In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-0522V

Filed: 15 June 2010

(Originally Filed (Unredacted): 19 May 2010)

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ROBERT VERYZER	*	
	*	
Petitioner,	*	**PUBLISHED**
	*	
v.	*	
	*	*Daubert* Motion to Exclude *In Limine*;
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Methodological Reliability; Scientific Method; Generally-Accepted; Specific Medical Expertise
	*	
Respondent.	*	
* * * * * * * * * * * * * * * * * * *	*	

Alan Milstein, Esq., Sherman, Silverstein, Kohl, Rose & Podolsky, Pennsauken, N.J., for Petitioner; *Traci Patton, Esq.*, United States Department of Justice, Washington, District of Columbia, for Respondent.

REDACTED[1] PUBLISHED ORDER GRANTING MOTION TO EXCLUDE

ABELL, Special Master:

On 17 October 2008, Respondent filed a set of motions *in limine* to exclude two sets of expert witness materials filed previously by Petitioner in support of his claim for compensation for a vaccine-related injury. Petitioner had filed expert reports, *curricula vitae*, and supporting documents from Andrew Moulden, M.D., PhD and Sherri Tenpenny, D.O. Respondent's motions seek exclusion of those expert materials arguing that their methodology is unscientific and unreliable, *via* a Motion made pursuant to *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). The Court here rules on Respondent's Motion.

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[1] The Court granted Petitioner's (timely filed) motion to redact, filed pursuant to 42 U.S.C. § 12(d)(4)(B), inasmuch as the information which Petitioner sought to redact constituted "medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy," pursuant to 42 U.S.C. § 12(d)(4)(B)(i). Therefore, those sections wherein the Court has redacted information have been marked with a bolded note of redaction, as well as the category of information that was redacted.

The Vaccine Act authorizes the Office of Special Masters to make rulings and decisions on petitions for compensation from the Vaccine Program, to include findings of fact and conclusions of law. §12(d)(3)(A)(I). In order to prevail on a petition for compensation under the Vaccine Act, a petitioner must show by preponderant evidence that a vaccination listed on the Vaccine Injury Table either caused an injury specified on that Table within the period designated therein, or else that such a vaccine actually caused an injury not so specified. § 11(c)(1)(c).

I. FACTUAL BACKGROUND

On 25 April 2001, Petitioner received both the Hepatitis B and Hepatitis A vaccines. Thereafter, Petitioner suffered ill symptoms of pain and neurological damage, which he believed resulted from the vaccinations he received. On 29 September 2003, Petitioner first filed a petition with this Court, pursuant to 42 U.S.C. § 300aa-11,[2] for compensation of a vaccine-related injury, arising out of his Hepatitis B vaccination (docket no. 03-2252V). At the time of that filing, the Hepatitis A vaccine had not been added to the Vaccine Table, found at 42 C.F.R. § 100.3(a), and a claim for compensation of injury from the Hepatitis A vaccination was not concurrently brought.

That petition faced several uphill challenges of proof, primarily due to trouble finding an expert to opine in support of Petitioner's claim that the Hepatitis B vaccine caused the condition(s) from which Petitioner allegedly suffered. Therefore, on 2 November 2004, Petitioner opted out of the Vaccine Program, "withdrawing" his petition under § 21(b) of the Vaccine Act after receiving the 240-day notice, pursuant to § 12(g) of same.

That case was thus concluded without a final order of the Court, and without the entry of judgment on the petition's claim for compensation. Around that same time, Hepatitis A was added to the Vaccine Table, on 1 December 2004. See 69 Fed. Reg. 69,945-46.

Having finished with the Vaccine Program, Petitioner then sued the vaccine manufacturer, SmithKline Beecham Corp., in the Supreme Court for the State of New York, naming both vaccines as likely culprits for his injuries. However, the vaccine manufacturer objected, arguing that one of the two vaccines administered, and upon which Petitioner was litigating (Hepatitis A), was now on the Vaccine Table but that Petitioner had not brought a vaccine claim thereupon. The state court ordered the action dismissed without prejudice by consent, to allow Petitioner to bring another claim to the Vaccine Program, this time for Hepatitis A.

Wherefore, Petitioner filed the instant Petition (docket no. 06-0522V), alleging that Hepatitis A actually caused Petitioner's injuries. In prosecuting the instant Petition, Petitioner initially retained a medical expert witness opining that the injury was necessarily caused by Hepatitis B, but not Hepatitis A or anything else. Petitioner then moved to amend the pending Petition to include a claim for injury allegedly related to his Hepatitis B vaccination, so as to claim recovery for the injury, and

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[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 *et seq*. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

to allege causation from the Hepatitis B vaccine. The Court denied the motion to amend (so as to include a claim for injury caused by the Hepatitis B vaccine) based upon 42 U.S.C. § 300aa-11(b)(2) and the doctrine of claim preclusion. Petitioner was then left to found any claim for recovery purely upon the Hepatitis A vaccination, inasmuch as any claim premised upon his Hepatitis B vaccination had been precluded with the prior petition.

After the Court's ruling on that issue, Petitioner sought out an expert whose opinion would support Petitioner's claim that Hepatitis A caused Petitioner's multifarious injuries. Between 26 and 27 August 2008, Petitioner filed expert reports, *curricula vitae*, and supporting documents from Andrew Moulden, M.D., PhD and Sherri Tenpenny, D.O. On 17 October 2008, Respondent filed a motion *in limine* to exclude both of these sets of expert witness materials due to their unreliability of methodology, pursuant to *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), one for each of the experts ("the Moulden Motion" and "the Tenpenny Motion," collectively, "the Motion"). On 25 November 2008, Petitioner filed a Response in opposition to Respondent's Motion, defending the credibility of both experts, and the reliability of their opinions, and arguing for the admissibility thereof ("the Response"). Finally, on 12 December 2008, Respondent filed a Reply in support of the Motion ("the Reply"). The Court, after carefully weighing the arguments presented, rules herein on Respondent's Motion to Exclude.

II. THE PARTIES' ARGUMENTS

Respondent premises the Court's authority to grant the relief requested on the higher court precedents of *Daubert v. Merrell Dow Phar., Inc.*, 509 U.S. 579 (1993); *Terran v. Sec'y of HHS*, 195 F. 3d 1302 (Fed. Cir. 1999), *reh'g and reh'g en banc denied*, (Fed. Cir. Feb. 2, 2000), *cert. denied*, 531 U.S. 812 (2000); and Vaccine Rule 8(b)(1), which states, "In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all *relevant and reliable* evidence governed by principles of fundamental fairness to both parties"[3] (emphasis added).

Respondent's Motion actually consists of two distinct motions, each requesting the exclusion of one of the two expert reports filed by Petitioner. Because the arguments for and against exclusion are in many cases specific to the claims made by the two experts proffered by Petitioner, the Court will examine them separately.

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[3] Respondent cited to a previous version of the Vaccine Rules, which have been revised since the Motion was filed. Respondent's citation was to Vaccine Rule 8(c), which is the predecessor to the provision provided, and the two are functionally identical. This rule is a procedural extension of § 12(d)(2)(B) of the Act, which states, in relevant part:

> "The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of title 28 [of the United States Code]. *Such rules shall—*
>
> ...(B) *include flexible and informal standards of admissibility of evidence*...

(emphasis added).

A. Dr. Moulden

Respondent objects specifically to Dr. Moulden's testimony not so much because he lacks training and credentials in the subject area, but based on the argument that he diverges quite obtusely from accepted scientific methodology. Dr. Moulden's theoretical mechanism he proffered to explain Petitioner's injury involves a "M.A.S.S. response," an eponymous, even proprietary phenomenon called "Moulden Anoxia Spectra Syndrome," and which, he said, damaged Petitioner neurologically, physiologically, and functionally. Moulden Motion at 6 citing Dr. Moulden's Expert Report ("Moulden Report") at 112.

Dr. Moulden does not ascribe credibility to the accepted theories typically proffered to explain vaccine injuries, instead believing that, as with "most people with vaccine-related injuries," Petitioner actually suffered from the root mechanism of vaccine injury: the MASS response, which he weaves into a pastiche of seemingly unrelated conditions, without limiting to the ones from which Petitioner was affected. Moulden Report at 5 -100.[4] According to Dr. Moulden's report, regardless of the contents of the particular vaccine, they all result initially in the same MASS response, albeit manifesting in sundry injuries such as Autism Spectrum Disorder,[5] Sudden Infant Death Syndrome, Guillain-Barré Syndrome, Gulf War Syndrome, and the heretofore unnamed "Gardasil War Syndrome." *Id*. at 60, 82-84. Even in describing the terminal effects of his MASS response, Respondent claimed, Dr. Moulden would not describe its specific activation, onset, or mechanism, demurring that such information "is proprietary level information and will not be disclosed for the purposes of [the] expert report."

Dr. Moulden stated in his report that "all vaccines are useless--always have been, always will be," that "vaccinations are the number one cause of chronic disease and disability in otherwise healthy individuals–globally," and that "all vaccines are causing death, brain damage, ischemic strokes, and chronic illness–to the brain, the body, and to our pets." Moulden Report at 91-93.[6]

To Respondent, "Dr. Moulden's opinions are precisely the kind of unreliable *ipse dixit* that the Supreme Court and numerous other courts have held to be inadmissible under *Daubert*." Respondent, by this reference to *Daubert*, does not merely contemplate the generally-applied principle of reliability as a precondition for reliance, but seeks the Court's application of the specific

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[4] Featured prominently in Dr. Moulden's report are several diagrams showing facial paralysis and strabismus resulting from ischemic lesions, into which categories he places Petitioner, due to eye and head movement patterns when Petitioner's visual gaze is in transition, which, Dr. Moulden asserts, were not present before the Hepatitis A and Hepatitis B vaccinations. Moulden Report at 1-15.

[5] Dr. Moulden attributed the loss of language in autistic disorders to "watershed ischemic strokes," which he said are "induced by vaccines–by direct vaccination and by indirect mechanisms," without providing further explanation. Moulden Report at 3.

[6] Respondent filed, as an Exhibit to the Motion to Exclude Dr. Moulden's Report, an advertisement for "BrainGuard," a product invented and marketed by Dr. Moulden, which is some sort of imaging scan that purports to detect damage caused by vaccines or other pharmaceuticals *via* the MASS response. It is risible in its claims, which do not merit further elaboration here.

ruling of *Daubert*: *in limine* exclusion of dubious expert testimony. "Although *Daubert* is often used to determine what weight to afford a medical opinion, Dr. Moulden's opinions are so lacking any reasonable basis that they should be disregarded, and Respondent requests that the Court exclude them *in limine* from further proceedings in this matter." Moulden Motion at 2. Specifically, Respondent seeks the exclusion of Dr. Moulden's opinion(s) "because (1) he is not qualified to offer an opinion about the causes of Mr. Veryzer's alleged injuries, and (2) his opinions on this issue are completely unreliable." Moulden Motion at 2-3.

Respondent reviewed the legal history up to and including the Supreme Court's opinion in *Daubert*, focusing on the emphasis placed on the term "scientific knowledge," which contemplated a congruence with the scientific method within an expert's approach, as well as in his final conclusion:

> The adjective "scientific" implies a grounding in the methods and procedures of science. Similarly, the word "knowledge" connotes more than subjective belief or unsupported speculation. The term "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds." . . . Of course, it would be unreasonable to conclude that the subject of scientific testimony must be "known" to a certainty; arguably, there are no certainties in science. . . . But, in order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation – i.e., "good grounds," based on what is known. In short, the requirement that an expert's testimony pertain to "scientific knowledge" establishes a standard of evidentiary reliability.

Moulden Motion at 4-5, quoting *Daubert*, 509 U.S. at 590. Discussing the development of this same point, Respondent noted that "[w]hile the original *Daubert* decision had admonished trial courts to focus solely on an expert's methodology (as opposed to his or her conclusions) when evaluating the reliability of the expert's opinions, the Court in [*General Elec. Co. v. Joiner*, 522 U.S. 136 (1997)] added that expert conclusions also matter." Moulden Motion at 5. Respondent quoted from *Joiner* on this point:

> [C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. *A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered*.

Moulden Motion at 5-6, quoting *Joiner*, 522 U.S. at 146 (emphasis added by Respondent).

Respondent finished her review of the development of the relevant case law by discussing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). The primary holding of *Kumho Tire*, as stated by Respondent, is that the *Daubert* reliability requirement "appl[ies] to all expert testimony of a technical, scientific or specialized nature," such that any and all "evidence billed as 'scientific' must be shown to meet the rigors appropriate to that field of science." Moulden Motion at 6. Furthermore, in *Kumho Tire*, the Supreme Court "reemphasized that trial judges have the discretion

to determine what factors are most appropriate for assessing whether expert opinions in a given case are based on 'good grounds.'" *Id*. Respondent labeled as a guiding principle the Court's instruction that trial courts, in ruling on reliability, "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id*., quoting *Kumho Tire* at 152.

Respondent moves on to argue why that case history, which arose in the context of the Federal Rules of Evidence (which are not made applicable to Vaccine Act cases (see § 12(d)(2)(B))) nevertheless bear deducible application in the context of the Vaccine Program. The linchpin Respondent seizes upon for this applicability of an exclusionary prerogative embedded in the Court's power is § 13(b), as interpreted through the lens of Vaccine Rule 8 (quoted in relative part *supra* at 3). To Respondent, "the rule retains explicitly the requirement that evidence considered in Vaccine Act proceedings be 'reliable' and the Vaccine Act provides explicitly for consideration of '*scientific evidence* contained in the record.'" Moulden Motion at 7, quoting § 13(b)(1). Respondent views these provisions as corollaries to FRE 702's "key language on which the Supreme Court's decision in *Daubert* is based [which is also] found in the Vaccine Act and implementing Vaccine Rules." *Id*. Respondent honed in on the words "relevant and reliable" in Rule 8, the inclusion of which, Respondent explained, "contemplates some degree of regulation" of the reliability of scientific evidence admitted into Vaccine Act cases. *Id*., quoting *Daubert* at 589.

Respondent went on to argue that the Federal Circuit has advocated–nay, ordered–the application of at least the general reliability requirement of *Daubert* in Article I courts such as the Court of International Trade, perhaps even using the specific factors given as exemplars in *Daubert*. Moulden Motion at 8-9, discussing *Libas, Ltd. v. United States*, 193 F. 3d 1361 (Fed. Cir. 1999). From there, Respondent reviewed the Federal Circuit's discussion of *Daubert* within Vaccine Act cases, specifically *Terran v. Sec'y of HHS*.[7] Respondent summarized the Circuit's opinion there as deciding that the Federal Rules of Evidence were generally inapplicable in Program cases, but accepting nevertheless that "*Daubert* is useful in providing a framework for evaluating the reliability of scientific evidence ... it is equally capable of being used to determine whether information is relevant and reliable in the context of the Vaccine Act." Moulden Motion at 10, quoting the Court of Federal Claims decision (affirming the special master), 41 Fed. Cl. 330, 336 (1998), which reasoning was affirmed by the Circuit, 195 F. 3d at 1316.[8]

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[7] *Terran v. Sec'y of HHS*, 195 F. 3d 1302 (Fed. Cir. 1999), *reh'g and reh'g en banc denied*, (Fed. Cir. Feb. 2, 2000), *cert. denied*, 531 U.S. 812 (2000).

[8] Respondent also saw, integral within the standards of proof delineated by the Federal Circuit, the reliability requirement expressed as a preconditioned component of causation. Moulden Motion at 10, citing *Knudsen v. Sec'y of HHS*, 35 F. 3d 543, 548 (Fed. Cir. 1994) for its reference to *Daubert* in requiring the support of "sound and reliable medical or scientific explanation" in a petitioner's burden of proof on the element of "logical sequence of cause and effect" in actual causation cases, and *Perreira v. Sec'y of HHS*, 33 F. 3d 1375, 1377 n. 6 (Fed. Cir. 1994) for its use of *Daubert* in support of its rule in the same context that, "An expert opinion is no better than the soundness of the reasons supporting it."

Respondent concluded her statement of the legal standard applicable in this matter by forwarding a progression of analysis:

> If the proposed expert crosses the foundational threshold of being "qualified" to render opinions on the relevant subject matter, the Court must then determine whether those opinions are "reliable" by ensuring that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co.*, 526 U.S. at 152; *see also Daubert*, 509 U.S. at 592-93, 597 (reasoning and methodology must be valid and reliable).

Moulden Motion at 12.

Based on this standard, Respondent argued for the exclusion, *in limine*, of Dr. Moulden's testimony, based upon contentions concerning whether he is qualified to opine on the topic at hand and regarding the minimum threshold reliability of his opinion.

Respondent's first challenge to Dr. Moulden concerns his authority and credibility as an expert witness. Respondent notes, concerning Dr. Moulden, that "he received his Ph.D. in psychology from the University of Ottawa in 1999 [and] his M.D. from McMaster University in 2000," but that "he is not currently licensed to practice medicine," that "[h]is medical license expired on June 30, 2008," that "[h]e does not have any hospital privileges," that "of the forty-five 'publications' Dr. Moulden lists on his CV, two are patent applications and twenty-six are unpublished and characterized by Dr. Moulden as 'In prep' and 'Intellectual Property,'" and that "he has not authored a single scholarly, published, peer-reviewed article in the field of Neurology." Moulden Motion at 12-13. Respondent added, "Of the remaining publications listed on his CV, Respondent could locate only four in peer-reviewed medical journals; all four of these appear to have been written while Dr. Moulden was a student and associated with a university." *Id*. at 13.

Secondly, Respondent launched a multi-tiered attack on the methodology undergirding Dr. Moulden's opinion, in that it "has not been tested and has no known rate of error," "has not been subjected to peer review or publication," and "is not based on principles generally accepted in the medical community." Moulden Motion at 13-14.

Addressing how Dr. Moulden's proposed mechanism–the MASS response–is untested, let alone not broadly accepted (or known), Respondent pointed out that "Dr. Moulden ... neither describes how this process can be seen, measured, and demonstrated nor explains how all immunizations cause this "MASS" response." Moulden Motion at 13. Respondent pointed out specific failures of explanation or basic logic, such as his claim that his postulate constitutes "the singular medical model that accounts for most, if not all, morbidities, irrespective of the varied symptom and organ[-]specific clinical diagnostic labels eventually applied," as well as his refusal to elaborate details of his novel construct until "the end of 2008[9] [when c]ore parts of [his] work will

[9] At the time of briefing, which was at the twilight of 2008, Dr. Moulden apparently had not released a more detailed explication of his theory. Petitioner's Response (discussed *infra*) was filed at the end of November 2008 and made no mention that Dr. Moulden had made such a release, and no supplemental notice was filed of such a release in the intervening months.

be Public [*sic*] released." *Id*., quoting Moulden Report at 99 and 109. Of similar secrecy is his newly-developed nerve damage diagnostic test, which Dr. Moulden seeks to market commercially under the name "BrainGuard." *Id*., quoting Moulden Report at 112; Resp. Ex. A. Due to these limitations and strictures, Dr. Moulden's theory cannot be proven. Moreover, they deprive the opportunity for others to disprove same.

The aura of mystery does not dissipate in discussing Respondent's second contention against Dr. Moulden's opinion. As Respondent summarized his statements, "Dr. Moulden will not be describing his findings in a scholarly peer-reviewed scientific journal; rather, his 'findings' will be 'partially released to 6 people/groups' in '6 red envelopes.'"[10] Moulden Motion at 14, quoting Moulden Report at 99. Dr. Moulden's *Curriculum Vitae* lists several publications, which might support or disparage his theory, except that they are in fact unpublished manuscripts listed as "in prep" or "intellectual property," either awaiting publication or being held indefinitely from publication by Dr. Moulden. Respondent concluded on this point that "Dr. Moulden's theory regarding the existence of a 'MASS' response has not been, and most likely never will be, subjected to peer review." Moulden Motion at 14.

Respondent's third point is to be congratulated on its precise statement of the law. She argues that "Dr. Moulden's theory is not based on principles generally accepted in the medical community." Moulden Motion at 14. Not every expert conclusion must be accepted by a majority of doctors to be admissible. However, Respondent focused on the fact that Dr. Moulden's opinion is, Respondent argued, incompatible with the principles–the professional, scientific methodology–of the medical community. Not only did Dr. Moulden neglect to reference published scholarly articles that might support his opinion in whole or in part, but "Dr. Moulden oppose[d] those principles generally accepted in the medical community."[11] *Id*. Said Dr. Moulden, "The entire medical model is both flawed and incorrect," and "[Louis] Pasteur's germ theory of mammalian disease is both incorrect and inaccurate," inasmuch as "disease is not being caused by any particular pathogen or strain of pathogen ... it is the non-specific immune response to foreign substances sin [*sic*] the body and blood stream that causes disease–all diseases." Moulden Report at 90-91. Given that germ theory is a bit of a cornerstone of medicine, it is not surprising that Respondent concluded, "By

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[10] The mention of red envelopes must have piqued the curiosity of Respondent as much as it did the Court's, as Respondent pointed out in a footnote that Dr. Moulden's Report contains a page of photographs, of which one appears to be Dr. Moulden holding bright red envelopes at a conference, alongside a photograph of him with Miss Jennifer McCarthy, captioned "sharing knowledge," and another image of him superimposed onto a screen-shot of a Larry King Live panel. Moulden Report at 99. It is that same page of his Report where he quotes himself as saying, "By the end of 2008 ... Core parts of my work will be Public [*sic*] released." *Id*. (ellipsis in original). The relevance of these materials to the case at hand is not patent on the face of the filing.

[11] On this point, Respondent mentioned in a footnote one page of Dr. Moulden's Report upon which are the visages of Drs. Paul Offit, Judy Gerberding, Marie McCormick, and Harvey Fineberg, each superimposed with the phrase "*Cogito Erratum Sum*!" (most closely translated as, "I think I am a mistake!"), an apparent attempt to caricature those individuals and Descartes' seminally modernist declaration, "*Cogito ergo sum*," meaning "I think, therefore I am." Moulden Motion at 15 note 17, describing Moulden Report at 66. The page also includes photos of Dr. Moulden in military regalia and some headshots of random (unidentified) other people. To call it bizarre and unprofessional would be an understatement, and that merely refers to the abuse of the Latin tongue.

categorically rejecting principles generally accepted in the medical community, Dr. Moulden himself provides the special master with the best evidence that his opinion in this case cannot pass a *Daubert* analysis and should be excluded."[12] Moulden Motion at 14-15.

In his opposition to Respondent's Motion, Petitioner first begins by summarizing Dr. Moulden's proposed mechanism of injury:

> M.A.S.S. is an immune response or ischemic tissue process triggered by vaccination with antigens and foreign substances which impairs oxygen delivery to the brain at a microscopic level thereby causing micro-vascular ischemic strokes. Ischemic strokes occur when oxygen demand exceeds oxygen supply.
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> ...[V]accines and foreign substances introduced to the human body cause the immune system to hyper-react as large white blood cells naturally rush to attack the foreign particles entering the bloodstream or tissue. The white blood cells are too big to enter capillaries, so they surround tiny capillaries where the foreign particles land and end up clogging and collapsing the capillaries. This cuts off pathways for smaller red blood cells to carry much-needed oxygen to different organs. When the white blood cells lodge near the brain or brain's small blood vessels, this lack of blood supply can cause much damage.

Response at 5-6, citing Moulden Report at 3, and quoting Exhibit A to Respondent's Moulden Motion (the internet advertisement for "BrainGuard") (internal marks omitted).

Petitioner dutifully recites in some detail the correspondence between cranial nerves and the neurological deficits that Dr. Moulden believes correspond to their damage, respectively. These supposed correspondences read more like a phrenology model or an acupuncture legend, with similar levels of proof in support: [***Listing of conditions REDACTED***]. Response at 6, citing Moulden Report at 112-14. Incidentally, Möbius' Syndrome is a congenital condition, so it would be rather curious that the administration of vaccine(s) to Petitioner in middle-age would cause such a condition.[13]

Petitioner continues his defense-by-summary of Dr. Moulden by stating the conclusion of the Report in question: "Dr. Moulden has indicated that adverse effects from vaccines are the body's natural response," and that response was "[s]pecifically, white blood cells acting under a hypersensitive response." Response at 6. Continuing, "It is not an individualized response, rather, the same pathological features are present in responses to other vaccines." *Id*. Petitioner then describes the Moulden Report: "Dr. Moulden's supporting data includes numerous clinical cases

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[12] Respondent moved, in the alternative, for an *in vivo Daubert* hearing on this issue. Moulden Motion at 15 note 18. However, as both parties have expressed themselves fully herein, as certainly as Dr. Moulden did in his lengthy report, no such hearing is deemed useful or necessary.

[13] Möbius' Syndrome is "agenesis or aplasia of the motor nuclei of the cranial nerves characterized by congenital bilateral facial palsy in various combinations, with unilateral or bilateral paralysis of the abductors of the eye..." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1825. That means it is a disease of non-development of a critical portion of a nerve, not the damage or destruction of same at some later time.

where the M.A.S.S. response has resulted in relation to various vaccines as well as photographs and images which visually depict elements of neurological damage." *Id.*

On the issue of the legal standard governing the Court in ruling on Respondent's Motion, Petitioner essentially stipulates to Respondent's analysis of the case law, from FRE 702, on to *Daubert*, then to *Terran*, concluding that "*Daubert* has been held to provide special masters with a helpful analytical framework for assessing the reliability of the evidence presented in vaccine cases." Response at 6-8. Petitioner's primary defense of Dr. Moulden, as well as that of Dr. Tenpenny, is that their methodology was scientific because they "employed differential diagnosis in reaching their conclusions." Response at 10. To Petitioner, this vindicates the individual and joint defects of their expert opinions, inasmuch as "[d]ifferential diagnosis has been recognized as a 'technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results, it is a method that involves assessing causation with respect to a particular individual." Response at 10, quoting *In re Paoli R.R. Yard PCB Litigation*, 35 F. 3d 717, 758 (3d Cir. 1994).[14]

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[14] *Paoli* is inapposite. Apart from the fact that Third Circuit rulings are not binding on this Court, the *Paoli* opinion does not apply the correct legal standard for the admissibility of expert testimony under *Daubert*, in that it does not require a threshold level of expertise. To be fair, *Daubert* had only been released the year before, and perhaps not many cases had discussed all the aspects of *Daubert* when the Third Circuit decided *Paoli*. The sole justification for overturning exclusion of an unqualified witness (who was still arguably more qualified to testify than either Dr. Moulden or Dr. Tenpenny) was the reasoning, "If the liberal standard of Rule 702 allows an engineer who teaches auto mechanics to testify in a products liability action about tractors, it surely allows a trained internist who has spent significant time reviewing the literature on PCBs to testify as to whether PCBs caused illness in plaintiffs." *Paoli* at 754, relying on *Hammond v. International Harvester Co.*, 691 F.2d 646, 741-42 (3d Cir. 1982). Reliance on the prior case of *Hammond v. International Harvester Co.*, which admitted in a products liability case involving tractors the testimony of an engineer whose only qualifications were experience in automotive and agricultural equipment sales and teaching a high school automobile repair class, would certainly be error now, following the Supreme Court's decision in *Kumho Tire*, *supra*.

On the issue of reliability, *Paoli* itself is, at best, a mixed blessing for Petitioner. Even though it does speak highly of differential diagnosis as a technique, the Court reiterated that "it is plain that the proponent must make more than a prima facie showing that a technique is reliable." 35 F. 3d at 743, quoting *United States v. Downing*, 753 F. 2d 1224, 1240 n. 21 (3d Cir. 1985). Application of *Paoli* also would place the evidentiary burden in the instant matter on Petitioner: "An expert's proponent must demonstrate by a preponderance of evidence that [the expert's] opinions are reliable." *Paoli* at 744. The Third Circuit stated a standard of required reliability which Petitioner here is hard-pressed to satisfy:

> The evidentiary requirement of reliability is lower than the merits standard of correctness. *Daubert* states that a judge should find an expert opinion reliable under Rule 702 if it is based on "good grounds," i.e., if it is based on the methods and procedures of science. A judge will often think that an expert has good grounds to hold the opinion that he or she does even though the judge thinks that the opinion is incorrect. As *Daubert* indicates, "[t]he focus ... must be solely on principles and methodology, not on the conclusions that they generate."

Paoli at 744, quoting *Daubert* at 595. But most damning to Petitioner, and belying the proposition for which he cited *Paoli*, was this passage:

> However, after *Daubert*, we no longer think that the distinction between a methodology and its application is viable. To begin with, it is extremely elusive to attempt to ascertain which of an expert's steps constitute parts of a "basic" methodology and which constitute changes from that methodology. If a laboratory consistently fails to use certain quality controls so that its results are rendered

Petitioner seeks to employ the following syllogism to persuade the Court that Dr. Moulden and Dr. Tenpenny are reliable: Presupposing "A" (differential diagnosis is a well-accepted method of winnowing potential causes or diagnoses to arrive at a most likely cause or diagnosis), and if "B" (Dr. Moulden and Dr. Tenpenny both used differential diagnosis[15]), then it follows that "C" (the doctors' expert reports followed well-accepted methodology). As Respondent pointed out in her Reply, differential diagnosis only works as an analytical framework when you are including and excluding potential *causata* on the basis of acceptably scientific medicine. *See infra*. Therefore, to include only a dubious, unproven and unexplained premise such as the MASS response, and to exclude any other cause without any in-depth analysis, would certainly lead to the unsurprising conclusion that Petitioner's experts arrived at the opinions that they did, but that does not make for "good grounds." As the *Paoli* opinion (*supra* at note 14), upon which Petitioner sought to rely, explains, "attempting to ascertain whether [an expert's shortcoming] constitutes a failure of methodology or a failure of application of methodology may be an exercise in metaphysics." 35 F. 3d at 745.

Petitioner also seeks to persuade the Court that the agreement between the experts allows them to mutually "bootstrap" one another's reliability. Because "[t]he conclusions of both of the experts support each other," they are each then reliable. This leads the Court to propose a *reductio ad absurdum*: Precisely how many individuals have to hold a wrong opinion before it is made right thereby? If the answer to this query is two, perhaps Petitioner's argument has merit.

Moving to the specific objections Respondent raised against the opinion of Dr. Moulden, Petitioner argued that Dr. Moulden "is qualified to offer his opinion in this case," and that "his opinion meets the requisite level of scientific reliability." Response at 17. Addressing first his qualifications, Petitioner details his "education, training, and experience." *Id*. Dr. Moulden's undergraduate degree had a "concentration in neurobiological psychology," within his masters degree "his focus was child development, developmental neuropsychology and brain development psychometrics," his Ph.D. in psychology trained in "clinical-experimental neuropsychology with a specialization in neuroscience and neurophysiology and sub-specialization in neuroscience and neurophysiology and sub-specialization in basic and applied neurosciences," and his clinical training for psychology was done in an outpatient mental health clinic, a neuropsychology department of a

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> unreliable, attempting to ascertain whether the lack of quality controls constitutes a failure of methodology or a failure of application of methodology may be an exercise in metaphysics. Moreover, any misapplication of a methodology that is significant enough to render it unreliable is likely to also be significant enough to skew the methodology.

Paoli at 745.

[15] It is not at all clear that either doctor *did* employ differential diagnosis. Nowhere in the report of either doctor is there a discussion of any other possible *causata* that might explain Petitioner's symptoms, onset, or course beyond the conclusion(s) they postulate. Although Petitioner asseverated that they had performed such an analysis, and promised to explicate where such appears within the expert reports (*see* Response at 10), both were noticeably lacking proof of such. The closest Dr. Tenpenny came to analyzing Petitioner's course through a differential diagnosis was her report's concluding statement that, "Because no other infectious, neoplastic, autoimmune or metabolic etiologies for these side effects were identified, there can be little doubt that Dr. Veryzer's problems were related to his vaccinations and compensation is certainly indicated." Tenpenny Report at 9.

health care clinic, and the "Memory Discords Clinics" at Ottawa General Hospital. *Id*. at 17-18. Though Dr. Moulden did not work treating patients in a clinical setting after graduating from McMaster University's medical school in 2000, Petitioner does not believe that makes him any less qualified to opine in this case: "Dr. Moulden has chosen to focus on his research; specifically in the areas of neurological, neuropsychiatric and neuroimmunological disorders." *Id*. at 18. Petitioner concludes his summation of Dr. Moulden's credentials thusly:

> Dr. Moulden also serves as a director of neurodevelopmental disorders at Thoughtful House in Austin, Texas. Recently, Dr. Moulden was elected leader of a federal political party in Canada, the Canadian Action Party, in this role he acts as an advocate for medicine in science, practice and policy. The foregoing demonstrates sufficient knowledge and competence in the field of neurology.

Response at 18.

On the primary issue bearing on the admissibility of Dr. Moulden's opinion–reliability–Petitioner made four arguments: I. His opinion is reliable because it is based on independent research he himself performed; II. His opinion is reliable because he performed a differential diagnosis and reviewed Petitioner's medical records in light of his MASS response hypothesis and other cases; III. His opinion is not made unreliable simply because he has not published his theory in a peer-reviewed publication; and IV. "Differential diagnosis is generally accepted."

Petitioner quotes from the Ninth Circuit's remand decision in *Daubert* to argue that the Court should consider "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation," and argues that such testimony "provides important, objective proof that the research comports with the dictates of good science." Response at 18, quoting 43 F. 3d 1311, 1317 (9th Cir. 1995). He adds, quoting from the same decision, "[I]ndependent research carries its own indicia of reliability, as it is conducted, so to speak, in the usual course of business." Response at 18-19, quoting 43 F. 3d at 1317. Petitioner seeks to lay hold of this persuasive authority, and to attach it to the specifics of this case, as it relates to Dr. Moulden's opinion:

> Here, Dr. Moulden's conclusion was elucidated through his own independent research, which, in turn, supports the reliability of his theory. As such, his theory cannot necessary [*sic*] be subject to peer review or general acceptance.

Response at 19.

From there, Petitioner defends Dr. Moulden's opinion on the grounds that he based his conclusion on a review of a physical "examination of the Petitioner, the results of a series of tests, review of Petitioner's personal medical history and Petitioner's descriptions of his personal activities." Response at 19. According to Petitioner, in forming his opinion Dr. Moulden also drew upon "video and photographic microscopy techniques," the temporal relationship between vaccination and symptom onset, "animal data that showed ischemic lesions as a function of vaccination at the injection site," coroner reports of vaccine-injured individuals which revealed ischemic damages diffusely through the brain," and "other clinical cases evidencing M.A.S.S.

responses to various vaccines." *Id*. Petitioner argued that the latter "help explicate Dr. Moulden's M.A.S.S. theory," such as a case seen as comparable where the vaccinee received the MMR vaccine, not a Hepatitis vaccine, but nevertheless "both experienced microvascular ischemic lesions post vaccine," and "both developed facial droop and right eye esotropia and mesial drift." *Id*. at 19-20. Petitioner also stated that "from page 112 through 116, Dr. Moulden explains in detail how the Hep[atitis] A vaccination caused Petitioner's multiple medical morbidities through the hypersensitized state and vasculitic response. *Id*. at 20. Petitioner viewed Respondent's criticism of the non-disclosed evidence of MASS response as a "red herring," because "Dr. Moulden's report clearly explains how the Hep[atitis] A vaccination is the cause of Petitioner's neurological damage." Petitioner concluded on this point that, "Dr. Moulden employed differential diagnosis in reaching his conclusion correlating Petitioner's Hep[atitis] A vaccination and his neurological damages," and that just because "Dr. Moulden used this technique to support his conclusion that Petitioner suffered a M.A.S.S. response is not sufficient grounds for excluding his opinion." *Id*.

Petitioner disputes what he sees as "Respondent's argument that lack of publication calls for exclusion of Dr. Moulden's opinions in this case," and "Respondent's assertion that Dr. Moulden's theory regarding M.A.S.S. response will likely never be subject to peer review," as contrary to the law and the facts (respectively). Response at 20-21. Petitioner cited three cases that explain why publication is not a prerequisite to reliability (all from other Circuits whose rulings are not binding on this Court). The truth is that this is an unremarkable point: the Supreme Court's ruling in *Daubert* explicitly provided that peer-reviewed publication, along with the other factors they listed there, were non-exclusive and non-elemental. 509 U.S. at 593; *see also Kumho Tire*, 526 U.S. at 151 ("[*Daubert*'s] list of factors was meant to be helpful, not definitive."). Therefore, the Court will not belabor this point further. What is odd is Petitioner's concluding statement, made without citation, that, "Here, through differential diagnosis, Dr. Moulden ruled out other possible causes of Petitioner's damages and expressed a valid scientific correlation between Petitioner's Hepatitis A vaccination and the objective neurological damages." Response at 21.

Petitioner's last defense of the reliability of Dr. Moulden's opinion is that Dr. Moulden used a differential diagnosis, which is a generally-accepted methodology, and therefore the other portions of Dr. Moulden's perspective that break with mainstream medicine (such as his rejection of germ theory) are insignificant. Response at 22. To Petitioner, "the fact that Dr. Moulden does not espouse Pasteur's [germ] theory has no bearing on the admissibility of his opinion in this case." *Id*. Petitioner summarized:

> Dr. Moulden has indicated that adverse effects from vaccines are the body's response, rather than an event related to the germ theory. Specifically, it is the body's response–white blood cells acting under hypersensitive response. Dr. Moulden explains the chain of events post-vaccination is not an individualized response, rather, the same pathological features are present in responses to other vaccines; as such, M.A.S.S. response is a mechanical problem: white blood cells being triggered by the vaccine.

Id., citing Moulden Report at 112-116. Petitioner concluded that because Dr. Moulden used differential diagnosis, which is a generally-accepted methodology, his opinion is based on a reliable foundation, even if one might quibble with his conclusions. *Id*. at 22-23. What is odd is that

Petitioner never did demonstrate that Dr. Moulden did in fact perform a differential diagnosis that considered and ruled out any other competing potential *causata*.

B. Dr. Tenpenny

Much of Respondent's position stated *supra*, at least as it relates to the Court's gatekeeping duty and its authority to grant the relief requested, is reduplicated in the Tenpenny Motion, and will not be restated here. However, the specific grounds for excluding Dr. Tenpenny's opinion testimony as inadmissible are somewhat different. Though her report was not as interlaced with the rustle of chiropteran flapping in campanological spaces as was Dr. Moulden's, Respondent still objected to the admission of Dr. Tenpenny's opinion, because her qualifications are not congruous with the level of expertise required by the issue at hand, and because "Dr. Tenpenny's opinions discussing the Hep[atitis] A vaccine are unreliable, and her opinions discussing the Hep[atitis] B vaccine are irrelevant." Tenpenny Motion at 2.

On the legal standard applicable to Dr. Tenpenny, Respondent repeated much of the discussion on reliability discussed *supra*. However, she also added to those sources citations addressing the minimal qualification necessary to render an expert's testimony admissible: "When performing his gatekeeper function, the special master must first determine whether the expert is qualified to render his opinions. The expert must have 'sufficient specialized knowledge' to assist the trier of fact in deciding the particular issues in the case." Tenpenny Motion at 3, quoting *Kumho Tire* at 156. Respondent also juxtaposed the qualification issue as precedent even to a reliability determination, or at least the first step of a reliability determination: "If the proposed expert crosses the foundational threshold of being 'qualified' to render opinions on the relevant subject matter, the Court must then determine whether those opinions are 'reliable' by ensuring that the expert 'employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Id*. at 4, quoting *Kumho Tire* at 152. Later, Respondent cited to clear precedent for the exclusion of expert testimony from an unqualified witness. Tenpenny Motion at 5, citing *Domeny v. Sec'y of HHS*, No. 94-1086V, 1999 WL 199059 at *14 (Fed. Cl. Spec. Mstr. Mar. 15, 1999), *aff'd*, (Fed. Cl. May 25, 1999) (unpublished), *aff'd*, No. 99-5130, 232 F. 3d 912 (Table), 2000 WL 420630 (Fed. Cir. April 10, 2000) (per curium) (unpublished) (special master refused to admit testimony from a dentist on the issue of neuropathy, indicating that the proffered "expert" had neither "the training nor the experience to assist the court" in a case involving Guillain-Barré Syndrome).

Dr. Tenpenny is board-certified in Emergency Medicine and Osteopathic Manipulative Medicine, having earned a Doctor of Osteopathy degree (D.O.) from Kirksville College of Osteopathic Medicine in 1985. *Curriculum Vitae* of Dr. Tenpenny. Curiously, Dr. Tenpenny stated in her report that she was "a physician with board certification in emergency medicine (through 2006)." Tenpenny Report at 3. She does not indicate whether she re-qualified for that certification in the report, which was dated 22 August 2008, and her *curriculum vitae* does not indicate whether her certification is current, only when it was first acquired (1995). Under the section in her *curriculum vitae* listing her experience in the field of Emergency Medicine within these United States, her dates of participation in the field begin in 1986 and terminate in 1998. The presumption this leaves on the face of the record is that she is no longer board certified in Emergency Medicine.

The only contradictory evidence is Dr. Tenpenny's asseveration that she was, at the time of the writing of her report in late 2008, "a physician with board certification in emergency medicine."

Respondent challenged Dr. Tenpenny's qualification on the ground that, "[r]ather than containing a section describing scholarly, published peer-reviewed articles, Dr. Tenpenny's CV contains a section describing her 'Lectures and Media Experience.'" Tenpenny Motion at 4. Respondent added that "all of her publications appear to be articles published in non peer-reviewed magazines," and that "she has apparently authored two books, one of which, *Saying No to Vaccines: A Resource Guide for All Ages*, appears to be a manual of sorts explaining how to avoid vaccinations." *Id*. at 5. Undisclosed among her publications was one work for which she was collaborating with Dr. Moulden, the other expert proffered by Petitioner to opine in this case, named *Tolerance Lost: M.A.S.S. Disorders on a Mass Scale*, which was listed on Dr. Moulden's website.

Beyond questionable aspects of Dr. Tenpenny's *oeuvre*, Respondent challenged her credibility in qualifications based upon her lack of relevant training. Respondent argued:

> Dr. Tenpenny does not possess medical training in immunology or neurological disorders, nor has she indicated that she has any experience in treating patients with Petitioner's conditions. Dr. Tenpenny describes her expertise in vaccines as a "personal investigation" that began in September, 2000, and she states that this research is not associated with any academic institution. As such, there is nothing in her background that qualifies Dr. Tenpenny to opine on a theory of causation between Hep[atitis] A vaccination and neurological injuries.[16]

Tenpenny Motion at 5.

Secondary to Dr. Tenpenny's qualifications to opine is Respondent's objection to the reliability of her expert opinion. Of tertiary, but still significant, concern to Respondent is the relevance of parts of Dr. Tenpenny's opinion. As these are closely related (albeit distinct) issues, they are discussed in tandem. Respondent argued on the issue of reliability:

> In her report, Dr. Tenpenny does not elucidate any theory explaining how a Hep A vaccine can cause the neurological injuries from which she claims petitioner suffers. Moreover, there is no evidence in the record that petitioner does, or ever did, suffer

[16] Dr. Tenpenny's opinion stipulates to the real potential for neurological complexity in parsing Petitioner's particular injury by describing it as a "central neurological phenomenon," leading to her belief that Petitioner's condition may be diagnosed as some version of acute disseminated encephalomyelitis (ADEM) or multiple sclerosis. Tenpenny Report at 5-6. These conditions are definitively neurological, and would require some expertise to form a well-reasoned and -articulated opinion on aetiology.

> ADEM[17] or MS,[18] two very distinct neurological injuries – the conditions on which Dr. Tenpenny focuses in her opinion.
>
> Dr. Tenpenny also discusses aluminum adjuvants in vaccinations, yet she fails to explain how the alleged amount of aluminum in the one Hep A vaccination petitioner received could have caused or substantially contributed to petitioner's alleged injuries.

Tenpenny Motion at 6.

On the matter of relevance, Respondent chiefly pointed out the error of Dr. Tenpenny in arguing that the Hepatitis B vaccine caused Petitioner's injuries. While Dr. Tenpenny is not required to ignore the interplay of the Hepatitis B vaccine as a concurrent cause or otherwise, in the course of parsing Petitioner's history, Petitioner is not aided by any proof of Hepatitis B causation because that claim has already been litigated, and is precluded from this action.

As it turns out, "Dr. Tenpenny's only support for the claim that petitioner has MS is the expert report of Dr. Girard." Tenpenny Motion at 6. Dr. Girard was the initial expert proffered by Petitioner in this case, the one who opined that it was really the Hepatitis B vaccine, and not at all the Hepatitis A vaccine, that caused Petitioner's injury. Respondent believes such reliance is either unreliable or irrelevant, or both:

> Dr. Girard states that his opinion that "hepatitis B can actually cause multiple sclerosis," is based on his review of the medical literature concerning Hep B and his assessments of subjects in France who received Hep B vaccinations. Girard Rep. at 21. Dr. Girard offers no evidence in his report to suggest that he has similar experience with Hep A vaccinations, or that he holds the opinion that Hep A vaccinations can cause multiple sclerosis. Petitioner has offered no evidence that Hep A and Hep B vaccinations cause similar reactions that result in MS, [***condition REDACTED***], or any other neurological impairment. Dr. Girard's expert report provides no evidence for Dr. Tenpenny's theory that petitioner's Hep A vaccination caused undiagnosed MS. Because petitioner cannot maintain any claims for injuries allegedly resulting from his Hep B vaccination, any conclusions stemming from petitioner's receipt of this vaccination are irrelevant.

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[17] Acute disseminated encephalomyelitis (ADEM) is "an acute or subacute encephalomyelitis or infiltration and demyelination; it occurs most commonly following an acute viral infection, especially measles, but may occur without a recognizable antecedent....It is believed to be a manifestation of an autoimmune attack on the myelin of the central nervous system. Clinical manifestations include fever, headache, vomiting, and drowsiness progressing to lethargy and coma; tremor, seizures, and paralysis may also occur; mortality ranges from 5 to 20 per cent; many survivors have residual neurological deficits." DORLAND'S (*supra* at note 13) at 610.

[18] Multiple Sclerosis (MS) is "a disease in which there are foci of demyelination of various sizes throughout the white matter of the central nervous system, sometimes extending into the gray matter. Typically, the symptoms of lesions of the white matter are weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that the term *multiple* also refers to remissions and relapses that occur over a period of many years.... The etiology is unknown." DORLAND'S (*supra* at note 13) at 1669 (emphasis in original).

Tenpenny Motion at 6-7. Respondent added that Dr. Girard never diagnosed Petitioner with multiple sclerosis, in part, at least, due to the fact that he himself was not a neurologist. *Id.* at 7 note 8.

Petitioner disputed Respondent's contentions concerning Dr. Tenpenny. Petitioner spent a great deal of the Response summarizing the opinions of Dr. Tenpenny, as he had that of Dr. Moulden. But the claims seem just as unfounded and baseless in Petitioner's telling.[19] Petitioner argues admissibility on the treble assertion that Dr. Tenpenny "is qualified to offer her opinion in this case," that "her opinion meets the requisite level of scientific reliability," and "her discussion of Petitioner's administration of the Hep[atitis] B vaccine will assist the Special Master in making a determination in this case." Response at 10-11.

On Dr. Tenpenny's qualification to offer an expert opinion, Petitioner reviews her *curriculum vitae*, stipulating that her board certification in emergency medicine lapsed in 2006. Response at 11. Beyond her actual credentials, which, frankly, do not much bear on the issues raised in the instant case, Petitioner notes that "Dr. Tenpenny's interest in vaccines was piqued after attending the National Vaccine Information Center meeting in September 2000; since that time, she has served as a medical team leader for the National Vaccine Information Center and has spent over 7,000 hours researching issues regarding vaccine-related information." *Id.* Without further explanation, Petitioner asserts that the instant case "presents facts where her research has been relevant," and that these cursory and largely irrelevant autodidactic pursuits "demonstrate[] sufficient knowledge and competence in the field of vaccine related injuries." *Id.* Apparently, Petitioner views vaccine-related injuries as a specific field of study, with sufficient knowledge of each physiological system that a precise expertise in, say, neurology is unnecessary for her to be able to describe (as she failed to do in her report) how a Hepatitis A vaccine caused multiple sclerosis or ADEM, which are significantly different conditions, with which, by the way, no other doctor has diagnosed Petitioner.

Petitioner found Respondent's citation to *Domeny*, *supra*, to be inapposite. For Petitioner the distinguishing facts are that, whereas the dentist offered in *Domeny* was not a medical doctor and had no experience with vaccine-related injuries, "Dr. Tenpenny is a medical doctor with over eight years of vaccine experience, and specifically, in the area of vaccine-related injuries." Response at 12. Petitioner also finds relevant Dr. Tenpenny's many media appearances giving her opinion on vaccine injuries, although he does not explain why the Court should. *Id.* A few clicks of the remote hammers home the reality that qualified knowledge is not now, if it ever was, a precondition to getting on television. Lastly on this issue, Petitioner objected to Respondent's emphasis on *scholarly* publication, inasmuch as "publication does not necessarily correlate with reliability, because in some instances well-grounded but innovative theories will not have been published." Response at 13, quoting *Daubert* at 593-94 (internal marks omitted).

Petitioner argued in support of the reliability of Dr. Tenpenny's opinion, contending that "Respondent erroneously argue[d] that Dr. Tenpenny's opinion is unreliable because she does not explain how the Hep[atitis] A vaccine can cause Petitioner's neurological injuries; however Respondent does not point to any evidence that would support a finding of an analytical gap between

[19] *See*, *e.g.*, Response at 4, quoting Tenpenny Report at 7 ([***quotation REDACTED***]).

the data and the opinion proffered." Response at 13. Petitioner believes that "Dr. Tenpenny's report causally connects the Hep[atitis] A vaccination and Petitioner's injury," and seemed to be saying that the potential diagnoses settled upon by Dr. Tenpenny were explanation enough for Petitioner's symptoms, and that this was sufficient to offer a mechanism of injury. *Id*.[20] Petitioner argued that, because Dr. Tenpenny reviewed the medical records pertaining to this matter, and summarized same in the first four pages of her report, her report has a sufficient foundation. *Id*. at 13-14.

It is unclear to the Court precisely what next point Petitioner was trying to make, when he stated:

> Dr. Tenpenny relied on a number of scientific studies and articles in reaching the opinion that the Hep[atitis] A vaccination caused Petitioner to suffer from a central nervous system event that could be characterized as a form of ADEM. Specifically, one article indicated that, in the context of ADEM, cessation of therapy, such as corticosteroids, leads to a recurrence of symptoms. Dr. Tenpenny noted that Petitioner experienced this documented occurrence; specifically, Petitioner suffered from [***condition REDACTED***] as a result of the vaccine and was treated with steroids and, upon cessation of treatment, the [***condition REDACTED***] returned.

Response at 14. Petitioner's argument is apparently that, because ADEM symptoms can return when prescribed treatment is stopped, and inasmuch as Petitioner's symptoms returned when he stopped using a similar treatment, it follows that the Hepatitis A vaccine can cause ADEM and that Petitioner himself suffered from ADEM. To state the argument plainly is to illustrate its *non sequitur*.

Petitioner's next argument is hardly worth mentioning, since it has been so roundly repudiated in actual causation cases since the beginning of the Vaccine Act. He argued that, "A number of courts have looked favorably on medical testimony that relies heavily on a temporal relationship between an illness and a causal event." Response at 14.[21] Petitioner perhaps does not realize that his characterization of Dr. Tenpenny's reliance on *post hoc ergo propter hoc* reasoning does not render her conclusions more reliable, but less so: "Here, Dr. Tenpenny considered the temporal relatedness of the side effects experienced by the Petitioner and the character and nature

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[20] Petitioner cites in support for this contention Tenpenny Report at 5-6. However, there is not one sentence explaining how a Hepatitis A vaccine could cause any of Petitioner's symptoms in that section of Dr. Tenpenny's report. That entire portion of Dr. Tenpenny's Report (as with the rest of it) catalogues the symptoms alleged by Petitioner, tries to categorize the symptom with a specific diagnosis (without explaining or supporting her choice of diagnosis), and makes wild, unsupported assertions about the course of those conditions. At no point does Dr. Tenpenny contemplate the initial question of causation under any scientifically medical perspective: namely, *can* the agent in question cause the condition(s) alleged, under a medically cognizable mechanism? This is the "plausible theory" discussed in the case law, and it is required to be postulated and explained before any attempt to tie facts of the individual case to the vaccine. It is the *sine qua non* of an expert report: the theoretical mechanism of injury. The absence of such makes her report unhelpful, even useless. Even in cases where Respondent does not posit a *Daubert* challenge to exclude, the Court would tell any Petitioner having filed such a report to go back to their expert because the report filed was insufficient. The question presented by Respondent's Motion is whether Petitioner and Dr. Tenpenny will be allowed a "do-over" or whether Dr. Tenpenny should be excluded from offering *any* opinion in this matter.

[21] The passage cited, from a Third Circuit case, actually stands for the inverse of Petitioner's argument; *i.e.*, it explains that reliance on temporal proximity to postulate a causal relationship is a false logic. Response at 14.

of Petitioner's side effects to be of utmost importance." Response at 14-15, citing Tenpenny Report at 4-5.

Regarding Respondent's objection that Dr. Tenpenny's report is unreliable, because it relies on the report of Dr. Girard (which identifies the Hepatitis B vaccine–not the Hepatitis A vaccine–as the cause of Petitioner's alleged injury), Petitioner's argument in rebuttal is that, "the discussion of Dr. Girard's opinion, which associated the Hep[atitis] B vaccine and Petitioner's deteriorating mental status and dementia as undiagnosed M[ultiple] S[clerosis], is presented as support for Dr. Tenpenny's conclusion that Petitioner suffers from ADEM[,] given the fact that 'ADEM may fall along the continuum of CNS demyelinating disorders that includes multiple sclerosis.'" Response at 16, quoting Tenpenny Report at 6. Petitioner also sought to defend Dr. Tenpenny's accounting of the aluminum Petitioner received between his two hepatitis vaccinations, summating that "Dr. Tenpenny concludes that the amount of aluminum contained in both vaccines could account for the adverse side effects experienced by the Petitioner." Response at 16, citing Tenpenny Report at 8.

Petitioner's last argument on the admissibility of Dr. Tenpenny's opinion as an expert relates to Respondent's argument that her opinion is irrelevant to the extent it discusses a causal relationship with the Hepatitis B vaccine. Petitioner argued that the only reason Dr. Tenpenny discussed the Hepatitis B vaccine was to draw a causal connection between the aluminum doses in each so as to paint the Hepatitis A vaccine as a substantial cause (notwithstanding that the Hepatitis B vaccine was then a concurrent substantial cause). Response at 16.

C. Respondent's Reply

In her Reply, Respondent noted that Petitioner did not dispute the applicability of the *Daubert* standard of reliability in scientific methodology within the Vaccine Program, but merely that his experts satisfied the requisite burden. Reply at 1. Respondent's Reply argues that, I. An incorrectly performed differential diagnosis, which deviates from correct practice so much that it may no longer bear that classification, is unreliable; and II. The opinions of the experts proffered by Petitioner are not even consistent between one another, and therefore do not bolster one another through corroboration, as Petitioner had argued.

Respondent began the Reply by enunciating the legal standard for analyzing the purported differential diagnosis of Dr. Moulden and Dr. Tenpenny: "[I]n order for a differential diagnosis to satisfy *Daubert*, the court must determine that the expert properly applied the method," and "simply invoking the term 'differential diagnosis' in response to a *Daubert* challenge does not automatically render an expert's opinion scientifically reliable." Reply at 2, citing two Third Circuit cases relied upon by Petitioner, *Heller v. Shaw Industries, Inc.*, 167 F. 3d 146, 156 (3d Cir. 1999) and *In re Paoli RR. Yard PCB Litig.*, 35 F. 3d 717, 745-46, along with the Supreme Court's decision in *General Elec. Co. v. Joiner*, 522 U.S. 136 (1997). Applying the relevant standard to Petitioner's argument, Respondent insisted that "the Special Master must determine whether the differential diagnos[e]s offered in this case by Drs. Tenpenny and Moulden are reliable." *Id.*

Regarding the issue of Dr. Tenpenny's qualification, Respondent argued that "Dr. Tenpenny is not qualified to diagnose the cause of neuro-immunological conditions like the ones she opines

about in this case, no matter what method she uses," inasmuch as she "has no specialized education or training in neurology or immunology," and her only "relevant 'experience' is her own self-directed research into vaccines." *Id*. at 2-3. "Nothing in Dr. Tenpenny's experience or education permits her "to diagnose neuro-immunological conditions or to offer opinions regarding the cause of those conditions." *Id*. at 3. This shortcoming is determinative in Respondent's reckoning, based on a string-cite of Vaccine Act cases and other federal cases, which collectively "have held that physicians, regardless of their medical degrees and training, may not testify on issues of causation that are outside their areas of expertise." *Id*. at 3-4.

In comparison, Respondent's objection to Dr. Moulden is addressed more to the reliability of his methodology than his official credentials of training or experience:

> Even assuming *arguendo* that Dr. Moulden's background in neuropsychology renders him qualified to diagnose the cause of neuro-immunological conditions, his "differential diagnosis" is still unreliable because his conclusion lacks any verifiable scientific support.... Differential diagnosis is a patient-specific process of elimination that medical practitioners use to identify the "most likely" cause of a set of signs and symptoms from a list of possible causes. A fundamental assumption underlying this method is that the final, suspected "cause" remaining after this process of elimination must actually be capable of causing the injury. In other words, a differential diagnosis "assumes that general causation has been proven for the list of possible causes it eliminates."
>
> A differential diagnosis involves two steps: (1) identifying a list of likely causes that explain the patient's symptoms or complaints (the "ruling in" step), and (2) eliminating causes on the list based on the medical history, physical examination, test results, etc., to arrive at the diagnosis (the "ruling out" step).

Reply at 4, quoting *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1413 (D. Or. Dec. 18, 1996) and citing *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001) ("In performing a differential diagnosis, a physician begins by 'ruling in' all scientifically plausible causes of ...injury. The physician then 'rules out' the least plausible causes of injury until the most likely cause remains."). Rather than honing in on the fact that Dr. Moulden did not actually consider and logically rule out other possible *causata* in arriving at his conclusion, Respondent's objection is directed to what he ruled in:

> Dr. Moulden's fatal flaw is that he "ruled in" a cause, his eponymous "Moulden Anoxia Spectra Syndrome" (or "M.A.S.S.") response, even though there is no reliable evidence to establish that such a syndrome actually exists. The only support for the M.A.S.S. response is Dr. Moulden's own purported research, which he has yet to disclose.

Reply at 5. Furthermore, Respondent argued against Petitioner's argument for independent research as a substitute for peer-reviewed publication:

> In an attempt to circumvent this problem, petitioner argues that Dr. Moulden's own "independent" research somehow bolsters the reliability of his opinions. Response Brief at 18-19. Without disclosing that research, however, both respondent and the

> Special Master are left with nothing more than Dr. Moulden's own word – his *ipse dixit* – that the M.A.S.S. response has any scientific support. No other credible evidence in this case supports Dr. Moulden's sweeping assertions. ... [The Court is] required to look beyond the mere averment by an expert witness that the data underlying his opinion is the type upon which others in the field reasonably rely.

Id.

The second main argument of Respondent's Reply is that "the opinions offered by Drs. Tenpenny and Moulden are not consistent, and therefore do not support each other," because they differ even on the fundamental issues of the actual diagnosis for Petitioner's injurious condition and the basic physiologic nature of his alleged reaction to the Hepatitis A vaccine:

> On the one hand, Dr. Tenpenny opines that petitioner's condition is consistent with acute disseminated encephalomyelitis ("ADEM"), or perhaps multiple sclerosis ("MS"), both of which are neurodemyelinating conditions. On the other hand, Dr. Moulden appears to opine that petitioner suffered a M.A.S.S. response resulting in ischemic lesions. Second, Dr. Moulden appears to suggest that petitioner's injury was caused solely by an immunological response to the hepatitis vaccines, while Dr. Tenpenny implicates not only an immunological response, but also potentially a toxic response to aluminum adjuvants in the hepatitis vaccines petitioner received.

Reply at 7 (citations omitted).

III. DISCUSSION

The Court takes this opportunity to clarify this area of law, which, admittedly, has not always been well-explained or consistently-applied within Program decisions. The first question is one of ascertaining binding authority to ascertain whether the Court has authority to grant the relief sought by Respondent's motion (exclusion of proffered evidence), and the second is to determine the conditions for the granting of such relief (the legal standard for when evidence should be excluded). Only then can the Court rule in favor of the relief requested, if those conditions have been met. As always, "We begin our analysis with the language of the Vaccine Act." *Markovich v. Sec'y of HHS*, 477 F.3d 1353, 1357 (Fed. Cir.2007). The Vaccine Act states, in relevant part:

> (b) Matters to be considered
>
> > (1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—
> >
> > > (A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

> (B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.
>
> Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.
>
> ...
>
> (c) "Record" defined
>
> For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa–11 of this title.

§ 13(b)-(c). The question here presented, which, if possible, should find its answer in the Act, is whether the Court has authority to exclude evidence, or whether, on the contrary, it must admit and consider everything filed or propounded by either party.

From these provisions of the Act, the Court derives that it must consider (in appropriate context) "*all* relevant medical and scientific evidence contained *in the record*," but that the record is itself "established" by the Court. It bears noting that the categories of materials that make up the record that "shall" be considered in ruling on a petition are items that would typically be categorized as treatment records, composed in the original diagnosis and treatment of the injured party for whom compensation is sought. The Act also states that no single discretionary pronouncement within those records is binding on the Court. However, beyond these parameters, which govern every Program petition, two clauses stand out.

First, subsection (b)(1) states that the Court must consider all evidence in the medical records, "in addition to all other relevant medical and scientific evidence." It is within this latter category that expert witness materials are included. To this category, the explicit modifiers "relevant," "medical," and "scientific" appear to be preconditions. There is no manifest statutory mandate for the Court to consider expert materials that do not at least facially meet these criteria. Second, the Act gives explicit authority, in subsection (c), to "establish" the record, and the record thus established is the record that subsection (b) (immediately preceding) instructs the Court to consider. Thus, if materials filed by a party do not satisfy the preconditions of subsection (b)(1), then subsection (c) would seem to grant the Court authority to exclude it, by not including it in the established record.

In *de Bazan v. Sec'y of HHS*, 539 F. 3d 1347 (Fed. Cir. 2008), the Federal Circuit's specific answer to Respondent's argument regarding *Daubert*, while stated in the negative, nevertheless contemplated that exclusion *in limine* is an option, provided it is timely raised and not waived:

> *Daubert* is inapposite here because the special master did not exclude any expert evidence under *Daubert*. Rather, the special master admitted and weighed both parties' evidence but simply decided that the government's evidence was more persuasive.

539 F. 3d at 1352 n. 4.

Given that the language of subsection (c) does not mandate a particular result in particular circumstances, it seems that the statutory language grants a degree of discretionary latitude–bounded by right reason–in deciding whether to exclude evidence. It would appear that the Federal Circuit already contemplated this application early in the Program, long before *de Bazan*, *supra*, as long ago as 1992:

> [Standards of review on appeal from Program Decision] vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard. *The latter will rarely come into play except where the special master excludes evidence*.

Munn v. Sec'y, HHS, 970 F.2d 863, 870 n.10 (1992) (emphasis added). This statement of the standard of review, incidentally, was merely a foreshadowing of the standard enunciated later by the Supreme Court. *See Kumho Tire*, 526 U.S. at 142, 152 (citing *Joiner*, 522 U.S. at 143 and 138-39 to state that "courts of appeals are to apply 'abuse of discretion' standard when reviewing district court's reliability determination," and "that a court of appeals is to apply an abuse-of-discretion standard when it reviews a trial court's decision to admit or exclude expert testimony.") (internal marks omitted).

These ruminations lead the Court to conclude that the Statute imposes a presumption of admissibility in § 13(b)(1), but that, for good cause shown and elaborated by the Court, the Court may, in its sound discretion, exclude evidence from the record, via the application of § 13(c), and that, on review, that decision will be reviewed for any abuse of discretion.

There remains a question of burden allocation, which was not addressed by either party's brief in any detail. As has been stated repeatedly in the context of the admissibility of expert testimony, the Court *qua* legal arbiter is to act in a gatekeeping capacity. In federal district courts, that gatekeeping role is governed by FRE 104(a), and under that rule, the proponent of the evidence has the burden of proof to demonstrate to a preponderance why evidence should be admitted. *Bourjaily v. United States*, 483 U.S. 171, 176 (1987) ("Therefore, we hold that when [] preliminary facts ... are disputed, the offering party must prove them by a preponderance of the evidence."). However, there is good reason to depart from that allocation of burden in the Vaccine Program.[22] Whereas, under the Federal Rules of Evidence, evidence is excluded until it is specifically admitted

[22] While the Court departs from the burden *allocation* followed under the Federal Rules of Evidence, it follows the typical rule regarding the *standard* of the burden of proof, which is the same in most Vaccine Program contexts: the "preponderance of the evidence" standard.

for consideration by the factfinder, practice in the Vaccine Program is inclusive, such that materials filed are presumed admitted unless grounds are presented by specific motion to exclude them. § 13(b)-(c). Stated simply, under the Federal Rules of Evidence, evidence is out unless and until it is brought in, whereas in the Vaccine Program, evidence is in unless and until it is put out. Given such a presumption under the Act, it is the party seeking to rebut the presumption that bears the burden of proof. Thus the party seeking exclusion of testimony bears the burden in the Program for demonstrating the ground for exclusion, and an equipoise in proof on this question cuts in favor of the proponent of the evidence.

Also, the Court agrees with Respondent's argument that Vaccine Rule 8 is the relevant rule of procedure to effectuate this process. The Court pauses briefly, however, only to note a later portion of Vaccine Rule 8–subsection (f)–as an exhortation for diligence. It is in the best interest of all for a party seeking exclusion of unreliable evidence to move for such relief as soon as notice has been had that sufficient grounds exist for such relief.

Given that statutory support, procedurally incorporated through Vaccine Rule 8,[23] the Court moves on to determine the standard for such a remedy. The first thing to note is that the specific locus of *Daubert*, the exclusionary rule of FRE 702 as a protection of lay juries, is not the same legal context appurtenant to the Vaccine Program. *See infra*. However, the principle of reliability as a precondition of reliance is a transferable concept. As the Federal Circuit has articulated, even where there is no lay jury to protect from confusingly spurious evidence posing as expertise, there remains a duty for the Court to examine the support for an expert's claims, so as to avoid relying on unreliable evidence. *See Libas*, *supra* at 6; *cf. Terran*, *supra* at 6. Because there is no jury, however, there is not the same level of care necessary to prevent the pollution of the factfinder's perspection. Nevertheless, it is a settled point of law that binds this Court to eschew unreliable evidence, in whatever procedural form that may take.

Therefore, given the fact that the Court must eschew unreliable evidence, and given that the Court has been granted by statutory provision the authority to exclude unreliable evidence, the Court states the conclusion that it may exclude unreliable evidence where the Court is persuaded to a preponderance that it is unreliable. However, there is justly a recalcitrance within the Vaccine Program to exclude evidence, because the Court need not be as protective of the factfinder from corruption as it would need to be with a lay jury, and due to considerations of judicial economy. This is a function of the judicial context of the Vaccine Program.

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[23] In the beginning of Respondent's Motion, under the heading "Authority For Relief Sought," Respondent listed Vaccine Rule 8, but did not include citation to the relevant statutory provisions. The Court here reminds all parties that the Vaccine Rules only provide standardized mechanisms to give effect to statutorily circumscribed authority. *See Lemire v. Sec'y of HHS*, No. 01-0647V, 2008 WL 2490654 *2 (Fed. Cl. Spec. Mstr. June 3, 2008) ("Court rules are not statutes, and thus [no] rule of the Court work[s] to grant to the Court any additional jurisdiction beyond what has been statutorily enacted by Congress. Therefore, the Court considers these procedural rules (and the burdens contained or set within them) within the context of the Vaccine Act as a jurisdiction-granting statute.") (citing *Patton v. Sec'y of HHS*, 25 F. 3d 1021, 1027 (Fed. Cir. 1994)). This is not a trivial point, but a requirement of the Constitution. See United States Constitution, Article III and Amendment X; see also *Lemire* at *5-*6 nn. 6-19.

In the Vaccine Program, then, exclusion from the record is an exceptional remedy, and should only be applied by the Court where the material sought to be excluded is so unreliable, it patently forfeits every trace of being helpful to the Court's consideration of the facts of the case. As stated *supra* in *Daubert* and its progeny, a merely dubious conclusion or a lopsided weighing of evidence does not satisfy the standard of exclusion. Exclusion is proper only where an expert's methodology is so divergent from the scientific method as to be nonsensical and confusing as a whole. Many merely unsuccessful theories and explanations posed by experts might be insufficiently supported by evidence, but the rare occasion where exclusion is appropriate occurs only where an expert's opinion flies so in the face of accepted science that it is completely unmoored from any supports to which it may be tenuously tethered. For reasons logical and practical, this is especially true in the Vaccine Program. As stated in a previous matter:

> Since the medical theory of causation under scrutiny is often the linchpin to the entire issue of entitlement, conservation of judicial resources will most often militate against a separate sub-proceeding in the case where the Court must decide "whether the reasoning or methodology underlying the testimony is scientifically valid and [] whether the reasoning or methodology properly can be applied to the facts in issue." *Daubert* at 592-93. As members of this bench hear these cases consistently, their mind is not a naïve *tabula rasa*, like "infants, tossed back and forth by the waves, and blown here and there by every wind of teaching and by the cunning and craftiness of men in their deceitful scheming." Eph. 4:14. They bring a background of knowledge and experience in evaluating medical and scientific theories and do not require the same procedural protection afforded to lay juries. In fact, the option is always available to the Court, even when Respondent does not object to evidence on relevance grounds, for the Court to challenge the relevance of proffered testimony. In sum, it may be totally appropriate in individual cases to challenge the scientific reliability of a proffered theory through a motion to exclude; however, due to practical considerations, that situation is a rarity.

Garcia v. Sec'y of HHS, No. 05-0720V, 2008 WL 5068934 *14 (Fed. Cl. Spec. Mstr. Nov. 12, 2008).

Likewise, the Court is filing, on even date, a ruling that bears on this issue, in which Respondent urged exclusion of a petitioner's expert witness where such redress was not warranted. There the Court explained:

> As Respondent's well-worn argument reminds, challenging admissibility on the grounds of reliability is a threshold question–a yes or no determination–not the involved comparison and contrast germane to probative weighing of evidence. *See Micro Chemical, Inc. v. Lextron, Inc.*, 317 F. 3d 1387, 1390-91 (Fed. Cir. 2003) ("Whether proffered evidence should be admitted in a trial is a procedural issue"). Most counsel appearing before the Program are wise enough to proffer only expert witnesses who are at least marginally qualified to opine on the topic at issue, and usually are of much higher caliber than that threshold level, often even world-respected authorities. Extremely rare will be the case where a party's expert witness is truly so patently unqualified to opine, or his opinion so unreliable in methodology,

> that exclusion from admission into evidence is warranted.[24] If the issues presented by the motion cannot be answered without hearing most or all of the testimony that would be heard at trial, it may be that the Court cannot rule on the motion until it has convened the entitlement hearing.

Garcia v. Sec'y of HHS, No. 05-0720V, "Order On Motion for Reconsideration," slip op. at 12-13.

To answer the first two questions tendered, then: First, the Court does indeed have authority to exclude unreliable evidence from the record to be considered by the Court in ruling on a petition. Second, such relief should be granted where a proper motion is timely made and preserved, and where the Court is persuaded that the opinion of the proffered expert is completely unreliable. To preserve the time and resources of the Court, such circumstances will most often be met where the evidence of unreliability is patent, and does not require hearing all evidence in the matter just to rule on the motion to exclude. Where evaluation of the challenged expert opinion requires hearing all the pertinent evidence, the Court may defer ruling on the motion until it rules on the issue in chief, or it may be more advisable to err on the side of admitting predominantly unreliable opinion evidence, but then to afford it but trifling probative weight. The question now remaining is whether these conditions have been met in the instant case.

A. Dr. Moulden

More than any arguments made by Respondent, or any failures to rebut by Petitioner, Dr. Moulden himself openly flaunts that he does not follow generally accepted medical science. He believes that none of the several theories found reliable by this Court over the years, none of the mechanisms identified by the IOM, and none of the medical literature on vaccine injury are correct. Even if this is not the heresy which Respondent would ascribe, it is undeniably a heterodoxy that veers sharply from the orthodox universe of accepted medical science. Similar to this is his belief that "all vaccines are useless," and that vaccines are the primary pathogen in the world. It seems incredible that Dr. Moulden would find vaccines more destructive than smallpox, polio, measles, or tetanus. Without being hasty, it may be fair to say that this diverges from the understanding of acceptable medical science, not least in the field of immunology. And it is hard to conceive of a belief that would diverge more from modern medical science than his rejection of germ theory.[25] On a fundamental level, Dr. Moulden breaks notably from medical science as it is practiced today. These are not prudential matters of opinion; these affect the very fiber of scientific methodology. As the Supreme Court stated in *Kumho Tire*, a reliable expert must adhere to "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." 526 U.S. at 152.

Similarly, in the one thing his expert report was supposed to do, *i.e.* describe from start to finish how the Hepatitis A vaccine received by Petitioner might plausibly have led to the injury he

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[24] Citing the instant case as an example.

[25] To be clear, the Court is not prejudicing Dr. Moulden for having an opinion outside the mainstream current of medical scientific thought. His opinion that, "The entire medical model is both flawed and incorrect," however, was made without a scintilla of logical or scientific support, and that is the reason for the Court's disregard for his opinion on this point (among others).

complained of, and show from Petitioner's medical records how that likely was what had transpired, Dr. Moulden was recalcitrant. To the extent he discussed this at all, he guarded his opinion on these matters as proprietary and secret. Presumably, he expected the Court simply to trust him that he had a cogent theory of causation and could, if he chose, defend its likely occurrence by reference to the record. To this, the Court quoth what the immarcescible Ronald Reagan was wont to say, that it will "trust, but verify." Since Dr. Moulden prevents the Court and everyone else from verifying his postulate, he can hardly expect his opinion to be accepted as a matter of trust, *ipse dixit*.

Dr. Moulden's educational credentials would appear to render him at least *prima facie* qualified to opine, but they do not aid his reliability. He has no *medical* expertise in the fields appurtenant to the injury he propounded. His experience in psychology does not make him a neurologist, regardless of any concentration or emphasis in neuropsychology. And his work in a clinical setting in psychology does not transfer to a clinical treating background in neurology. Clinical treating experience has been used as a criterion of reliability, especially where a medical expert has treated patients with the same or similar injury as the one alleged and/or diagnosed. However, since Dr. Moulden has no practical medical experience, he cannot lay hold to such support.

Petitioner counters this point by explaining that Dr. Moulden chose instead to channel his efforts purely into research, and that may indeed be admirable. However, inasmuch as he has publicly released none of the results of his research, his toil in the laboratory does not bolster the reliability of his opinion either. One is left to assume that his experiments have followed the pattern of hypothesis, testing, theory, duplication of results, and falsifiability. However, the lack of published results leaves this supposition as a mere article of faith. Furthermore, as Respondent pointed out, the absence of publication within the medical field also makes testing, duplication of results, and falsifiability impossible for any others to perform. One of the identifiable hallmarks of science is the requirement of theoretical falsifiability; even if an individual theory has not undergone sufficient testing to prove or disprove its viability, the requirement remains that it must be falsifiable under some potential (even if not yet discovered) rubric, else it cannot bear the name "scientific" but is an article of faith.[26] Petitioner even hoisted himself by his own petard by his citation to *Paoli* (*supra* at note 14), which states that an opinion is only reliable when premised upon "good grounds," by which that court described an expert theory and conclusion that was "based on the methods and procedures of science." 35 F. 3d at 744. There is a word for a postulated system that purports to be a unified theory of everything, explaining all phenomena by its one, reductionist theory: *ideology*.[27]

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[26] The Court does not here disparage generally faith in the unprovable; however, in the context of legal proof of scientific elements, such as is the Vaccine Program, only the falsifiable and thus scientific is helpful in the Court's resolution of the questions with which it is statutorily charged.

[27] Regarding the folly of ideology:

> As an *a priori* construction, formulated without regard to facts or ethics, ideology is distinct from science and philosophy on the one hand, and from religion and ethics on the other. Ideology is not science–which it pretends to be. Science accepts the results of the experiments it devises, whereas ideology systematically rejects empirical evidence.... All ideologies are aberrations. A sound and rational ideology cannot exist.

Indeed, Dr. Moulden's seraphic vision of a MASS response smacks of a *pensée unique*, perhaps even devolving into an *idée fixe*. To be so engrossed in one way of perceiving reality, so as not to recognize the distinction between congenital defects and infection, is not helpful to understand reality, and it cannot prove helpful to the Court's understanding. Thus, the Court stares askew at Dr. Moulden's statements such as "Pasteur's germ theory of mammalian disease is both incorrect and inaccurate [because] disease is not being caused by any particular pathogen or strain of pathogen [but] is the non-specific immune response to foreign substances [in] the body and blood stream that causes disease–all diseases." Moulden Report at 90-91.

Dr. Moulden's only objective offer of proof for his construct is the eye and face muscle patterns of people he includes (along with Petitioner) in his category of vaccine-injured individuals.[28] He relates their lasting sequela to several small ischemic events (strokes) in the brain, based on a postulated inability of white blood cells, multiplied and activated in response to the vaccine, to traverse small blood vessels. He then leaps to conclude that these small strokes cause sundry and different injuries (depending on the individual), but completely without explanation or evidence: not a clue as to how this hypothesis could be observed or tested physically. Without explaining large portions of his construct, it is impossible for others to test it by falsification experiments. It is thus also impossible for the Court to rely on his opinion. An edifice is only as strong as its supports, and with Dr. Moulden's opinion, most–if not all–of the weight-bearing beams are missing. *See Perreira v. Sec'y of HHS*, 33 F. 3d 1375, 1377 n. 6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it."); *Knudsen v. Sec'y of HHS*, 35 F. 3d 543, 548 (Fed. Cir. 1994) (ruling that a petitioner's proof regarding actual causation "must be supported by a sound and reliable medical or scientific explanation").

In response to the objections raised by Respondent, Petitioner simply recapitulated Dr. Moulden's theory, but tendered no reasoned defense of his opinion, at least on the merits of its claims. For example, Petitioner summarized Dr. Moulden's statements about white blood cells not being able to fit into small blood vessels and stroke resulting therefrom, but without providing any support (as Dr. Moulden had surely provided none) that such a phenomenon can and does occur. Response at 5-6. The Court is certainly not aware, from its years of experience in other cases, of any problem of blood cells communicating across and through blood vessels. Similarly, Petitioner rehashes the patent nonsense of Dr. Moulden, that this congestion of white blood vessels leading to tiny strokes, "is not an individualized response," but is instead "the same pathological feature[] present in responses to other vaccines." Response at 6. If it were not an individualized response, then every person would suffer the same phenomenon in response, and would manifest *sequelae*. That people react differently to vaccination, and react differently to different vaccines (as is a plain

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Jean-François Revel, LAST EXIT TO UTOPIA, 53 (Diarmid V. C. Cammell trans., Encounter Books 2009) (2000). By contrast, the customary American approach, and that of the law, is one that is distinctly *a posteriori*.

[28] It remains unclear to the Court why Dr. Moulden only includes a few individuals in his categorization. Since he believes that all vaccines cause this response in all people, irrespective of individual response, and the vast majority of the population has received vaccines, it remains a mystery how he can differentiate injured parties from non-injured parties, especially when he does not seem to have recorded what these allegedly injured parties were like before vaccination for comparison.

and demonstrable fact borne out by a reading of Vaccine Act cases) is a clear rebuttal of such a spurious notion. It is actually rather shocking that Petitioner would not only proffer such a fatuous opinion in first place, but would rise to the defense of mere twaddle.

Petitioner's sole argument in defense of the reliability of his experts was that they followed differential diagnosis to arrive at their conclusions, and because differential diagnosis is a reliable, generally-accepted methodology, their methodology was reliable. If only that were true. Nowhere did the Court find that Dr. Moulden performed a correct differential diagnosis of considering every reasonable explanation for Petitioner's injuries, winnowing them out by how closely they correlated to the actual course of Petitioner's condition, and choosing a limited set of diagnoses, or a single diagnosis, to ascribe to Petitioner. Petitioner could not and did not point to a single part of Dr. Moulden's Report where this was done.

Given that Dr. Moulden diverges (even veers) from accepted medical science on such a fundamental level in his methodology, that there is no single indicium of reliability that would bolster his opinion, and that the fact that his opinion would manifestly be unhelpful to the Court's resolution of the issues presented in this matter, the Court rules that Dr. Moulden's opinion shall be excluded from the record to be considered in ruling on the Petition, and that he shall not testify at any hearing held herein.

B. Dr. Tenpenny

The Court turns now from the singular approach of Dr. Moulden to the more ramose report of Dr. Tenpenny. The problems raised regarding admissibility with Dr. Tenpenny's opinion are related to those bearing on Dr. Moulden, but remain distinct. Whereas Dr. Moulden's academic training and credentials afforded him a *prima facie* level of expertise even to render an opinion, Dr. Tenpenny is not entitled to any such presumption by her training or background, so the Court here considers whether, as a threshold matter, she has a demonstrated level of expertise that would qualify her to opine, before considering if the scientific methodology used in reaching her opinion is reliable.

Dr. Tenpenny is a doctor of osteopathy,[29] and was (for a time) a practicing, board-certified doctor of emergency medicine. She is perfectly qualified to opine in those disciplines, and the Court does not impugn her expertise in either of those areas of practice. However, the question presented by Respondent's Motion is whether those qualifications allow her to opine on the matters of this Petition.

In short, osteopathy is not neurology. Dr. Tenpenny described Petitioner's condition as akin to either multiple sclerosis or ADEM, without really explaining how she would arrive at either diagnosis. Indeed, the basis for her multiple sclerosis categorization is another doctor's expert report

[29] Osteopathy is "a system of therapy founded by Andrew Taylor Still (1828-1917), based on the theory that the body can make its own remedies against disease and other toxic conditions when it is in normal structural relationship and has favorable environmental conditions and adequate nutrition. It uses generally accepted physical, medicinal, and surgical methods of diagnosis and therapy, while placing chief emphasis on maintenance of normal body mechanics and on manipulative methods of detecting and correcting faulty structure." DORLAND'S (*supra* at note 13) at 1336.

from earlier in the litigation (who was also not a neurologist), and not her own expertise. While one may respect Dr. Tenpenny's service in osteopathy and emergency medicine, a patent review of her report demonstrates her lack of familiarity with the finer points of neurology, the area into which, she posits, Petitioner's injury falls. In doing so, she disqualifies herself.

The Court recognizes the possibility of overlap between specialties, such as a neurologist testifying to immune-mediated processes, or an immunologist testifying to dermatological reactions to an antigen. But these are aspects of true overlap between disciplines that an expert in one discipline would need to master to treat patients. In order to treat a patient with Guillain-Barré Syndrome, a neurologist must have familiarity with the immune challenge and auto-immune process that is thought to drive the disease process in that disorder. That much is understood.

Nevertheless, it is much more attenuated for the Court to rely on the explanatory opinion of an osteopath and erstwhile emergency medicine doctor to explain how a vaccine can and did cause...whatever Petitioner's injury might be. Lacking expertise in neurology, Dr. Tenpenny is none too sure of what Petitioner's actual injurious condition is. Maybe it is ADEM. Or perhaps it is Multiple Sclerosis. They're both neurological disorders affecting myelination of the central nervous system, are they not? From this alone, though, it is apparent that Dr. Tenpenny is overmatched by the subject matter. There is a wide difference between the causes, development, phase, and other elements of pathology in each illness, and no one well-versed in neurology would equivocate between such divergent diagnoses. Whereas ADEM is monophasic and usually related to an immune challenge, multiple sclerosis is typically chronic, and is generally understood to be idiopathic, even cryptogenic in its origin. In light of this, it is difficult not to perspect Dr. Tenpenny's opinion as a generalized–even wild–guess, based on mere matching of symptoms alleged with textbook descriptions of illnesses.[30] That is something a well-educated layman could do, and does not implicate expertise.

To this, Petitioner argues that Dr. Tenpenny is something of an autodidactic polymath, and that her expertise is not limited to her areas of formal study, but extends to all manner of potential vaccine injury. The basis for this claim is Dr. Tenpenny's reading diet in the area of vaccine injury, and her loquacious discussion in print and electronic media concerning same. Though these may be useful in a variety of contexts, they do not equate with medical expertise. Truly, by the standard Petitioner espouses, the Undersigned would be accounted a medical expert, after 19 years of reading medical literature, reviewing individual cases, and hearing scientific and medical testimony. However, it is clear that this argument is not persuasive. Expertise is not acquired through osmosis or accretion, just as television interviews do not an expert make. Her ideas on vaccine injury have not been exposed to any critical analysis of those in the relevant field, let alone peer-reviewed medical journals. There is no way to ascertain whether Dr. Tenpenny's opinion is credibly accepted by those who would know; there are only the patent defects in her report that militate for the opposite.

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[30] The fact is that Petitioner's symptoms do not dovetail concretely with either illness, which is why Dr. Tenpenny has alternately either split the difference between the two, or referred to Petitioner's condition as some variant subset of ADEM in particular.

Regarding those patent defects, it would be highly likely that, were the Court to find Dr. Tenpenny held sufficient expertise to render an opinion, the Court would not find her opinion reliable. She does not explain one iota of how the Hepatitis A vaccine could cause the injuries Petitioner alleges (let alone the two conditions she proposed), and she makes no reference to Petitioner's medical records to prove that any such mechanism was at work. The focus of her report is merely to attempt to render a diagnosis for Petitioner, which she does poorly if at all. It is thoroughly worthless to the Court, and is not helpful enough, not relevant enough, to be admissible, considering the strong arguments against its admissibility. Petitioner's only defense of her report is that she used differential diagnosis to arrive at her conclusions. As noted *supra*, she did no such thing. Her only mention of potential alternate *causata* was a conclusory ending sentence that, since no other diagnosis had been proposed (and she certainly had not proposed any), it must have been the vaccine(s). Nowhere in her report did she consider other specific diagnoses, weigh each according to their correspondence with Petitioner's course, and settle on one based on reason. She did not even perform a differential diagnosis as between multiple sclerosis and ADEM, two very different illnesses, from either of which, she stated, Petitioner might have suffered. She perceived only one potential cause, proceeded not to critically examine it, and then concluded that it was the cause. In this regard, her report was thoroughly unscientific.[31]

IV. CONCLUSION

Therefore, in light of the foregoing, the Court **FINDS** that neither Dr. Moulden nor Dr. Tenpenny followed acceptably scientific methodology in arriving at their disparate opinions; **FINDS** that, as a result, their expert reports were, and their hearing testimony would be, unreliable; **FINDS** that Dr. Tenpenny is unqualified to opine on matters in which she has no special expertise (in this case, neurology); and **RULES** in favor of Respondent's Motion to Exclude their opinions in this matter. Neither should be permitted to waste the Court's (or counsel's) time at a hearing held merely to endure testimony that is patently unreliable.

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[31] Petitioner's defense on this point, which attempts to portray Respondent's position as unreasonable, only succeeds in demonstrating itself to be patently fallacious:

> Incredibly, Respondent is taking the position that there is no scientific basis for the assertion that the Hep[atitis] A vaccination caused a previously healthy individual to suffer an adverse reaction, where no alternative causes exist. Even if Petitioner's reaction to Hep[atitis] A was an anomalous response, it is the only basis for Petitioner's injuries.

Response at 9. How are we to know that "no alternative causes exist"? Petitioner provided nothing but his own *ipse dixit*, mixed with a generous portion of *post hoc ergo propter hoc* argumentation that assumes the desired conclusion in the face of admitted unlikely circumstances ("anomaly"). And while Petitioner would prefer that the Court accept such reasoning, a mere glance at the mass of Decisions in the Program would have answered that it surely cannot. See, e.g., Grant v. Sec'y of HHS, 956 F. 2d 1144, 1148-49 (Fed. Cir. 1992) (holding that mere temporal association is not sufficient to prove causation in fact, and that, without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation").

Wherefore, Petitioner is hereby **ORDERED** to seek out a credibly qualified, methodologically reliable expert witness to opine on the specific matter at issue in this case: namely, *can* the Hepatitis A vaccine cause Petitioner's injury, and if so how; and *did* the Hepatitis A vaccine follow such a process in Petitioner's case, with reference to his medical records.

A status conference scheduling same shall be scheduled and convened as soon as practicable. Contact with the Court may be had by contacting my law clerk, Isaiah Kalinowski, Esq., at 202-357-6351.

IT IS SO ORDERED.

s/ Richard B. Abell
Richard B. Abell
Special Master