In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-0720V

Filed: 19 May 2010

* * * * * * * * * * * * * * *	*
ROBERTO GARCIA,	*
	*
Petitioner,	*
	* **PUBLISHED**
v.	*
	* *Daubert v. Merrell Dow Pharms., Inc.*;
SECRETARY OF HEALTH AND	* Methodological Reliability;
HUMAN SERVICES,	* Scientific Method; Generally-Accepted;
	* Waiver of Argument
Respondent.	*
* * * * * * * * * * * * * * *	*

Ronald Craig Homer, Esq., Conway, Homer & Chin-Caplan, Boston, Massachusetts, for Petitioner; *Linda Sara Renzi, Esq.*, United States Department of Justice, Washington, District of Columbia, for Respondent.

PUBLISHED ORDER ON MOTION FOR RECONSIDERATION[1]

ABELL, Special Master:

On 12 November 2008, the Court filed a published entitlement ruling which found that Petitioner had suffered Guillain-Barré Syndrome (GBS),[2] and that his Tetanus-Diphtheria (Td)

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[1] Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this ruling within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

[2] GBS is "an acute, immune-mediated disorder of peripheral nerves, spinal roots, and cranial nerves, commonly presenting as a rapidly progressive, areflexive, relatively symmetric ascending weakness of the limb, truncal, respiratory, pharyngeal, and facial musculature, with variable sensory and autonomic dysfunction; typically reaches its nadir within 2-3 weeks, followed initially by a plateau period of similar duration, and then subsequently by gradual but complete recovery in most cases." STEDMAN'S MEDICAL DICTIONARY 1899 (28th ed. 2006).

vaccine was a substantial cause in bringing that condition to pass. Pursuant to Vaccine Rule 10(c), on 3 December 2008, Respondent moved for reconsideration of that opinion due to Respondent's belief that the Court's conclusions "failed to apply the appropriate legal standards, and was thus contrary to law." Motion at 2. On 11 December 2008, Petitioner responded in opposition to Respondent's Motion, and on 18 December 2008, Respondent filed a Reply. The case continued to proceed into the damages phase concurrently with these deliberations. The Court here rules on Respondent's Motion.

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

As part of Petitioner's filings prior to trial, Petitioner filed the expert report of board-certified neurologist Dr. Derek Smith. Petitioner's Exhibit (Pet. Ex.) 6. Respondent did not elect to file a motion *in limine* to exclude Dr. Smith's opinion.

In preparation for the entitlement hearing, on 30 April 2007 the Court ordered both parties to file prehearing memoranda stating their arguments for and against Petitioner's entitlement to compensation. In Respondent's Prehearing Memorandum, she "acknowledge[d] that in 1994 the Institute of Medicine ('IOM') concluded that the evidence favors a causal relation between tetanus toxoid and GBS," but went on to explain that the IOM's pronouncement had been negated by recent studies, based upon a 1997 epidemiological study that did not support such a relationship.[3] Respondent also argued that the timing interval in the instant Petition did not fit well with the temporal association proposed by the IOM's findings. In her Prehearing Memorandum, Respondent never moved for the exclusion of Dr. Smith's testimony on the basis of inadmissible unreliability. Outside of the Vaccine Program, such a so-called "*Daubert* motion"[4] would typically be filed by the time of the prehearing memorandum, or (at the latest) at trial, in order to avoid suffering a waiver of the objection. *See, e.g., Trading Technologies Intern., Inc. v. eSpeed, Inc.*, 595 F. 3d 1340, 1349-1360 (Fed. Cir. 2010); *Micro Chemical, Inc., v. Lextron, Inc.*, 317 F. 3d 1387, 1390 (Fed. Cir. 2003); *MEMC Electronic Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 248 Fed. Appx. 199, 201-03

[3] Respondent did not argue that the IOM reversed its prior conclusion. In reality, the IOM's conclusion still stands, that a theoretical basis exists for a tetanus-GBS causal relationship, as does specific clinical findings that such relationship has been expressed in a clinical setting.

[4] A Daubert motion is a motion to exclude methodologically unreliable expert witness testimony, typically filed *in limine*, to prevent such dubious testimony from confusing and even tainting the factfinder. It is premised on the Supreme Court case of *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

(Fed. Cir. 2007); *Atmel Corp. v. Silicon Storage Technology, Inc.*, 76 Fed. Appx. 298, 312 (Fed. Cir. 2003); *but see Crystal Semiconductor Corp. v. TriTech Microelectronics Intern., Inc.*, 246 F. 3d 1336, 1354-1360 (Fed. Cir. 2001) (abrogated on other grounds, *see Minebea Co., Ltd., v. Papst*, 444 F. Supp. 2d 68, 141 (D.D.C. 2006)).

At the entitlement hearing, the Court specifically asked each party whether they intended to proffer objections to the experts' admissibility on *voir dire*, beyond the regular cross–examination on the details of the experts' opinions; Respondent declined (as did also Petitioner). Based in part upon the parties' declination, as well as upon the Court's review of the experts' reports, *curricula vitae*, and supportive medical literature, the Court ruled then and there that both experts "certainly appear to be eminent and qualified in their respective fields and with their respective backgrounds." Hearing Transcript at 5. In the Entitlement Ruling, the Court incorporated that ruling, by stating, "Both experts were personally and professionally credible; that premise is beyond a cavil of doubt in the Court's mind. However, the Court must analyze the differences between the opinions offered to determine whether Petitioner has established a logical sequence of cause and effect that is biologically plausible to tie together the factual sequence and explain Petitioner's injury." Entitlement Ruling, slip op. at 10, citing *Walther v. Secretary of HHS*, 485 F.3d 1146 (Fed. Cir. 2007) and *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Only in her Posthearing Brief did Respondent, for the first time, argue that Dr. Smith's theory of causation (the one he had first postulated in this matter several months prior) was unreliable. Respondent's Posthearing Brief at 21 ("Dr. Smith's speculation that petitioner's Td vaccine caused or contributed to his GBS within twenty-four hours of administration lacks peer review, acceptance, and 'good grounds.' His causation hypothesis is nothing more than 'subjective belief or unsupported speculation,' and is thus patently inadmissible under *Daubert*."). As noted in the Entitlement Ruling, "Respondent spen[t] an entire section of [Respondent's Closing Brief] arguing that "*Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) applies to Vaccine Act Proceedings," in order to then argue that Dr. Smith's testimony should be excluded because it was not reputable under a *Daubert* analysis." Entitlement Ruling at 10.

The Entitlement Ruling addressed Respondent's argument as follows:

> The Court pauses here only to add, that within cases in the Vaccine Program, direct application of *Daubert* is infrequent, largely because, in each case, the special master is statutorily authorized to act as finder of fact and to apply the law to those facts once found. §12(d)(3)(A)(I). Moreover, the Federal Rules of Evidence, which the Court in *Daubert* was interpreting, do not apply in Vaccine Act proceedings by the explicit words of the Vaccine Act. §12(d)(2)(B); Vaccine Rule 8(a). As such, the need to protect the fact finder from confusing, unreliable expert opinion through a separate examination performed by the legal arbiter, *when they are the same person in every case*, quickly becomes logically attenuated, especially where, as here, there is no rule of evidentiary admissibility that requires it. 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.

Moreover, evaluating a medical theory upon a motion to exclude would often prove redundant or unnecessary. This bifurcated question of "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) closely resembles the "can it"–"did it" question of aetiology and causation that is the heart of entitlement considerations in actual causation cases. In fact, this Court has, in times past, employed analytical factors such as those referenced in the *Daubert* case for the purpose of evaluating a proffered medical theory, not in the context to which *Daubert* refers ([*in limine*] motions to exclude unreliable evidence as inadmissible), but on the central question of causation. See *Terran v. Secretary of HHS*, Case No. 95-0451V, 1998 WL 55290 *11 (Fed. Cl. Spec. Mstr. Jan. 23, 1998) (finding petitioner's theory of causation insufficient because it was "not generally accepted in the scientific community," had "not been subjected to peer review publication because ... it is not generally accepted and would not get published in the United States," and had "not been satisfactorily tested" as no tests had then been developed). However, since that time, the Federal Circuit has provided significantly more guidance on the analytical standards to be used in the Vaccine Program to evaluate evidence (including expert testimony) in determining the issue of causation, such that the Court no longer needs to lift factors from persuasive authority because there has been provided direct, mandatory authority to follow. *See* [*Shyface v. Sec'y of HHS*, 165 F.3d 1344 (Fed. Cir. 1999)], [*Althen v. Sec'y of HHS*, 418 F. 3d 1274 (Fed. Cir. 2005)], [*Pafford v. Sec'y of HHS*, 451 F. 3d 1352, 1355 (Fed. Cir. 2006), *rehearing and rehearing en banc denied*, (Oct. 24, 2006), *cert. den.*, 168 L. Ed. 2d 242, 75 U.S.L.W. 3644 (2007)], [*Walther v. Sec'y of HHS*, 485 F. 3d 1146 (Fed. Cir. 2007)], and [*de Bazan v. Sec'y of HHS*, 539 F. 3d 1347, 1352 (Fed. Cir. 2008)]. Thus, in this current context, the similarity between this preliminary "gateway" question and the ultimate issue of the Court's determination of entitlement raises the substantial concerns of redundancy and inefficiency.

> Those cases where exclusion of proffered testimony is appropriate are therefore not common. Most often, the central question of the case is how well the expert's theory comports with the facts culled from the medical records and fact witness testimony (if any is offered). This question is one of persuasiveness and logical relevance, not admissibility. Nevertheless, there is certainly a component of scientific reliability and/or validity that will bear upon the Court's determination of whether Petitioner's expert was persuasive enough to surmount the preponderance standard, or if Respondent's expert was more persuasive *per contra*. To be sure, the Federal Circuit's guidance on this point is clear in cases like [*Knudsen v. Sec'y of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994)] (each petitioner "must proffer a *plausible* medical theory"), *Althen*, *supra* at 1278 ("a medical theory causally connecting" coupled with "a *logical* sequence of cause and effect"), and *de Bazan*, *supra* at 1352 ("onset of symptoms [must occur] within a timeframe for which, given the medical understanding of the disorder's aetiology, it is *medically acceptable* to infer causation-in-fact") (emphasis added). But in this context, the question of whether an expert's theory possesses scientific *bona fides* goes to the persuasiveness of the evidence on the question of aetiology and causation; the Court is not actually applying *Daubert* for the purpose of determining credibility [or] admissibility of the testimony.

Garcia v. Sec'y of HHS, No. 05-0720V, 2008 WL 5068934 *14-15 (Fed. Cl. Spec. Mstr. Nov. 12, 2008). It is this discussion in particular that Respondent wishes the Court to reconsider.

II. THE PARTIES' ARGUMENTS

Respondent's Motion asks the Court to reconsider its conclusion(s) on an essentially purely legal question, or set of questions:

> [I] Dr. Smith's hypotheses failed to meet *Daubert*'s reliability requirements and were, therefore, entitled to no weight. [II] [The Court ruled] that *Daubert* is essentially inapplicable in Vaccine Act proceedings. [III] The Special Master also found that respondent had waived his *Daubert* objection.

Motion at 2 (numbering added). The first objection Respondent raised argues that the Court incorrectly applied the law to the facts in this individual case, and the latter two argue that the Court is confused on the legal and/or procedural standards binding upon proceedings in the Vaccine Program. Despite these three-fold objections, Respondent's Motion is primarily consumed with the second objection, and seeks unswervingly to prove that "*Daubert* applies in Vaccine Act proceedings." Motion at 3 *et seq*.

Respondent read the Entitlement Ruling's interpretation of Daubert and the Federal Circuit's opinion in *Terran*[5] to say that "*Daubert* is inapplicable (or optionally applicable) to cases in the Vaccine Program." Motion at 3. Respondent cited to and discussed *Seaboard Lumber Co. v. United States*, 308 F. 3d 1283, 1301-02 (Fed. Cir. 2002) to demonstrate that, even in the bench trial context, where there is no jury to protect from scurrilous expert theories, "the *Daubert* standards of relevance and reliability for scientific evidence must nevertheless be met." Motion at 3-4, quoting *Seaboard* at 1302. Respondent likewise cited *Libas, Ltd. v. United States*, 193 F. 3d 1361 (Fed. Cir. 1999), to postulate that a court should not afford probative weight to expert testimony where the basis of that testimony is of unknown or dubious reliability. Motion at 4, citing *Libas* at 1366.

Respondent also argued beyond a vague concept of "applying *Daubert*," adding that there must necessarily be, in every case, a "separate and distinct" "*Daubert* inquiry," which, presumably, the Court must raise *sua sponte*, even when both parties affirmatively waive argument on the issue. Motion at 5-7. Respondent correctly notes that, "The test articulated in *Daubert*, however, is not one of causation, but rather one of scientific reliability," the difference being, "If the evidence fails to meet the standard of scientific reliability, then it should be excluded, or given no weight." Motion at 6. Respondent disagreed with the Entitlement Ruling, arguing that the Federal Circuit decisions cited by the Court "do not provide the necessary tools for evaluating the scientific reliability of evidence proffered by petitioners in Vaccine Act proceedings" because they "offer no framework for evaluating scientific evidence." Motion at 7. This leads Respondent to conclude that there must inevitably be, in every Vaccine Act case, a bifurcated analysis of expert testimony, hermetically split between analyzing scientific reliability to determine if the expert is credible and his testimony admissible, vis-à-vis analyzing actual causation in the light of the testimony's probative weight.

Respondent objected also to the Court's finding of a waiver of Respondent's *Daubert* objection in this case. Motion at 8-11. Respondent on the one hand agrees with the Court's approach, that exclusion of evidence pursuant to a *Daubert* objection should be *in limine*, but complains that Respondent's efforts to do so in other cases have been rebuffed. Motion at 8-9, citing an Unpublished Order from the Omnibus Autism Proceeding. Based upon this experience, Respondent alleges that there are conflicting rulings on the procedure of tendering *Daubert* objections, and that waiver should not be effected in this case "when the law on this issue is unsettled." Motion at 9.[6]

Another argument raised by Respondent against waiver betrays the point made about the necessity in every case for a bifurcated analysis: that raising a *Daubert* challenge only after the expert in question has testified in the hearing raises no problem, because "*Daubert* hearings are regularly conducted by federal court judges to consider testimony from an expert to determine whether the expert's opinions are scientifically reliable." Respondent's argument seems to be that the Court should formally bifurcate its analysis to separately examine reliability, *sua sponte*, so as not to be

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[5] *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).

[6] Respondent's Motion also argues that Respondent preserved a *Daubert* objection because her Prehearing Memorandum contained a general citation to *Daubert* in its "boilerplate" rules section.

confused by spurious medical testimony, but that there is no problem caused if the Court hears such spurious expert opinion at trial, because the Court can sort everything out in one step in ruling on entitlement. This is a patently confused argument that only worsens in elaboration. Respondent cites in support of this argument that such a *post hoc* approach has been utilized by certain members of this Court. Of the five cases listed as exemplars, two were remanded on a motion for review, and one was remanded on a motion for review and then subsequently overruled by the Federal Circuit, in language that directly contradicts the relief Respondent sought by their belated motion to exclude. *Andreu v. Sec'y of HHS*, 569 F. 3d 1367 (Fed. Cir. 2009) ("A trial court makes a credibility determination in order to assess the candor of a fact witness, not to evaluate whether an expert witness' medical theory is supported by the weight of epidemiological evidence."). As further explanation, Respondent proposes that no harm will come from avoiding a reliability inquiry until after the record is closed and the Court is considering the evidence in ruling on entitlement.

In further betrayal of her earlier point regarding bifurcation, Respondent concedes that, "as a practical matter, Respondent may not be in a position to state the full basis for a *Daubert* motion, and the Court may not be in a position to rule on the motion until the expert testifies at the hearing. ... Thus, because of the unique procedural rules applicable in Vaccine Act proceedings, it is rarely possible for Respondent to file a fully-developed *Daubert* motion prior to the hearing." Motion at 10-11. These considerations only bolster the Court's statement on the issue in the Entitlement Ruling. However, to Respondent, this creates an inequity: "Even if respondent filed such a motion, it is likely that the Special Master would deny it as premature. In short, the Special Master's finding that any *Daubert* argument is waived once the testimony is heard creates an unjust Catch-22 for Respondent." Motion at 11.

Respondent's last point of contention with the Entitlement Ruling disputes the Court's finding that Dr. Smith was reliable and persuasive, assigning error thereto because his testified-to opinion "was based on pure speculation and unsupported hypotheses," such that "his testimony was scientifically unreliable under *Daubert* and insufficient to meet petitioner's burden under *Althen*." Motion at 11. Respondent bases this rather strong claim on Dr. Smith's reference to his medical theory of causation as a "hypothesis" in explaining the rather singular course that Petitioner's GBS followed. Motion at 12. His stipulation that there was no empirical, laboratory-based, human study in the context of GBS to prove dispositively that his theory was at work in Petitioner's case was interpreted by Respondent as speculative postulation and conjecture in the absence of knowledge. Respondent argues that, inasmuch as Dr. Smith could not point specifically to medical literature in support of his theory in particular respects, "his testimony was speculative, unpersuasive, and scientifically unreliable," to a sufficient degree that total exclusion of his opinion is called for. Motion at 13-14.

Petitioner's arguments in opposition to Respondent's Motion are brief; Petitioner basically agreed with the Court's analysis in the Entitlement Ruling. Petitioner's only specific disputes to Respondent's Motion are focused on what the Petitioner sees as Respondent's attempt to heighten the burden of proof under *Althen*, *supra*.

Petitioner attacked what he referred to as "Respondent's persistent use of [*Terran*] to misuse *Daubert* to elevate the Vaccine Program's standard of proof." Petitioner pointed out what he saw

in an error in Respondent's reading of *Daubert*, which Petitioner believed undermines the Motion for Reconsideration: Respondent never challenged Dr. Smith's methodology, merely his medically theoretical conclusions. Response at 4 (quoting portions of *Daubert* to state "it is the methodology underlying the testimony that must be scientifically valid. The inquiry envisioned is ...a flexible one. It's overarching subject is the scientific validity and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission, not on the conclusions that they generate.") (internal marks omitted). In Petitioner's view, Respondent's arguments for exclusion under *Daubert* are misplaced because they focus on Dr. Smith's conclusion, instead of his methodology.[7]

Petitioner, who was represented by counsel who appear often before the Court, provided a history of Respondent's consistent position ("*Daubert* 'applies' and must be followed!") over the course of many cases, and two cases before the Federal Circuit in particular, wherein Respondent "asked the Federal Circuit to pronounce that special masters are required to apply *Daubert* to Vaccine Program proceedings," only to have the Circuit decline to do so. Response at 4, referencing Respondent's briefs to the Federal Circuit in *Althen*, *supra*, and *Capizzano v. Sec'y of HHS*, 440 F. 3d 1317 (Fed. Cir. 2006). From that, Petitioner argued that the Circuit's declination was a rejection of Respondent's position.

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 Court does here reconsider the subject as requested, as well as its discussion in the Entitlement Ruling. However, for the reasons discussed *infra*, the Court does not alter its substantive factual findings or conclusions of law contained therein.

The first, most fundamental point of clarification concerns precision of language, which, in this context, is almost coequal with accuracy.[8] Respondent's insistence that *Daubert* "applies" is an impermissibly vague formulation; it is a statement without a specific, discernible meaning. Few cases, and almost no Supreme Court cases, have merely one holding, let alone one application. "*Daubert*" is not a term of art, nor is it a unified theory of everything. It is a decision in a distinct context with specific rulings, each with specific levels of narrow to general applicability. Respondent's statement of the issue is reductionist to a vanishing point. In short, Respondent's

[7] As noted in the Entitlement Ruling, exclusion is only appropriate under *Daubert* where an expert's proffered testimony is so faulty or deviant in methodology that it must be excluded *in toto* as lacking in credibility. In contrast, where an expert's methodology is at least generally aligned with accepted scientific method, his conclusions are weighed on probative merit; they are not excluded, even if the factfinder may consider his testimony to be less persuasive than that of the other party's expert.

[8] Said Orwell in an essay, "The slovenliness of our language makes it easier to have foolish thoughts." *Politics and the English Language* (1946).

fixation amounts to a form of onomatodoxy,[9] using the incantation "*Daubert*", without reference to a specific holding, as a talisman to deliver us all from experts that go bump in the night.

For instance, regarding Respondent's argument that the Entitlement Ruling held that "*Daubert* is inapplicable (or optionally applicable)," the Court was elaborating the specific holdings of the Federal Circuit in Program cases that interpret *Daubert*'s applicability in the Program (*Terran* and *de Bazan*). Applicability is not an either/or proposition. In legal reasoning, almost any reasoned judicial opinion has some analogous applicability with any other case, at least on some general or universal level, while simultaneously maintaining important distinctions of fact that might require distinguishment. Any legal argument by analogy requires a joint process of induction–deriving the narrowest grounds of a general ruling in common between the two from the particulars in the opinion sought to be applied–and deduction–applying the general rule inductively derived to the particular facts of the case in which application is sought. The first step is Aristotelian, the latter Platonic. This process may often be performed incorrectly, but it is the essence of the common law approach.

To a certainty, Respondent is not likely advocating that every holding in the Supreme Court's *Daubert* opinion applies directly and literally to the facts in this case, or to Program cases as a whole. Therefore, it would be meet for Respondent to specify which specific holding or holdings Respondent seeks to induce from *Daubert* and deductively apply in Program cases. If Respondent's underlying argument is that the Court must test the reliability of medical theories before relying on them in its causation findings, that is correct, and was manifestly agreed to in the Court's Entitlement Ruling. In fact, within the Entitlement Ruling, the Court never stated that *Daubert* has no bearing, or that its central, most general ruling on the necessity for a threshold reliability determination was to be ignored; instead the Court merely summarized what it explains here in greater detail: that a direct, literalist application of *Daubert* is neither required nor practical in the Vaccine Program, even if the same concerns addressed in *Daubert* are addressed within Program cases in a manner that appropriately suits the context of the Vaccine Program.[10]

The *Seaboard* case that Respondent cited illustrates this distinction well. After inductively reading *Daubert*'s specific holdings, the Circuit culled the logical reasoning at its root, and then applied the logic to the context of government contracts. 308 F. 3d at 1301. The Circuit's conclusion is the same as the one reached in the Entitlement Ruling, that protection of a naïve factfinder is less of a concern in a system with only bench trials, but that there must still be a mechanism to check if evidence is reliable before relying thereupon. *Id*. at 1302; *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 158-59 (1999) (Scalia, J., concurring). The same could

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[9] *See*, *e.g.*, the Imiaslavie (Имяславие) heterodoxy of the early 20th century.

[10] The Supreme Court itself, in *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999), stated the essential holding in *Daubert* thusly: "In *Daubert*, this Court held that Federal Rule of Evidence 702 imposes a special obligation upon a trial judge to 'ensure that any and all scientific testimony ... is not only relevant, but reliable.'" If that requirement is a "special obligation" of FRE 702, then, in the strictest sense, that holding does not apply to this Court, to which the Federal Rules of Evidence is not authoritative, by the express wording of its authorizing statute. *See* 42 U.S.C. § 300aa-12. It may nevertheless be appropriate to extrapolate and analogize, through the operation of inductive and deductive logic, reasoning that may be applied in the Vaccine Program, but that is not the same as applying a specific holding that is mandatory authority.

be said of the other case discussed by Respondent's Motion (i.e. *Libas*), in which the Court specified the holding they were adopting from *Daubert*, albeit a rather general one: "[R]eliability is the touchstone for expert testimony." Motion at 4, quoting *Libas* at 1365-66.[11] Instead of noting this process of inductive sifting, Respondent used a straw man argument to describe the Circuit's precedent as "the fact that the judge is the fact-finder does not render *Daubert* inapplicable." Motion at 4. The question is not whether *Daubert* is to be applied; the question is how, which holdings, and to what level of procedural complexity.

As a rule, members of this bench are supposed to state their analysis of expert testimony, including their analysis regarding its reliability. When the Court checks the expert's opinion against the medical records (and/or fact witness affidavits) in the "did it" phase of causation analysis, or compares the expert's theory to the medical literature filed in the case, that is to determine the level, if any, of reliability in that expert's proffered opinion. It is to establish the reliability to see if the Court may afford it sufficient weight to a preponderance.

What Respondent views as a conflation of issues is really only a procedural streamlining made possible by the expertise gained by the members of this bench over time. In deciding whether a petition is entitled to compensation, it is axiomatic that the Court first assess the reliability of each expert's theory and explanation against the facts of the case (derived primarily from the medical records) and the backdrop of accepted medicine (derived primarily, but not exclusively, from the filed medical literature and other analogous cases in the Program).[12] Only then, if and only if that preliminary question has been answered[13] in the affirmative, can the Court comparatively weigh the competing theories and explanations of causation proffered in the matter for their persuasiveness (i.e. probative weight). The Court need not bifurcate the inquiry procedurally or explicitly in order to answer both questions effectively, because of the unity of role between factfinder and legal arbiter.

Respondent argued that "The test articulated in *Daubert* ... is not one of causation, but rather one of scientific reliability.... If the evidence fails to meet the standard of scientific reliability, then

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[11] Likewise, the Circuit's position in *Libas* is in accord with this Court's explanation in the Entitlement Ruling, and would not seem to lend much support for Respondent's insistence on a requirement for *sua sponte* procedural bifurcation:

> [I]f a trial court relies upon expert testimony, it should determine that the expert testimony is reliable. It would make little sense to say that a trial court in its factfinding role should accord much if any weight to expert testimony, the reliability of which is not established.

Libas at 1366.

[12] This initial reliability inquiry is also connected to examining the expert's professional credibility, and each one of the two may influence the other.

[13] In practice, it has often been the case that, when one party filed an expert report that was cursory, vague, or conclusory, one that did not address both the "can it" and "did it" aspectual questions of causation, the Court has ordered the party to file a supplemental expert report to satisfy this defect, so that the reliability of the expert's theory may be properly assessed by the opposing party and by the Court, *prior to trial*.

it should be excluded." Motion at 6. Respondent is predominantly correct on both points.[14] However, these statements illustrate the confusion surrounding the Federal Circuit's *Terran* opinion, especially the way Respondent has argued for its interpretation and application. For it was the petitioner in *Terran* who argued that application of *Daubert* should be limited to deciding reliability on a motion to exclude expert testimony, and should not be "a broader tool for analy[sis]" on general causation, which is what the special master (the Undersigned) had done[15] in determining entitlement. 195 F. 3d at 1316. The Federal Circuit disagreed, finding such application on the general issue of vaccine causation to be permissible. *Id*. And neither the Undersigned nor the Federal Circuit adopted a *Daubert* "test" that would require experts to meet a set of criteria, but instead used those factors flexibly ("as a tool or framework") to analyze and compare how persuasive was each expert's testimony. *Id*., citing *Kumho Tire*, 526 U.S. at 151 ("[*Daubert*'s] list of factors was meant to be helpful, not definitive."). The Circuit found that such use of *Daubert*'s factors was permissible as a method of assaying an expert's theory, such that it did not constitute an abuse of discretion by the trial judge. This is not the same thing as requiring the same analytical approach in all future Program cases. Nor is it tantamount to incorporating those factors into a rigid, elemental test. Clearly, in *Terran*, the Circuit had a golden opportunity to rule that *Daubert* was universally binding in its every holding upon the Vaccine Program, but did not.[16] The Circuit ruled on the issue on appeal: whether it was error for the Undersigned to employ the (explicitly nonexclusive) criteria suggested in *Daubert* as criteria for actual causation analysis, in the time period before the Federal Circuit had elaborated greatly on the topic. *See generally* Entitlement Ruling. Respondent's reading of a "strong indication" from the *Terran* opinion, that *Daubert* (whether one particular holding, or all of them) is binding, mandatory authority, is not supported by the portion she cited, nor by any other sentence in the Circuit's opinion. While the specific holdings in *Daubert* and *Terran* are binding, and not merely persuasive, it is the extrapolation into other contexts that renders certain logic persuasive and not mandatory. As one example, a trial judge's application of the *Daubert* factors to assess flexibly an expert's theory in deciding causation was not error; however, that holding does not necessarily mean that a petitioner's expert must in every case satisfy all four of those factors in order to be admitted into the record, as Respondent seems to advocate. The extrapolation is not necessarily an illogical one to make, but it is not one that has been expressly accepted in a way that binds this Court.

Respondent objected to any mention that portions of *Daubert* are persuasive, not mandatory authority. True, rulings of the Supreme Court are binding on all lower federal courts, by the constitutional mandate of Article III to the Constitution. However, not every holding in divers and

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[14] To be completely accurate, *Daubert* announced no bright-line, elemental standard, which is what is typically conveyed by the term "test" used by Respondent here. A non-exclusive factorial analysis, such as the one in *Daubert*, is not properly termed a test.

[15] *Terran v. Sec'y of HHS*, No. 95-451V, 1998 WL 55290 *11 (Fed. Cl. Spec. Mstr. Jan. 23, 1998). There the Undersigned found that one aspect of the petitioner's theory did not pass the initial hurdle of reliability, and was not therefore persuasive either, but that the larger aspects of the theory, which had been met with approbation by the IOM, were reliable and persuasive.

[16] As Petitioner pointed out, the Federal Circuit has had a similar chance in several cases since that time also, but has not elected to incorporate the reading of *Terran* pressed by Respondent.

sundry cases will have direct, literal applicability in other legal or judicial contexts. The facts at issue and the issue presented in *Daubert* dealt specifically with the Federal Rules of Evidence and jury trials, neither of which are germane to Vaccine Act proceedings. In that sense, the rules that can be derived from its holdings are derivative, not direct. One specific way in which *Daubert* is persuasive and not mandatory authority was expressly denoted as such: the use of the listed factors of reliability. 509 U.S. at 593. The Supreme Court in *Daubert* stated that the factors discussed were both non-integral and non-exclusive. *Id*. at 594-95. True, this Court may use those factors in analyzing reliability of expert testimony. However, no single factor, or combination of those factors, is outcome determinative in that analysis. *Kumho Tire* at 141.

Since *Terran*, the Federal Circuit has elaborated the actual causation standard in greater detail. Respondent is correct that the Federal Circuit's opinions in *Althen*, *de Bazan*, *Pafford*, and *Shyface* do not primarily discuss threshold determinations of reliability; indeed, they pertain to the more nuanced analysis of probative weight that is much more common, and often more difficult, than the former. Nevertheless, the Court's point stands. Embedded within those cases, the Circuit kept reliability, and the confirmation of objective, outside reality, a touchstone in analyzing expert theory and explanation of facts. This the Circuit communicated by the use of adjectives like "medically appropriate," "plausible," and "logical." Such a consideration bears reliability of methodology in the expert's thought pattern into the weighing of one expert's opinion against another's.[17] Respondent is then incorrect to state that "those cases offer no framework for evaluating scientific evidence to ensure that the evidence has adequate support." Motion at 7. That was precisely what those cases were concerned with: evaluating expert testimony to determine whether it was probative enough to persuade the Court to rely thereupon on the issue of causation.

The confusion about the substantive, qualitative difference between admissibility and probative weight ultimately springs from a procedural misunderstanding. The hoary maxim holds true: "Substantive rights are secreted in the interstices of procedure." 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

[17] Such a process is precisely what the Court did in ruling on entitlement in this case. The Court tried to analyze each expert's stated opinions against the backdrop of the other expert's reasoned explanation and the medical records. Unfortunately, on several issues, Dr. Spiro, in testifying for Respondent, stated his opinion without explaining its basis in the facts of this case, known scientific fact, or the opinion of others in the respective medical field, as reflected in medical literature. *See*, *e.g.*, Entitlement Ruling at 10 ("The Court presumes until shown otherwise that members of an IOM panel represent the mainstream of medical thought. Dr. Spiro is entitled to his professional skepticism, but, given the lack of any stated basis for his stance, he did not persuade the Court to similarly embrace Pyrrho's *akatalepsia* on the issue."); *Id.* at 11 ("Dr. Smith's testimony revealed to the Court Petitioner's theory of causation; Dr. Spiro's testimony required the Court to accept his conclusions based solely upon the credibility of his personal conviction.").

methodology, that exclusion from admission into evidence is warranted.[18] 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.[19]

From the moment the Court rules to admit the expert testimony onward, the Court is required (as are the parties) to address the relative merits of the theory presented, so as to determine if it is more or less persuasive than that of the other party's expert. To talk of exclusion at that point is analogous to occluding the passage of egress in rural animal housing after equine departure therefrom is completed. *Macsenti v. Becker*, 237 F.3d 1223, 1231 (10th Cir. 2001) (holding that a *Daubert* objection to expert reliability had been waived where the objecting party "did not object to the testimony when it was admitted during trial," but only raised an objection "after the close of all the evidence by a motion to strike [the testimony at issue], and by a motion for judgment as a matter of law, presented also at the conclusion of all of the evidence"); *see also Marbled Murrelet v. Babbitt*, 83 F. 3d 1060, 1066 (9th Cir. 1996) ("Although we recognize that evidence which is unreliable is necessarily insufficient, the appropriate time to raise *Daubert* challenges is at trial."); *see also Maritime Overseas Corp. v. Ellis*, 971 S.W.2d 402, 410 (Tex. 1998) (citing *Babbitt* approvingly to conclude that "to prevent trial or appeal by ambush, we hold that the complaining party must object to the reliability of scientific evidence before trial or when the evidence is offered.").

Contrary to Respondent's argument, objections concerning whether a party's expert is fit to cross this threshold may certainly be waived. Respondent has not provided any legal reasoning, other than flexibility and lenience for the party seeking exclusion, for why such an objection cannot be waived. Certain defects (*e.g.*, subject matter jurisdiction) cannot be waived and must be raised by the Court *sua sponte*, even if no party raises the defect as an issue. *Metz v. United States*, 466 F. 3d 991, 998 (Fed. Cir. 2006). These, however, are a special class of defects, and no argument was put forth to persuade the Court that such special treatment is warranted. Any other objections (or other arguments) are waived if not raised in a timely fashion. Vaccine Rule 8(f)(1).

The reasons for this policy are many, but one is that it prevents error at the moment when it may be suitably corrected, before incurring unnecessary time outlay or expense.[20] If Dr. Smith's

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[18] *See*, *e.g.*, the Court's ruling in *Veryzer v. Sec'y of HHS*, No. 06-0522V, "Published Order Granting Motion To Exclude," filed on even date.

[19] As discussed *infra*, the mere fact that the Court may need to wait until after hearing the testimony of a challenged expert to resolve a challenge does not absolve the challenging party from timely raising and preserving a *Daubert* challenge from the moment notice is had of the expert's lack of qualification or unreliability.

[20] One treatise states the principle this way:

> If the administration of the exclusionary rules of evidence is to be fair and workable, the judge must be informed promptly of contentions that evidence should be rejected, and the reasons supporting the contentions. The burden is placed on the party opponent, not the judge. Accordingly, the general approach is that a failure to make a specific objection at the time the offer is made, is a waiver on appeal of any ground of complaint against its admission.

opinion did not provide enough explanation in support, why wait until after the record is closed to point that out, when earlier notice of the objection allows for the good doctor to elaborate. If Dr. Smith's methodology is so far-fetched as to warrant exclusion, why would Respondent wait until after trial to raise the issue, after Petitioner had expended time and treasure in preparation, and after the Court heard extensive testimony from him at trial? Even if the typical harm, that of a factfinder hearing the testimony of an unreliable expert opinion,[21] is less pronounced when before the special masters within the Vaccine Program, the considerations of judicial economy are still present. A straightforward application of the Rules leads to an outcome that is more efficient, more fair, and more likely to arrive at the truth in most cases.

The Federal Circuit has also explicitly recognized the substantive distinction within the context of procedural form. When Respondent argued her *Daubert* position to the Federal Circuit in *de Bazan*, the Court ruled that Respondent's argument was "inapposite" because the case did not pertain to a properly raised *Daubert* objection to exclude expert evidence; because the expert testimony was already admitted, it was then to be weighed on persuasive merit and probative weight, and that aspectual holding of *Daubert* would not then apply. 539 F. 3d at n.4.

The Court next comes to Respondent's argument that, even where neither party raises an objection to the reliability of an expert theory, the Court is required to conduct a formally bifurcated "two-step analysis" in ruling on entitlement in every case: separating the threshold inquiry into reliability from the more involved examination of causation. Motion at 7. As has just been articulated, there is no reason to infer a *sua sponte* duty of the Court to raise reliability where specific grounds for objection have not been raised by a party by a timely *in limine* motion, preserved as necessary. Such a motion would be the only context where such bifurcation would be necessary, and only as a practical point: the general causation analysis ordinarily must of necessity follow the taking of expert testimony at the hearing, whereas the Court's ruling on the motion to exclude must precede that more general comparative analysis (either before testimony is even taken, on the basis of the expert's submitted report, or, if deferred until after trial, immediately prior to considering causation analysis generally). In cases where no timely objection is raised, there is no reason to formally bifurcate the analysis between reliability and probative weight. Because reliability is a precondition to probative weight in order for a special master to rely upon an expert's testimony, the two questions may often be addressed in tandem. In a phrase, no special master is going to rely upon evidence that is unreliable, without their analysis transparently bespeaking same, and opening up the decision to review and appeal. In any event, Respondent clearly did not raise or preserve a specific

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Kenneth S. Broun, 1 MCCORMICK ON EVIDENCE § 52 (6th ed. 2006); *see also* 22 Charles Alan Wright & Kenneth W. Graham, Jr., FEDERAL PRACTICE AND PROCEDURE § 5168.1 n. 48 (2000 Supp.); *United States v. Armedo-Sarmiento*, 545 F. 2d 785, 793 (2d Cir. 1976) (ruling that where defendants did not object to the testimony of a questionably controversial witness at trial, but only on appeal, "Had appellants voiced timely objection, perhaps a less controversial [witness] could have been found," but that "[u]nder the circumstances, there is no merit to appellants' present claim of error.").

[21] This was the primary issue in *Daubert*, which led to the disagreement on how to interpret Federal Rule of Evidence 702. *Daubert* at 589.

objection to the methodological reliability of Dr. Smith in a timely fashion, and waiver clearly operates to render her later objection nugatory and otiose.

Respondent's Motion also asks the Court to reconsider its holding that Respondent waived her objection and *Daubert*-premised motion to exclude. Motion at 8-10. Respondent noted that she in essence agrees with the Court's reasoning here and in the Entitlement Ruling, that a *Daubert* motion to exclude should be filed when a petitioner's expert first gives notice of his unreliable opinion. Motion at 8. However, Respondent claims to have been placed in an untenably contradictory conundrum by another member of this bench in his governance of the Omnibus Autism Proceeding (OAP). Respondent's position is that she would gladly file motions to exclude as a matter of course, but for the reproof received at the hands of the other special master.

As an initial answer to this argument, the Court counsels generally that *Daubert* motions should not, in any event, be filed *pro forma* in every case as a matter of course. Exclusion for unreliability of expert methodology might apply in a fraction of cases, but they will not be the majority of cases. Motions to exclude should not be leveled as dilatory boilerplate filings, but should only be made where a good argument exists in justification, and where the grounds for exclusion are made explicit and specific. The Court should not have to guess what is being objected to, nor have to infer why reliability might somehow be absent. As noted *supra*, the standard for exclusion on a *Daubert* motion means that most cases that may lack sufficient probative weight in the final analysis will nevertheless overcome a *Daubert* challenge of exclusion.

Secondly, Respondent is aware that unpublished decisions, much less unpublished orders, are neither binding nor even persuasive in most cases. This is especially in the special context of the autism proceedings. What may work as a well-functioning rule in most Vaccine Act petitions may have been specially excepted in that setting because of the sheer volume of cases involved. *See*, *e.g.*, the provision made for "short form" petition forms for autism cases. Certainly, the special masters handling the autism cases did not indicate that the special procedural streamlining followed in those cases was to apply universally to cases outside of that context. Even if that point was not clarified, a two-page unpublished Order with only one citation in support can hardly be taken as redirecting the substantive and procedural law in the Program. Respondent herself stipulated that her reading of the governing law (pertaining to *in limine* filing) is as it has been herein expressed, and it should be clear that the Order cited to does not operate to alter that structure. Similarly, it is a contrivance for Respondent to pit this Order against the backdrop of accepted practice in order to claim that "the law on this issue is unsettled." Motion at 9. As referenced above, the Federal Circuit's specific answer to this question of procedure in footnote four of the *de Bazan* opinion clarifies any question that may have lingered.[22]

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[22] In *de Bazan*, when Respondent argued for the use of *Daubert* to the Circuit, the Circuit responded by delineating the line between admissibility and probative weight:

> The government argues that the Court of Federal Claims erred by discounting the special master's consideration of the medical evidence without an analysis under *Daubert*. However, *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.

Respondent again misunderstands the issue by arguing that *Daubert* may be raised after the hearing without harm. The reason the objection must have been raised as soon as Respondent had notice of the defect, is so that Petitioner could have then elected to change experts to avoid the objection, or the Court could have barred the objected-to expert's testimony, forcing Petitioner to find another expert. Similarly, Petitioner, knowing that reliability was a challenged issue, could seek to correct the cause of the objection by filing more supportive medical literature, or focusing in greater detail upon the reliability of the expert's opinion. Respondent's timely motion gives notice in time for a remedy to be taken. Waiting until after Petitioner's only expert had testified to move for his exclusion approaches litigation by surprise. If, however, Respondent had timely raised a motion to exclude *in limine*, and, should the Court not have granted the motion immediately, had preserved this objection at trial and in the Posthearing Brief, there would have been a remedy available to be taken by Petitioner. If Petitioner did not choose to avail himself of a remedy when notice was given, it would be upon his own head. *See* Ezekiel 3:18-21. By seeking to nullify Petitioner's expert testimony only after it has been tendered, what Respondent appears to seek is a way to allow only one party's expert testimony into the record: in essence, to deny Petitioner the opportunity to present expert testimony on his behalf into the record considered by the Court. If the Court wished to avoid this circumstance, it might be necessary to order the filing of additional expert reports, even to convene another entire entitlement hearing; this is a patent waste of judicial resources. Since these results could be avoided by a timely-raised objection, it is incorrect for Respondent to assert that no harm is caused by an objection made out of time.

Respondent makes a similar error in arguing that waiver is not made merely because the Court hears the expert's testimony, as testimony from the expert may need to be heard to rule on a *Daubert* motion to exclude for want of reliability. Motion at 9. The conclusion propounded does not follow from the argument offered. As explained *supra*, the Court's mind is not corrupted by hearing an unreliable expert theory, as will necessarily be the case where the Court acts as both factfinder and legal arbiter. The problem with waiting until after the entitlement hearing to raise the objection does not lie with the Court having heard the testimony and being improperly influenced thereby. The problem is that such delay fails to give specific notice of defects when such notice would actually be of use. The requirement of giving notice of a party's position is the primary reason the Court orders expert reports prior to an entitlement hearing. Such a fundamental *grundnorm* is woven over and across the warp and woof of the judicial approach, as part of the process which, in some form, Americans are all due. *See*, *e.g.*, *Cleveland Bd. of Education v. Loudermill*, 470 U.S. 532 (1985).

Respondent's citation (Motion at 10) to the Federal Circuit's opinion in *Libas* does not contravene this point. The Circuit's holding actually cuts against Respondent's position. In *Libas*, a textile importer challenged a governmental classification of a product before the Court of International Trade, and appealed to the Circuit when unsuccessful there. 193 F. 3d at 1362-63. The challenge was primarily a challenge to the reliability of methodology by which the classification was made, implicating *Daubert* and *Kumho Tire*. *Id*. at 1365. If *Libas* is analogous to the Vaccine Program context, then the argument could be made that *Daubert* and *Kumho Tire* are not strictly

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539 F. 3d at 1352, note 4 (internal marks omitted).

applicable to the Program. *Id*. at 1366 ("*Daubert* and *Kumho Tire* were decided in the context of determining standards for the admissibility of expert testimony under the Federal Rules of Evidence, which are not at issue here."). The Circuit ruled generally, however, in a way that provides guidance in Program cases, and which is in complete accord with the Court's rulings in this case:

> [T]he proposition for which [*Daubert* and *Kumho Tire*] stand, that expert testimony must be reliable, goes to the weight that evidence is to be accorded as well as to its admissibility. Neither the plain language of the relevant Supreme Court opinions nor the underlying principles requiring reliability for expert testimony are narrowly confined in application to questions of admissibility. The difference between weight and admissibility, moreover, is in many instances a close question.

Libas at 1366. The Court did note that the reliability question was not put to rest simply because the textile importer did not raise a *Daubert* objection early in the proceeding. *Id*. at note 2. The issue was not waived because the procedure in that type of case requires the filing of all records relating to the subject of the petition, including the classification made by the regulatory authority. *Id*. The classification was not truly expert testimony, an opinion prepared specifically for litigation to aid the Court in a factual determination, but more analogous, within Vaccine Act cases, to treaters' opinions in medical records. Therefore, in *Libas*, the importer could not move to exclude the classification, and the "only recourse was to argue against the weight accorded to the [classification] test." *Id*.

This does nothing but to affirm the Court's analysis in the Entitlement Ruling and herein, that reliability is a precondition to affording probative weight, and that, where a motion to exclude would be inapposite, the legal standard must still include a check on reliability, as do indeed the cases cited in the Entitlement Ruling and *supra*. *Libas* does not support Respondent's position that an objection to reliability, in the form of a motion to exclude an entire portion of evidence, may be brought at any time without encountering a waiver; it does, however, support certain positions stated throughout this ruling, to wit: I. In specific statutory contexts (such as the Vaccine Act), motions to exclude evidence will be sparse, as a function of procedural and judicial structure; II. Reliability must still be ascertained, and may often be embedded within the process of weighing probative merit, not necessarily as a bifurcated proceeding; III. Even where exclusion of evidence is not proper, its relative reliability will still be relevant to disposition of the case's merits.

Finally, on the issue of waiver, Respondent curiously provides, as purported persuasive authority, citation to a number of decisions from the Vaccine Program in which *Daubert* analysis was foregone until after the entitlement hearing. At the time Respondent filed the instant Motion, three out of the five were at some level of appeal, and since that time, two were remanded by a judge of the Court of Federal Claims, and one was reversed by the Federal Circuit. Upon further review, none of the cases cited applied *Daubert* in the way advocated by Respondent.[23]

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[23] In *Hager v. Sec'y* of HHS, No. 01-0307V, 2008 WL 4763736 (Fed. Cl. Spec. Mstr. Oct. 15, 2008), the special master used the *Daubert* factorial indicia of reliability to assess the probative value of the petitioner's theory; however, he most certainly did not exclude or disregard any portion of written or spoken testimony, but merely discussed its probative weight in coming to his findings and conclusions. Respondent's reliance thereupon is therefore misplaced. In reversing the special master, Judge Firestone found that the same "expert testimony regarding a medical theory ... was supported by sufficient scientific evidence to sustain a finding that the petitioners met their preponderant evidence

In sum, if a party seeks exclusion because the opposing party's expert patently lacks even a modicum of reliability, down to the foundation of his methodological approach, the correct procedure is to file a motion to exclude as soon as the party seeking exclusion receives notice of such defect. However, because that sort of motion *in limine* seeks such an extraordinary remedy, the defect complained of should be fairly patent *prima facie* in order to carry the burden required for outright exclusion. Mere differing of ultimate conclusions or points of emphasis in the record do not meet or surmount this burden. It is this distinct procedural context to which the Court has been referring as "direct" application of *Daubert*'s primary holding on the central issue presented in that case, that of protection of the factfinder from expert testimony of a confusingly spurious nature.

The broader mandate of the Supreme Court's reasoning in *Daubert* is a general safeguard against scientifically unreliable evidence being relied upon by any factfinder in a scientifically

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burden." 89 Fed. Cl. 71, 86. Based upon the weight afforded that testimony, Judge Firestone concluded, "Ms. Hager met her burden of showing a medical theory causally connecting the vaccine and her [injuries,] that Ms. Hager met her burden under *Althen* to establish a medically acceptable temporal relationship between the ... vaccinations and the onset of her illness[, and,] in setting forth the medical theory and temporal relationship, Ms. Hager established by a preponderance of the evidence a logical sequence of cause and effect showing that the vaccine was the reason for the injury."

In *Graves v. Sec'y of HHS*, Case No. 02-1211V, 2008 WL 4763730 (Fed. Cl. Spec. Mstr. Oct. 14, 2008), the same special master concluded that, because the evidence presented in the case did not prove the reliability of the expert theories propounded by the petitioner's experts, the petitioners had not met their burden of proof. *Graves* at *15. There is not one jot or tittle of excluding expert testimony. Only after deeply considering the expert's testimony, against the backdrop of medical literature filed in the case, did the special master decide that the evidence was not sufficiently persuasive to surmount a preponderance. This is a world away from the specific issue presented in *Daubert*, and a close reading of the two cases would easily reveal that fact. Aside from the common theme/term of reliability, citation to Graves does not prove Respondent's point. Senior Judge Merow remanded the matter back to that special master, requiring a factual question be answered before the legal challenges to the decision could be made. 2009 WL 989772 (unpublished order).

The portion Respondent cites in *Carter v. Sec'y of HHS*, No. 04-1500V, 2007 WL 415185 (Fed. Cl. Spec. Mstr. Jan. 19, 2007), was a footnote to a string cite in the decision's boilerplate list of rules, and only reiterates what has been said herein regarding the Federal Circuit's holding in *Terran*, while providing a *caveat* that later cases have modified the strictures governing proof on the issue of causation. It says absolutely nothing to support exclusion of expert testimony first objected to after the entitlement hearing.

In the Decision on Remand in *Andreu v. Sec'y of HHS* cited by Respondent (No. 98-0817V, 2008 WL 2517179 (Fed. Cl. Spec. Mstr. May 29, 2008)), the special master stated that the specific opinions proffered by the petitioner's expert "fail[ed] *Daubert*'s reliability requirement [and were] contravened by the medical literature filed as evidence and [were] unsupported by [the] clinical presentation." *Id*. at *5. Actually, the special master in that case was analyzing reliability (as called for by *Daubert*) concurrently with analyzing probative weight of the petitioner's theory. How Respondent views this as supportive of her position is unclear. Furthermore, when the Federal Circuit eventually reversed and remanded that decision, the Circuit cited *Daubert* only for general maxims of reliability in weighing expert theories, not in the specific context of exclusion from admissibility of spurious expert methodology. 569 F. 3d 1367, 1379.

Lastly, it is singular that Respondent cites *Sanchez v. Sec'y of HHS*, No. 04-1361V, 2008 WL 3174348 (Fed. Cl. Spec. Mstr. Jul. 18, 2008). In that case, the special master ruled, in response to Respondent's arguments to the contrary, that the petitioner's expert's "methodology appears perfectly legitimate under *Daubert* and *Althen*." *Id*. at *18.

complex case where expert testimony is necessary. This pertains less to a particular procedural context, and constitutes more of a broad rule or principle. Thus, even where no particular *Daubert* objection has been timely raised, the Court in every case must first assess if an expert's testimony is reliable at all, and, assuming the affirmative, then determine how reliable it is in weighing its probative value. But the members of this bench are not, as Respondent has urged, required to bifurcate their analysis in every case, where doing so would be redundant or duplicative. *Kumho Tire* at 152 ("The trial court must have the same kind of latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides whether or not that expert's relevant testimony is reliable....*That standard applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion*.")[24] (emphasis added).

It is in this latter, broader context that the Federal Circuit's opinions, such as those given as examples in the Entitlement Ruling section quoted *supra*, provide tests of reliability on both the threshold question and as a matter of degree in probative evaluation. However, it is important to see that this is not a narrow, direct application of the *Daubert* holding, but a broader interweaving of its fundamental concern. *Kumho Tire* at 152 (The objective of *Daubert*'s gatekeeping consideration "is to ensure the reliability and relevancy of expert testimony."); *Id*. at 158-59 (Scalia, J., concurring) (the "trial-court discretion in choosing the manner of testing expert reliability [] is not discretion to abandon the gatekeeping function;" instead, it is "discretion to choose among reasonable means of excluding expertise that is *fausse* and science that is junky").

The remainder of Respondent's position reargued the issue of causation, and specifically asks the Court to change the probative weight given to Dr. Smith's testimony, inasmuch as Respondent believes Dr. Smith's testimony was "based on pure speculation and unsupported hypotheses." Motion at 11. By this measure, argued Respondent, Petitioner's expert testimony was "scientifically unreliable," such as to run afoul of *Daubert*, and likewise failed to satisfy the test of causation stated in *Althen*. Respondent bases this claim on the fact that Dr. Smith referred to his medical theory as a "hypothesis" instead of a theory. Motion at 12, citing Transcript at 17, 32, 42, 48, and 50.[25]

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[24] Indeed, the Supreme Court's opinion in *Kumho Tire* is in accord with the Court's analysis in the Entitlement Ruling, and as elaborated herein, that the Court's analysis need not be bifurcated where reliability is not timely raised as an issue:

> Otherwise, the trial judge would lack the discretionary authority needed both to avoid unnecessary "reliability" proceedings in ordinary cases where the reliability of an expert's methods is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert's reliability arises.... Thus, whether *Daubert*'s specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine.

Kumho Tire at 153-53.

[25] Respondent's version of the Transcript appears to be one page offset from the Court's version, such that those pages would be 16, 31, 41, 47, and 49. Citations to the Transcript herein are to the official Court version.

Dr. Smith had not appeared regularly as an expert witness before, and, at the Hearing, did not use the precision of language that is the hallmark of the legal profession. He used terms that a more frequently retained expert would be warned against. For instance, he characterized his medical opinion as a "best guess," but one that was "based on reasonable assumptions." Tr. at 16. He did offer his opinion to a preponderance of the evidence, at least so long as he did not "hear a hypothesis that [he would] find more credible." Tr. at 16. In other words, the opinion he offered was, to him, the most reasonable explanation of Petitioner's injury based on the evidence in the record and his knowledge about the then-current state of neurology at that moment.

Dr. Smith agreed that the Pollard article (which both Dr. Smith and the Court relied upon) did not support one aspect of his theory of Petitioner's injury, that of physiologically descending onset symptoms:

> Q But the Pollard article does not support your hypothesis that an asymmetrical presentation makes it more likely than not that a TD vaccination caused the GBS?
>
> A I don't believe that it does.
>
> ...
>
> Q Would you say that it's speculation that the asymmetrical presentation of the weakness in the upper extremities that Mr. Garcia suffered demonstrates vaccine causation, or do you think that there's scientific evidence to support that?
>
> A No. I'm not arguing that there's scientific evidence. It's speculation based on common sense.

Tr. at 31. His use of the term "speculation" is the target of Respondent's argument that the basis of his opinion is unreliable. Respondent also objected to Dr. Smith's use of the term hypothesis.[26] However, as seen in the immediately foregoing and following quotations, it was Respondent's Counsel who first ascribed the terms "hypothesis" and "hypothetical" to Dr. Smith's proffered theoretical mechanism of injury.

> Q Okay. Now, this is your hypothesis as to how this occurred. Is that correct?
>
> A Correct.
>
> Q Is there anything in the medical literature that supports your hypothesis?
>
> A Well, there's a lot, for example, in the animal literature or the immunologic literature that would support the idea of prepriming or immune activation. Something that is specific to Guillain-Barré in humans, probably not.

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[26] The cardinal definition of hypothesis from the RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE (2d ed., unabr. 1987) is "a proposition, or set of propositions, set forth as an explanation for the occurrence of some specified group of phenomena, either asserted merely as a provisional conjecture to guide investigation [] or accepted as highly probable in the light of established facts." According to Dorland's a hypothesis is "a supposition that appears to explain a group of phenomena and is advanced as a basis for further investigation; a proposition that is subject to proof or to an experimental or statistical test. See also *theory*." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 899 (30th ed. 2003) (SAUNDERS).

Tr. at 41-42. There was yet another exchange on cross-examination that employed the term "hypothesis" to describe Dr. Smith's proffered theory:

> Q And what's the basis for that opinion?
>
> A This is based on a lot of basic immunology....
>
> Q ...Is there any evidence in GBS that this can occur?
>
> A This isn't something that can be measured within humans. There is what I would call *ex vivo* data where people have taken lymphocytes out of people who either had Guillain-Barré or not and seen how quickly they proliferate against various nervous system antigens. I think that there is experimental evidence or I would say experimental designs that indicate that people think this is potentially an important thing to look at.
>
> Q So it's basically a hypothesis that has not been proven?
>
> A I would agree with that.
>
> Q Is there anything in the medical literature that supports your hypothesis of a latency period for a cell's mediated immune response -- maybe I just asked this -- without a preprimed immune response occurring within 24 hours?
>
> A We have no way of measuring preprimed or not preprimed. Given that we don't know how to measure that then there's not going to be any literature specific to the presence or absence of it.

Tr. at 46-48. Respondent also challenged the support within medical literature for the specifics of Dr. Smith's explanation of the facts in this case in light of his theory of causation.

> Q Can you cite to any literature[27] where the occurrence of GBS occurred within 12 hours of a tetanus vaccine?
>
> A No.
>
> Q Within 24 hours of a tetanus vaccine?
>
> A No.
>
> Q So again, this is your hypothesis that is not supported in the scientific literature?
>
> A I would say that's correct.

Tr. at 49. Respondent takes these expressions of Dr. Smith to state that Dr. Smith's expert opinion was "no more than mere conjecture." Motion at 13.

In the Vaccine Program, as in some other legal contexts, certain terms have achieved almost the status of terms of art. *Speculation* is not as concrete or trustworthy as a *hypothesis*, which is less

[27] "It might not be surprising in a particular case, for example, that a claim made by a scientific witness has never been the subject of peer review..." *Kumho Tire*, 526 U.S. at 151.

so than a *theory*, which itself might be merely *possible*, actually *plausible* (*i.e.* rationally believable), or fully *probable* (*i.e.* more likely than not). Someone not familiar with the strict boundaries imposed on these terms as logical categories can be excused for such loose speech, because it is the actuality, not the label ascribed thereto that matters most. In the inverse, if Dr. Smith had merely stated his conclusions, and then asserted that some merely conjectural, unexplained conception was a very probable theory, that would not make it so. Similarly, as reflected in the Entitlement Ruling, the Court was persuaded by the proofs and corroborating explanation provided by Dr. Smith at the Hearing and in the materials he submitted *via* Petitioner. If anything, it was Respondent's expert whose testimony did not persuade, and was conclusory to the point of being cursory. Expert testimony is admitted for the sole purpose of aiding the factfinder by explaining potentially complex matters. *See generally* 29 Wright and Gold, FEDERAL PRACTICE AND PROCEDURE, § 6262 (1997). Bald, unexplained assertions supported only by a fiat of credentials does not meet this standard. Reasoned explanation does. As Respondent herself correctly pointed out in her Posthearing Brief: The opinions of experts "can be no better than the soundness of the reasons that stand in support of them" (*Fehrs v. United States*, 620 F.2d 255, 265 (Ct. Cl. 1980)); and "[t]he conclusions of an expert are only as sound as their factual predicate." (*Castillo v. Sec'y of HHS*, 1999 WL 605690, at *13 (Fed. Cl. Spec. Mstr. July 19, 1999)).

On a similar point, the Court found Dr. Smith's acknowledgments of the limits of his knowledge to be helpful, and actually *enhanced* the strength of his testimony. It gave the opinions he did state an added level of honesty, humility, and credibility, because of his care in not overstating the certainty of his opinions. Moreover, his admission that his theory had not been tested and proven by laboratory or epidemiological testing did likewise. Certainly Respondent is aware that not every aspect of a medical theory must be proven by empirical testing for that theory to be accounted plausible, and even probable by the Court. Dr. Smith was transparent in delineating which portions of his theory had been either proven, generally accepted, or respectably theorized, and which were conclusions he made based upon those sets.

Respondent also fixes upon a concession made by Dr. Smith to the possibility that the temporal proximity between onset of GBS and the Td vaccination that preceded it was coincidental. Motion at 13. Actually, it would be quite presumptuous if Dr. Smith did not concede the possibility of coincidental association, as that is of course possible in every case presented in the Program. However, admitting the possibility of one explanation does not negate or subtract from an opinion which weighs the evidence in the case and finds a different causal connection instead. In many cases, experts often stipulate that a particular mechanism might be possible, even if they do not believe the same mechanism is medically plausible, let alone probable as the most likely agent of causation. It displays a closed-minded approach to forswear even the possibility of alternate causation (or in this case, a lack of ascertainable causation), and is generally unhelpful to the Court. Much more helpful is the expert witness who discusses why one potentiality is more likely than another, by appeals to scientific reason and by reference to evidence in the record.

For these reasons, the Court reaffirms its factual findings regarding the weight afforded to Dr. Smith, and the factual findings made in reliance thereupon. The Court has reconsidered the Entitlement Ruling, but does not elect to disturb the findings made therein.

IV. CONCLUSION

Therefore, in light of the foregoing, the Court reaffirms its ruling in favor of entitlement in this matter.

IT IS SO ORDERED.

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