1280 (citing Knudsen, 35 F.3d 543, 549 (Fed. Cir. 1994)). Moreover, the Federal Circuit stated, “The purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” Id.

Following the three-part test for determining causation-in-fact in “off-Table” Vaccine Act cases set forth in Althen III, the Federal Circuit in Capizzano v. Secretary of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006) (Capizzano III), again rejected the requirement of “either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Id. The Federal Circuit found that requiring particular types of evidence to prove causation was “inconsistent with allowing ‘the use of circumstantial evidence envisioned by the preponderance standard.’” Id. (citing Althen, 418 F.3d at 1280).

However, the Federal Circuit’s decisions in Althen III and Capizzano III do not preclude the use of medical literature in evaluating expert testimony. In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 593 (1993), the Supreme Court stated that whether a theory or technique has been subjected to peer review and publication is a “pertinent consideration.” The Court continued, “The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an

opinion is premised.” *Id.* at 594. In *Terran v. Secretary of HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), *cert. denied*, 531 U.S. 812 (2000), the Federal Circuit approved the special master’s use of *Daubert* as “a tool or framework for conducting the inquiry into the reliability of evidence” and affirmed the special master’s rejection of a proposed theory that did not meet *Daubert* standards. Thus, the legal requirement that a petitioner support her proposed causation theory with a “sound and reliable medical or scientific explanation” is undisturbed. *Knudsen*, 35 F.3d 543, 548 (Fed. Cir. 1994); *see also Grant*, 956 F.2d at 1148 (“A reputable medical or scientific explanation must support this logical sequence of cause and effect.”). When considering the evidence in a case, the special master is to “consider all relevant and reliable evidence, governed by principles of fundamental fairness to both parties.” Vaccine Rule 8(c).

_____ In this case, petitioner offers the medical opinion of Harold E. Buttram, M.D., to demonstrate that the administered DTaP vaccinations caused and subsequently aggravated Matthew’s diabetes. Dr. Buttram presently works as a family physician in a private practice in Pennsylvania. *See Curriculum Vitae* of Harold E. Buttram, M.D. at 1. Dr. Buttram’s previous positions include working in a private practice in the areas of Internal Medicine, General Internal Medicine and Obstetrics, and Family Practice and Environmental Medicine. *Id.* at 2. Dr. Buttram’s practice areas of specialty are General Internal/Family Practice and Environmental Medicine.⁷ *Id.* at 1. Dr. Buttram is certified as a diplomate in the International Board of Environmental Medicine, the American Academy of Environmental Medicine, and the American Board of Clinical Metal Toxicology. *Id.* at 1; *Curriculum Vitae*, Appendix at 1. Dr. Buttram does not have expertise, board certification, or training in the areas of immunology or diabetes. Dr. Buttram is not one of Matthew’s treating physicians. Dr. Buttram’s expressed opinions are based on his general medical knowledge and his own personal study and review of

⁷ While Dr. Buttram does not specifically describe the practice of Environmental Medicine, he explains that the American Academy of Environmental Medicine (AAEM), of which he is a member:

far excels any other medical organization today of which I am aware, and that is in teaching the dangers of the various classes of potentially toxic commercial chemicals, such as volatile organic compounds, which consist of many thousands of synthetic commercial products largely derived from petrochemicals. Also based on personal observation, physicians in mainstream medicine rarely recognize illnesses brought about by these exposures due to lack of training in this area.

Curriculum Vitae, Appendix at 2 (emphasis in original).

medical articles and literature.

In support of his opinion that Matthew's DTaP vaccinations caused and significantly aggravated Matthew's diabetes, Dr. Buttram relies heavily on the theories of John B. Classen, M.D. See Expert Report of Harold E. Buttram (P. Report) at 6-9. Dr. Buttram provides extracts from a presentation by Dr. Classen at a 1998 conference sponsored by the American Academy for the Advancement of Medicine (ACAM). Id. During the 1998 ACAM conference, Dr. Classen presented his theories concerning a causal link between the hemophilus influenzae and hepatitis B vaccinations and insulin dependent diabetes mellitus (IDDM). Id. However, as pointed out by respondent's expert, Neal A. Halsey, the scientific community has rejected Dr. Classen's theories on the ground that his theories are based on flawed analytical methodology.

This court has previously considered and discredited the theories advanced by Dr. Classen.⁸ In Baker v. Secretary of HHS, No. 99-653V, 2003 WL 22416622 (Fed. Cl. Spec. Mstr. Sept. 26, 2003), Dr. Classen testified on behalf of petitioner that the DT, polio, HiB and hepatitis B vaccinations administered to her son caused his IDDM. Baker, 2003 WL 22416622, at *2. Relying on the Daubert standards of evidentiary reliability, Special Master Millman rejected Dr. Classen's testimony as she found:

overwhelming evidence in epidemiologic and medical articles, based on extensive research in various countries, concluding that there is no valid proof that childhood vaccinations cause IDDM. Dr. Classen stands alone (with his first cousin on occasion) in his credo that 50% of IDDM in children under the age of seven years is caused by vaccinations. He analyzed the Finnish data in a manner so as to come to the exact opposite conclusion of the Finnish epidemiologists who analyzed the same data.

Baker, 2003 WL 22416622, at *33 (citations omitted). Specifically, Special Master Millman stated:

Dr. Classen's unreliable methods and analysis include: multiplying the odds ratios or relative risks of various vaccines to obtain a cumulative incidence of IDDM; using a one-tailed instead of a two-tailed test in the Finnish study; changing the axes [used by one of the Finnish epidemiologists] which changed the curves for the Finnish data; doing a meta-analysis of

⁸ For a more extensive discussion, see Baker v. Secretary of HHS, No. 99-653V, 2003 WL 22416622 (Fed. Cl. Spec. Mstr. Sept. 26, 2003).

different vaccines; selectively picking data points from the Finnish and New Zealand data that agree with his hypothesis while eliminating those that do not; and ignoring the other environmental factors that can affect [the] incidence of IDDM (year of birth, latitude, Caesarean section, older maternal age, infections, day care, breast feeding, growth rate in infancy, water acidity, and the linear rise in IDDM rates even before vaccinations were instituted) because calculating [the] risk of IDDM from them would be difficult. He commits, as Dr. Halsey says, the ecological fallacy [of] emphasizing one intervention (vaccination) while ignoring all other environmental interventions.

Id. at *34. Special Master Millman determined that “Dr. Classen’s inappropriate methodology, profit motive,⁹ sole focus on vaccines to the exclusion of other environmental factors, and absence of epidemiological training, board-certification, and relevant professional experience make his testimony unpersuasive and not credible.” Id. at *36 (footnote added).

In respondent’s expert’s report, Dr. Halsey challenges Dr. Buttram’s opinion, which is based primarily on Dr. Classen’s hypothesis that vaccines cause diabetes, on the same ground – specifically, the application of flawed scientific methods – that several expert panels have challenged and rejected Dr. Classen’s theory. R. Ex. A at 2. Dr. Halsey reports that he chaired a panel which reviewed Dr. Classen’s hypothesis and found that the evidence did not support the hypothesis.¹⁰ Id. Dr. Halsey also indicates that a National Institutes of Health panel concluded “that existing studies in humans do not indicate an increase in type 1 diabetes that is attributable to any vaccine or the timing of vaccine administration.”¹¹ R. Ex. A at 2-3. Moreover, in 2002, the Institute of Medicine Vaccine Safety Committee reviewed much of the information on which Dr. Buttram relies

⁹ “Since August 1991, Dr. Classen has been the CEO and sole employee of Classen Immunotherapies, Inc., which he describes as a small biopharmaceutical company that has developed vaccine technology to prevent type I diabetes and autoimmune diseases.” Baker, 2003 WL 22416622 at *10.

¹⁰ See The Institute for Vaccine Safety Diabetes Workshop Panel, Childhood Immunizations and Type 1 Diabetes: Summary of An Institute for Vaccine Safety Workshop, 18(3) PEDIATRIC INFECTIOUS DISEASE J. 217 (1999).

¹¹ Childhood Immunization Schedule and Diabetes: An Unfounded Hypothesis, Clinical Infectious Disease Hot Page (August 1998).

and concluded that the “evidence favors rejection of a causal relationship between multiple immunizations and increased risk for infections and for type I diabetes.”¹² R. Ex. A at 3.

The scientific community has rejected Dr. Classen’s theories as detailed in his articles because the human studies that have been conducted do not support his conclusions and his analytical methods do not comport with the Daubert requirement of reliability. Dr. Buttram’s heavy reliance on articles authored by and relied upon by Dr. Classen in support of petitioner’s expert’s opinion of causation significantly diminishes the value of Dr. Buttram’s opinion. It is of note that 11 of the articles on which Dr. Buttram relies were authored by or were relied upon by Dr. Classen in his 1998 ACAM conference presentation discussing his theory regarding a causal link between the hemophilus influenzae and hepatitis B vaccinations and IDDM.¹³ Because the articles address a causal link between IDDM and vaccines that are not the vaccines at issue in this case, the articles are not relevant to the causation issue here. Dr. Buttram’s reliance on

¹² Immunization Safety Review Committee, Immunization Safety Review: Multiple Immunizations and Immune Dysfunction, The Institute of Medicine (May 29, 2002).

¹³ See Dr. Buttram’s references: (3) U.S. Department of Education, National Center for Education Statistics: Digest of Education Statistics (2002) (includes the report of John B. Classen, M.D., Epidemiology Data Linking Vaccines to Type 1, Insulin Dependent Diabetes (IDDM)); (16) J.B. Classen & D.C. Classen, Association Between Type 1 Diabetes and Hib Vaccine, Causal Relation Likely, 319 BMJ 1133 (1999); (17) J. Eskola et al., A Randomized, Prospective Field Trial of a Conjugated Vaccine in the Protection of Infants and Young Children Against Invasive Haemophilus Influenzae Type B Disease, 323 NEJM 1381 (1990); (18) J. Tuomilehto et al., Record High Incidence of Type I (Insulin Dependent) Diabetes in Finish Children, 42 DIABETOLOGIA 655 (1999); (19) J. Tuomilehto et al., Rapid Disappearance of Haemophilus Influenzae Type b Meningitis After Routine Childhood Immunizations With Conjugate Vaccine, 340 LANCET 592 (1992); (20) H. Peltola, Rapid Disappearance of Hemophilus Influenzae Type b Meningitis after Routine Childhood Immunizations With Conjugate Vaccine, 340 LANCET 592 (1992); (21) R. Booy et al., Efficacy of Hemophilus Influenzae Type b Conjugate Vaccine PRP-T, 344 LANCET 362 (1994); (22) D. Brewster, The Epidemiology of Haemophilus Influenzae Invasive Disease in Scotland Prior to Immunisation, 51 HEALTH BULLETIN 358 (1993); (23) S. Gardner et al., Rising Incidence of Insulin Dependent Diabetes in Children Under 5 Years in Oxford Region: Time Trend Analysis, 315 BMJ 713 (1997); (24) J.B. Classen, Diabetes Epidemic Follows Hepatitis B Immunization Program, 109 NEW ZEALAND MED. J. 195 (1996); (25) J.B. Classen & D.C. Classen, The Safety of Military Immunization and the Risk of Insulin-Dependent Diabetes, 2(4) CLINICAL PRACTICE ALTERNATIVE MED. 247 (2001).

Dr. Classen's theories and articles that do not satisfy the Daubert standard of evidentiary reliability is misplaced. By offering Dr. Classen's articles in support of his opinion, Dr. Buttram fails to provide a reputable medical or scientific explanation for his theory that Matthew's four DTaP vaccinations caused and significantly aggravated Matthew's diabetes. See Grant, 956 F.2d at 1148.

Respondent's expert, Dr. Halsey, also criticizes Dr. Buttram's suggestion that the thimerosal content in the administered vaccines may have contributed to Matthew's health complications and diabetes. R. Ex. A at 3 (referencing P. Report at 4-5). Dr. Halsey notes that the information regarding autism and attention deficit hyperactivity disorder contained in the first paragraph on page four of Dr. Buttram's report is "irrelevant" to this case.¹⁴ R. Ex. A at 3. Dr. Halsey contends that the second paragraph of page four of Dr. Buttram's report contains several untrue statements, most notably the bolded statement that "[t]here are no long-term (months or years) safety studies on any childhood vaccine in use today." Id. (referencing P. Report at 4). Dr. Halsey states that there are numerous clinical trials, the results of which are available for review, documenting longer term vaccine-safety studies than indicated by Dr. Buttram. R. Ex. A at 3. Dr. Halsey further states that, because petitioner seeks compensation in this case for the alleged aggravation of his diabetic condition, Dr. Buttram's "discussion [in the second

¹⁴ Specifically, Dr. Buttram states:

As a general background, at the present time America and America's children are in the midst of an epidemic of chronic disease and disability. The US Centers for Disease Control (CDC) reports that 1 American child in 166 has been diagnosed with autism spectrum disorder. (1) In 1970, autism affected 1 in 2,500 children. (2) By 1991, 5,000 autistic children were in the public school system; by 2001 that number had grown to 94,000. (3) Today nearly 3 million children in public schools are classified as learning disabled as compared with 796,000 in 1976. (4) Comparable increases have been taking place in the attention deficit hyperactivity disorder (ADHD) with 4 million children between ages 3 and 17 being diagnosed with this condition. (5, 6) These dramatic increases cannot be attributed to changes in classification or increased awareness.

P. Report at 4.

Dr. Halsey does not specify why this information is irrelevant. The undersigned surmises, however, that the information is irrelevant because autism and attention deficit hyperactivity disorder are not the injuries alleged in this case.

paragraph of page four of his report] of autism, Alzheimer's disease, Gulf War syndrome, and other disorders is not relevant to this case and includes many incorrect or misleading statements." Id.

The undersigned agrees with Dr. Halsey that Dr. Buttram's report is of little assistance in establishing that Matthew's DTaP vaccinations caused or aggravated his diabetes. Dr. Buttram's opinion is presented, in part, as a discussion of theories of causation of medical conditions unrelated to IDDM, which is Matthew's medical condition. Dr. Buttram's offered opinion on a possible causal link between various vaccines and diverse medical conditions is neither relevant to nor probative of the particular issue of causation in this case.

The undersigned also considers the materials that Dr. Buttram has cited in support of his opinion of causation. Dr. Buttram cites 23 references which include medical articles and reports. See P. Report at 9-10; Petitioner's Sixth Submission of Required Documents; Petitioner's Seventh Submission of Required Documents. A careful examination of these articles and reports indicates that they fail to address the relevant vaccine or injury in this case in which petitioner alleges that the DTaP vaccinations administered to her son, Matthew, aggravated his diabetes.

Dr. Buttram cites three of the articles in support of his opinion that thimerosal or mercury "may have played [a role] in [causing] Matthew's health complications."¹⁵ P. Report at 3. Dr. Buttram states:

In regard to the relevance of the thimerosal/mercury issue in the case of Matthew Meyers, the physiologic shock resulting from multiple vaccines with multiple known toxins, which have never been adequately tested for their safety, and which are given at the highly vulnerable age of early infancy, cannot help but overstimulate and alter their immune systems, shifting them from the protective cellular immunity system to a dominance of the allergy and autoimmune-prone humoral system. (13-15)

¹⁵ See Dr. Buttram's references: (13) D.S. Robinson, Predominant TH2-Like Bronchoalveolar T-Lymphocyte Population in Atopic Asthma, 326 NEW ENGLAND J. MED. 298 (1992); (14) P.G. Holt et al., Allergic Respiratory Disease: Strategic Targets for Primary Prevention During Childhood, 52 THORAX 1 (1997); (15) F. Imani et al., Infection of Human B Lymphocytes with MMR Vaccine Induces IgE Class Switching, 100(3) CLINICAL IMMUNOLOGY 355 (2001).

Id.

As respondent's expert, Dr. Halsey, points out, Dr. Buttram's statement "does not constitute evidence of a causal relationship." R. Ex. A at 3. The three articles that Dr. Buttram cites in support of his assertions about "the physiologic shock resulting from multiple vaccines with multiple known toxins" provide no information at all about diabetes as a possible complication of vaccines. R. Ex. A at 3 (quoting P. Report at 3 and referencing P. Report at 10). The articles address allergic reactions related to asthma, rather than the medical condition alleged in this case.

Dr. Buttram references an additional 19 articles which fail to support his opinion that the thimerosal or mercury component of the administered DTaP vaccines caused Matthew's diabetes. The articles discuss vaccines that are unrelated to the DTaP vaccine, injuries that are unrelated to diabetic conditions, and theories that do not address whether DTaP causes or aggravates diabetes.¹⁶

¹⁶ See References: (1) American Academy of Pediatrics, Autism A.L.A.R.M. (January 2004); (2) California Department of Developmental Services, DDS report, www.dds.ca.gov; (7) J. Schubert et al., Combined Effects in Toxicology – A Rapid Systemic Testing Procedure: Cadmium, Mercury, and Lead, 4 J. TOXICOLOGY AND ENVIRONMENTAL HEALTH 763 (1978); (8) A.B. Abou-Donia et al., Neurotoxicity Resulting from Exposure to Pyridostigmine Bromide, DEET, and Permethrin; Implications of Gulf War Chemical Exposures, 48 J. TOXICOLOGY AND ENVIRONMENTAL HEALTH 35 (1996); (9) N.A. Halsey, Limiting Infant Exposure to Thimerosal in Vaccines and Other Sources of Mercury, 282 JAMA 1763 (1999); (10) CASSARETT & DOULL'S TOXICOLOGY, THE BASIC SCIENCE OF POISONS 834-37 (Curtis D. Klaassen ed., McGraw-Hill) (6th ed. 2001); (12) R. Blaylock, Chronic Microglial Activation and Excitotoxicity Secondary to Excessive Immune Stimulation: Possible Factors in Gulf War Syndrome and Autism, 9(2) J. AMERICAN PHYSICIANS AND SURGEONS 46 (2004); (13) D.S. Robinsion, Predominant TH2-Like Bronchoalveolar T-Lymphocyte Population in Atopic Asthma, 326 NEW ENGLAND J. MED. 298 (1992); (14) P.G. Holt et al., Allergic Respiratory Disease: Strategic Targets for Primary Prevention During Childhood, 52 THORAX 1 (1997); (15) F. Imani et al., Infection of Human B Lymphocytes with MMR Vaccine Induces IgE Class Switching, 100(3) CLINICAL IMMUNOLOGY 355 (2001); (17) J. Eskola et al., A Randomized, Prospective Field Trial of a Conjugated Vaccine in the Protection of Infants and Young Children Against Invasive Haemophilus Influenzae Type B Disease, 323 NEJM 1381 (1990); (18) J. Tuomilehto et al., Record High Incidence of Type I (Insulin Dependent) Diabetes in Finish Children, 42 DIABETOLOGIA 655 (1999); (19) J. Tuomilehto et al., Rapid Disappearance of Haemophilus Influenzae Type b Meningitis After Routine Childhood Immunizations With Conjugate Vaccine, 340 LANCET 592 (1992); (20) H. Peltola, Rapid Disappearance of Hemophilus Influenzae Type b Meningitis after Routine Childhood Immunizations With Cojugate Vaccine, 340 LANCET 592 (1992); (21) R. Booy et al., Efficacy of Hemophilus Infulenzae Type b Conjugate Vaccine PRP-T, 344 LANCET 362 (1994);

The articles and literature that Dr. Buttram has cited in support of his opinion of causation do not address the vaccine that Matthew received or Matthew's diagnosed medical condition. Dr. Buttram's reliance on Dr. Classen's discredited theories and Dr. Buttram's broad and generalized assertions about the health risks associated with various vaccinations and the literature to which he has referred in his opinion do not provide a sound, reliable, and relevant medical or scientific explanation to establish a causal link between the administered DTaP vaccinations and Matthew's type I diabetes.

III. CONCLUSION

Because petitioner has failed to provide a relevant and reliable medical theory supporting a logical sequence of cause and effect, petitioner has failed to establish a prima facie case for compensation under the Vaccine Act. Accordingly, the court must dismiss this case for want of proof. The Clerk of the Court shall enter judgment. The Clerk of the Court shall deliver this Decision to the parties by overnight mail delivery.

IT IS SO ORDERED.

Patricia E. Campbell-Smith
Special Master

(22) D. Brewster, The Epidemiology of Haemophilus Influenzae Invasive Disease in Scotland Prior to Immunisation, 51 HEALTH BULLETIN 358 (1993); (23) S. Gardner et al., Rising Incidence of Insulin Dependent Diabetes in Children Under 5 Years in Oxford Region: Time Trend Analysis, 315 BMJ 713 (1997); (24) J.B. Classen, Diabetes Epidemic Follows Hepatitis B Immunization Program, 109 NEW ZEALAND MED. J. 195 (1996); (25) J.B. Classen & D.C. Classen, The Safety of Military Immunization and the Risk of Insulin-Dependent Diabetes, 2(4) CLINICAL PRACTICE ALTERNATIVE MED. 247 (2001).