IN THE SUPERIOR COURT OF THE STATE OF DELAWARE
IN AND FOR NEW CASTLE COUNTY

STATE OF DELAWARE,	)	
	)	
	)	
v.	)	DEF. ID: 0507014155
	)	
	)	
STEPHANIE MCMULLEN,	)	
	)	
Defendant.	)	

Date Submitted: May 18, 2006
Date Decided: June 1, 2006

Upon Consideration of Defendant Stephanie McMullen's Motion in Limine to Limit Expert Testimony.
GRANTED in part and **DENIED** in part.

MEMORANDUM OPINION

Christina M. Showalter, Esquire and Josette D. Manning, Esquire, DELAWARE DEPARTMENT OF JUSTICE, Wilmington, Delaware. Deputy Attorneys General for the State.

Edmund D. Lyons, Jr., Esquire, THE LYONS LAW FIRM, Wilmington, Delaware. Attorney for the Defendant.

SLIGHTS, J.

I.

In this opinion, the Court must decide whether the State's proffered medical experts reliably have reached a diagnosis of Pediatric Condition Falsification ("PCF") for an alleged victim of child abuse.[1] The opinions have been challenged under Delaware's *Daubert* standard as both irrelevant and unreliable. [2]

[1] PCF is a relatively new diagnostic term derived from the "umbrella" diagnosis Munchausen Syndrome by Proxy ("MSBP"). It applies to pediatric patients suffering from a form of child abuse in which an adult, usually a caretaker, falsifies or induces physical or psychological symptoms of illness causing the child to receive medical or psychiatric treatment for the illness. Docket Item ("D.I.") 88 at 3. *See also infra* text at II.B.2.; STEDMAN'S MEDICAL DICTIONARY, syndrome (27th ed. 2000) (Defining munchausen syndrome by proxy as "a form of child maltreatment or abuse inflicted by a caretaker (usually the mother) with fabrications of symptoms and/or induction of signs of disease, leading to unnecessary investigations and interventions, with occasional serious health consequences, including death of the child.").

[2] *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 137 (1999).

The Defendant, Stephanie McMullen ("McMullen"), is the natural mother of the alleged victim, Reilly McMullen ("Reilly"), and is charged with Assault by Abuse or Neglect[3] and Reckless Endangering in the First Degree.[4] At trial, the State's medical experts are expected to testify that the facts of this case justify a diagnosis of PCF. McMullen has filed a motion to exclude such testimony under *Daubert*.[5] According to McMullen, testimony regarding PCF, MSBP, or any other derivation or characterization of that disorder/syndrome (such as Factitious Disorder by Proxy ("FDBP") or Illness Falsification ("IF")), is inherently unreliable as a matter of medical science. She also argues that the physicians involved with Reilly employed unreliable methodologies to make the diagnosis in this case. Accordingly, she urges the Court to fulfill its role as evidentiary gatekeeper by striking the unreliable expert opinion testimony.

After reviewing the initial and supplemental briefing, and conducting an extensive evidentiary hearing, the Court is satisfied that the State has met its burden of establishing by a preponderance of the evidence that expert testimony from Drs. Allen DeJong and Basil Zitelli regarding PCF is sufficiently relevant and reliable to pass

[3] DEL. CODE ANN. tit. 11, § 615 (2001).

[4] DEL. CODE ANN. tit. 11, § 604 (2001).

[5] D.I. 76.

through the *Daubert* filter.[6] The two doctors employed objective diagnostic techniques and sound methodology in diagnosing PCF in this case. Their testimony is based on "scientific knowledge" and is sufficiently reliable to be presented at trial. The proffered testimony will assist the trier of fact at trial and will not confuse the issues. As to these experts, McMullen's motion is **DENIED.**

The diagnosis of PCF (or MSBP, FDBP, and IF) made by the State's other experts -- Drs. Keith Mann, Christopher Franz, Cecelia DiPentima, and Stephen Schaffer -- is not sufficiently reliable to pass muster under *Daubert*. The State has failed to demonstrate that these witnesses possess the expertise to make the diagnosis or that they employed a reliable methodology in doing so. Accordingly, McMullen's motion is **GRANTED** as to these experts.

II.

1. Background

[6] The State has represented that its experts will refer only to PCF, and not MSBP, FDBP or IF. D.I. 88 at 8. The State will be held to this representation at trial.

Between January 6, 2005 and April 21, 2005, the alleged victim, Reilly McMullen, was admitted to Alfred I. duPont Hospital for Children ("A.I.") on three different occasions for fever, vomiting, and diarrhea.[7] He was 18 months old at the time of the first hospitalization. Throughout his various stays at A.I. (totaling 64 days), Reilly's treating physician, Dr. Patricia Scott (a pediatrician), along with several medical specialists in the areas of hematology, rheumatology, gastroenterology, oncology, infectious disease, genetics, neurology, opthamology, and immunology, conducted an exhaustive battery of invasive and non-invasive medical tests on Reilly. Until early April 2005, with the exception of an influenza diagnosis during his first hospitalization in January, no definitive diagnosis could be made to explain Reilly's seemingly persistent illnesses.[8]

[7] Reilly was admitted to A.I. from January 6, 2005 through January 12, 2005; January 31, 2005 through March 6, 2005; and March 31, 2005 through April 21, 2005. D.I. 76, Ex. A.

[8] *See* D.I. 70, Ex. A; D.I. 88 at 1-4.

In April, during Reilly's last hospitalization, blood cultures revealed three different types of bacteria in his blood -- two of the bacteria (e-coli and klebsiella) are commonly found in fecal matter and the third (stentrophomonas maltophilia) is commonly found in a hospital setting. His doctors opined that these bacteria were the causes of his illness. After ruling out "sick gut syndrome" (a perforated intestine/bowel) and infection from a catheter or intravenous line as potential sources of the bacteria, Reilly's doctors became concerned that someone (namely his mother, McMullen) was purposely introducing the bacteria into Reilly's system intravenously. This concern caused Dr. Scott to contact the Division of Family Services ("DFS") and file a report of abuse. In her report to DFS, Dr. Scott noted "that documented cases of Munchausen Syndrome by Proxy/Factitious Disorder include [victims'] IVs being injected with fecal matter causing sickness symptoms." She also conveyed to DFS that Reilly's "mother [McMullen] is a nurse at A.I. ... and has medical knowledge."[9] DFS commenced an investigation and also notified the New Castle County Police Department ("NCCPD"), which started its own investigation. The NCCPD was able to secure and execute search warrants on McMullen's vehicles, residence, and place of employment. McMullen ultimately was arrested and charged with Assault by Abuse or Neglect and Reckless Endangering in the First Degree. Specifically, she is accused of recklessly causing serious physical injury to her son, Reilly, by an act of abuse or neglect in violation of DEL. CODE ANN. tit. 11, § 615, and recklessly engaging in conduct which created a substantial risk of death to Reilly by introducing harmful substances into his body in violation of DEL. CODE ANN. tit. 11, § 604.[10]

2. The *Daubert* Hearing

[9] *Id.*

[10] *See* D.I. 8, Ex. A; D.I. 88 at 4.

A hearing was held on May 3, 2006. The State presented testimony from two of its proffered experts, Allen DeJong, M.D. and Basil Zitelli, M.D. McMullen called no witnesses.

1. Allen DeJong, M.D.

Dr. DeJong is a board certified pediatrician with a specialty in diagnosing sexual and physical abuse in children. Since 1997, he has been employed by A.I. as the Medical Director for the Children at Risk Evaluation Program -- a program designed to assess and evaluate suspected child abuse. Dr. DeJong is also a Clinical Professor of Pediatrics at Jefferson Medical College.[11]

[11] D.I. 92 at 27-30.

Throughout his more than 30 year career in pediatrics, Dr. DeJong has examined between 4,000 and 5,000 children to assess whether they have been exposed to sexual or physical abuse. He has diagnosed PCF six times during his career and describes the condition as a type of child abuse where a child's caretaker inflicts physical or psychological injury on a child through one of several mechanisms -- either by falsifying the child's medical symptoms or history, exaggerating the child's legitimate medical symptoms, or intentionally inducing the symptoms in the child through physical means.[12]

[12] *Id.* at 30, 39, 101.

According to Dr. DeJong, there are over 400 published papers in pediatric and medical journals relating to PCF. Over half of those papers are case reports and a majority of the papers have been subjected to peer review. In addition, many medical textbooks have chapters dedicated to PCF and one pediatric text in particular is devoted entirely to disorders related to MSBP and PCF. He acknowledges, however, that there are no *reliable* control group studies or experimental design studies of PCF. The absence of such data is not surprising to Dr. DeJong given that PCF is not a medical condition that easily lends itself to a controlled experimental design. Specifically, Dr. DeJong explained that too many uncontrollable confounders would be present in any control study of PCF, any one of which could skew the data.[13] For instance, the only control study known to Dr. DeJong is entitled "Evaluation of Covert Video Surveillance in the Diagnosis of Munchausen Syndrome by Proxy: Lessons From 41 Cases."[14] This study involved monitoring by hidden video cameras suspected cases of MSBP from 1993 to 1997 at the Children's Healthcare of Atlanta at Scottish Rite Hospital. The study revealed a diagnosis of MSBP in 23 of the 41 suspected cases. Dr. DeJong explained that the results of this study were questionable given that it was susceptible to both false positives (incorrectly diagnosing MSBP) and false negatives (failing to diagnose MSBP when it is the correct diagnosis) because of the inability covertly to monitor the patients 24-hours a

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[13] *See* NIOSH ENERGY-RELATED HEALTH RESEARCH PROGRAM, Glossary *available at* http://www.cdc.gov/niosh/2001-133o.html (Confounders are "[f]actors that distort or mask the true effect of exposure in an epidemiologic study."); NATIONAL PARTNERSHIP FOR IMMUNIZATION, NPI REFERENCE GUIDE ON VACCINES AND VACCINE SAFETY, Glossary (2d ed. 2002) *available at* http://www.partnersforimmunization.org (A confounder is a "factor that must be taken into account when designing or interpreting a scientific study. Failure to consider confounding factors can lead to misinterpretation of the results.").

[14] David E. Hall, *et al.*, *Evaluation of Covert Video Surveillance in the Diagnosis of Munchausen Syndrome by Proxy: Lessons From 41 Cases*, 105 Pediatrics 1305 (2000).

day. The abuse could have been occurring outside of the hospital at the child's home or other locations where the cameras could not monitor the activity. Hence, the time frame away from the hospital was a confounder that could not be controlled and, thus, directly affected the reliability of the study.[15]

Dr. DeJong testified that PCF is a generally accepted diagnosis in the pediatric community. He admits, though, that diagnosing PCF can be extremely difficult because the child's medical history is typically false (often by design of the caretaker), the medical record is not always in one location, the diagnosis cannot be made within a short time frame (it often takes months or even years), and there is no specific medical, psychiatric, or other test that will lead a doctor to a definitive diagnosis. Dr. DeJong maintains, nevertheless, that there is a medically sound methodology that leads to the diagnosis of PCF.[16]

[15] D.I. 92 at 40, 109-115, 145-150.

[16] *Id.* at 44, 49-50, 73. *See also id.* at 52 (There is no "boilerplate or template type of approach" in diagnosing PCF.).

In explaining the methodology, Dr. DeJong stated that, initially, a doctor collects as much medical history of the child as possible, looks for specific medical explanations for the child's symptoms, and discusses the medical history with the child's primary care physician and any consultants or specialists involved in the child's care. The doctor then proceeds to engage in a differential diagnosis.[17] To work through a differential diagnosis that includes PCF requires the diagnostician to engage in a "diagnosis of exclusion." That is, the doctor looks for medically plausible conditions that may be the cause of the child's symptoms. The doctor then performs the necessary medical tests to diagnose that condition and either include the condition as a possibility or exclude the condition depending on the results of the tests. The doctor repeats this process for every listed condition on the differential diagnosis until he is left with a diagnosis of exclusion -- meaning the only reasonable explanation left is a diagnosis of PCF. Because each case is unique, in that each child will present with a different set of symptoms, there is no "standard" differential diagnosis that will lead to a diagnosis of PCF. [18] Dr. DeJong maintains, however, that the essence (or "bulk") of

[17] Differential diagnosis is a "term used by physicians to refer to the process of determining which of two or more diseases with similar symptoms and signs the patient is suffering from, by means of comparing the various competing diagnostic hypotheses with the clinical findings." FED. JUD. CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 481 (2d ed. 2000).

[18] D.I. 92 at 51-53, 132. Dr. DeJong noted that many other medical conditions cannot be diagnosed by a single definitive test or methodology. For instance, no standard diagnostic test exists

the differential diagnostic methodology will be the same between two doctors in two different, but similar, locations when pursuing the course that ultimately leads to a PCF diagnosis.

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to diagnose Alzheimers, Shaken Baby Syndrome, or "Kawasaki Disease." These diagnoses are made from inferences and medical deductions derived from symptoms, history, test results, and the exclusion of other conditions. *Id.* at 162-166.

In this case, Dr. DeJong was consulted in April 2005 to assist the A.I. treatment team in diagnosing Reilly's illness. He spoke with Dr. Scott, Reilly's treating physician, and a number of other physicians and specialists who were brought in as consultants in the case. He reviewed Reilly's medical history from birth and the various medical tests and procedures performed on Reilly, but did not personally conduct a medical examination of Reilly or run any tests. After ruling out a feeding disorder, immune disorder, cancer, and "sick gut syndrome," and based upon the multiple blood cultures that were positive for unusual bacteria, Dr. DeJong eventually reached the diagnosis of PCF.[19]

2. Basil Zitelli, M.D.

Dr. Zitelli is a board certified pediatrician. Since 1978, he has been a faculty member at the University of Pittsburgh School of Medicine where he has been part of the Diagnostic Referral Service. He has been involved as a consultant in numerous child abuse cases across the country and, specifically, has reviewed or been involved in at least 30 to 50 cases involving a suspected diagnosis of PCF. Dr. Zitelli is an editor of the "Atlas of Pediatric Physical Diagnosis," has published several articles on MSBP and PCF, has lectured frequently on MSBP and PCF, and has testified in other jurisdictions as an expert regarding MSBP and PCF.[20]

[19] *Id.* at 31, 32, 35-37, 158-161.

[20] *Id.* at 179-188.

In explaining the evolution of the term PCF, Dr. Zitelli testified that PCF is derived from, and is a component of, the "umbrella" diagnosis of MSBP. In 1977, Dr. Roy Meadow, a pediatrician in the United Kingdom, published the "landmark" paper "Munchausen Syndrome by Proxy, The Hinterland of Child Abuse." In that paper, Dr. Meadow described two cases where factitious illness occurred in children. The article apparently created quite a stir in the medical community as several doctors, in numerous countries, came to the realization that they too had encountered children with unexplained symptoms that may well be attributable to factitiously induced illness. The pediatric medical community began to accept MSBP as a medical diagnosis and to recognize it as a form of child abuse.[21]

[21] *Id.* at 194-198.

As is often the case in medicine and science, however, the newly discovered diagnosis received much scrutiny and was ripe for refinement. The medical community began to question to whom the diagnosis of MSBP should attach -- the child victim or the caretaker perpetrator of the abuse. This debate ultimately led to an international medical conference in the mid 1990s where multiple medical disciplines met to seek consensus on the parameters of the diagnosis. The product of this conference was a consensus paper in which it was determined that if a physician is treating a child and the child's factitious illness, then the condition should be diagnosed as PCF. If, however, the focus of the treatment is on the perpetrator of the factitious illness, then the illness (or psychiatric disorder) should be diagnosed as FDBP. Hence, it is now generally recognized that MSBP is an "umbrella" diagnosis that contains two components -- PCF (the pediatric component) and FDBP (the perpetrator/caretaker/adult component).[22]

Dr. Zitelli testified that PCF is a generally accepted diagnosis in the pediatric community and is relied upon by pediatricians when making decisions regarding the treatment of a child. When asked how PCF can be so widely accepted in the medical community if there are no control studies that have tested the diagnosis, Dr. Zitelli responded:

> It is through repeated observations, observational experience, reports throughout the literature, follow-up of children who have ... had certain interventions applied to them, interventions such as reuniting with the family or such as separation from the family[.] And, so, [since] it is unethical to have a control group [because doctors cannot intentionally induce illness in children in an effort to create a control group] ... our only way of testing this and of looking at this is through direct observational

[22] *Id.* The caretaker suffering from FDBP falsifies or induces illness in the child as a means to garner attention for him or herself. *See* STEDMAN'S MEDICAL DICTIONARY, disorder.

experience, and the pediatric literature is replete with case upon case upon case of children who have been victims of falsified illness, and then what happens with them, depending upon interventions.[23]

[23] D.I. 92 at 205.

Dr. Zitelli concedes that it is extraordinarily difficult to make a diagnosis of PCF. No single definitive medical test reveals the condition. No definable series of symptoms will be associated with each case. No clinical algorithms have been developed to aid doctors in the diagnosis. And much, if not all, of the patient's medical history is false because the caretaker providing the history is often the perpetrator of the abuse. Nevertheless, Dr. Zitelli still maintains that physicians employ both a scientific methodology and objective diagnostic criteria to diagnose PCF.[24]

[24] *Id.* at 200-201, 204, 211-212, 233, 261.

The methodology, according to Dr. Zitelli, first involves a meticulous review of the child's medical records. If the records identify a series of events or symptoms that do not follow physiological parameters -- that is, through evidence based medicine[25] a doctor detects a biological or physiological inconsistency and concludes that the symptoms can only be explained by looking beyond the body's normal function -- then the physician justifiably should place PCF in the differential diagnosis. The next step is to narrow the differential diagnosis by systematically testing for known medical causes of the symptoms while at the same time removing the child from potential sources of induced illness (e.g. his caretakers). If the child has a true underlying illness, then separation from the alleged perpetrator should not, itself, improve the condition -- the illness will proceed whether a caretaker is present or not. If, however, the illness subsides after separation has occurred, then this factor supports a PCF diagnosis. Finally, the physician/investigator should look for toxins in a child's system and, if found, determine whether they would be present in the body but for the intentional introduction of the toxin(s) by a perpetrator. In summary, the objective criteria outlined by Dr. Zitelli that could lead to a diagnosis of PCF are: (1) physiological or biological inconsistency in the presentation of the child that cannot be linked to known medical conditions;

[25] Evidence based medicine is "the process of applying relevant information derived from peer-reviewed medical literature to address a specific clinical problem; the application of simple rules of science and common sense to determine the validity of the information; and the application of the information to the clinical problem." STEDMAN'S MEDICAL DICTIONARY, medicine.

and/or (2) separation of the child from a suspected perpetrator and subsequent recovery; and/or (3) presence of unexplained toxic agents in the child's body.[26]

[26] D.I. 92 at 260-265.

Dr. Zitelli was consulted by the State to review Reilly's case. After reviewing Reilly's extensive medical record, Dr. Zitelli made a diagnosis of PCF. He based his finding on the fact that, despite exhaustive medical examinations and tests performed on Reilly, there were no significant medical abnormalities that could explain his recurrent fever, vomiting, and diarrhea. Further, the presence of unusual bacteria in Reilly's blood led to the conclusion that the bacteria was intentionally introduced into his system. Lastly, Reilly's health immediately improved, and he had "no further episodes of gram negative bacteremia or sepsis," after he was started on 24-hour nursing supervision, including during visits with McMullen and all other family members.[27]

1. The Other Experts

[27] *Id.* at 215-217, 220.

In addition to Drs. DeJong and Zitelli, the State seeks to offer the expert testimony of Keith Mann, M.D., Christopher Franz, M.D., Cecelia DiPentima, M.D., and Stephen Schaffer, M.D. ("the other experts").[28] The curriculum vitae for each doctor speaks for itself,[29] and the Court will not review the extensive medical experience of these doctors given that McMullen does not appear to question their credentials.[30] Suffice it to say, the other experts are extremely well-qualified, board certified pediatricians who participated directly in the care of Reilly between January and April 2005.[31] In their respective areas of expertise, each of these physicians is most assuredly qualified to discuss their role in the care of Reilly, including the tests that each of them conducted to rule out various medical causes for Reilly's illness within their medical discipline. Yet none of these other experts has a demonstrated familiarity with MSBP or any of its component parts. Indeed, the Court could discern nothing from the record that would support a conclusion that these other experts understand the difference between PCF and FDBP,[32] or that they employed any methodology

[28] *See* D.I. 76; D.I. 94; D.I. 88; D.I. 95.

[29] *See* D.I. 88, Exs. 1-6.

[30] *See* D.I. 76; D.I. 94.

[31] *See* D.I. 76 at 7-8; D.I. 88, Exs. 1-6.

[32] The terms were often used interchangeably and, arguably, inappropriately throughout the medical record.

whatsoever to reach the diagnosis. If anything, their references to PCF, FDBP, IF and MSBP appear to be afterthoughts.

III.

McMullen has filed a motion *in limine* to limit the testimony of the experts. In support of her motion, McMullen contends that testimony pertaining to the diagnosis of PCF, MSBP, or any other derivation or characterization of that disorder/syndrome (such as FDBP or IF) cannot withstand scrutiny under *Daubert* because the diagnosis (in general and as rendered in this case) is neither relevant nor reliable. Specifically, she questions the reliability of a diagnosis that has no diagnostic guidelines (as promulgated by the American College of Pediatrics or otherwise), has neither been tested nor subject to rigorous scientific review by comparison against control groups of patients without the diagnosis, and has no known potential rate of error in its incidence as acknowledged by pediatricians who diagnose PCF. At the end of the day, McMullen maintains that the diagnosis of PCF is nothing more than a label that has been applied to anecdotal reports within the medical community by those who champion the cause of child abuse prevention. In this case, McMullen alleges that the physicians who diagnosed PCF in Reilly failed adequately to account for other causes of his illness and were too quick to draw the conclusion that Reilly had been the victim of abuse.[33]

Not surprisingly, the State argues that the PCF diagnosis in this case satisfies the *Daubert* requirements of relevance and reliability. The State contends that the methodologies for diagnosing PCF are well settled and amply documented in the peer reviewed literature on the subject. As for its relevance, the State claims that the specialized knowledge regarding PCF that its highly-trained

[33] D.I. 76 at 20-21.

experts will offer the jury undoubtedly will assist the trier of fact to understand the evidence and determine a fact in issue. In fact, according to the State, without an understanding of PCF, the jury understandably would be reluctant to accept that a caretaker could engage in such abhorrent behavior towards a child. Lastly, the State continues to maintain that the concerns raised by McMullen can readily be exposed during cross examination of the experts at trial.[34]

IV.

A. The *Daubert* Standard

Delaware's Uniform Rules of Evidence, provide:

[34] D.I. 88 at 7-9; D.I. 95 at 2.

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.[35]

Even prior to *Daubert*,[36] the Delaware Supreme Court acknowledged the predominant role of the Rules of Evidence in assessing expert testimony, and identified several factors to guide the trial courts in determining when to allow an expert opinion to reach the jury:

1) The expert witness is qualified (D.R.E. 702);
2) The evidence is otherwise admissible, relevant, and reliable (D.R.E. 401 and 402);
3) The bases for the opinion are those reasonably relied upon by experts in the field (D.R.E. 703);
4) The specialized knowledge being offered will assist the trier of fact to understand the evidence or determine a fact in issue (D.R.E. 702); and

[35] *See* D.R.E. 702 ("Rule 702").

[36] 509 U.S. 137.

5) The evidence does not create unfair prejudice, confuse the issues, or mislead the jury (D.R.E. 403).[37]

[37] *Minner v. Am. Mortgage & Guar. Co.*, 791 A.2d 826, 842-843 (Del. Super. Ct. 2000) (citing *Nelson v. State*, 628 A.2d 69, 74 (Del. 1993)).

Then, in 1999, the Delaware Supreme Court explicitly adopted *Daubert* as the law of this state in recognition that our rules of evidence mirrored the federal counterparts upon which *Daubert* was decided.[38] Thus, "under *Daubert*, *Kumho*, and *M.G. Bancorporation*,[39] the Trial Judge acts as the gatekeeper to ensure that the scientific testimony is not only relevant but reliable."[40] As the trial court performs this function, it must be mindful not only of the factors offered by *Nelson,* but also of the similar guidance offered by *Daubert* in the form of non-exclusive factors for consideration, including: (1) whether the technique or scientific knowledge has been tested or can be tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error and the control standards for the technique's operation; and (4) whether the technique has gained general acceptance.[41] These factors do not function as a "definitive checklist or test."[42] Rather, courts should apply the factors, as set forth both in *Nelson* and *Daubert*, in a

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[38] *See M.G. Bancorporation, Inc. v. Le Beau*, 737 A.2d 513, 521 (Del. 1999).

[39] *See Daubert,* 509 U.S. 579 (1993); *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137 (1999); *M.G. Bancorporation, Inc.*, 737 A.2d 513.

[40] *Minner*, 791 A.2d at 843.

[41] *Daubert*, 509 U.S. at 593-594.

[42] *Kumho,* 526 U.S. at 150 (quoting *Daubert*, 509 U.S. at 593).

flexible manner that takes into account the particular specialty of the expert under review and the particular facts of the underlying case.[43]

[43] *Id.* at 152.

At its core, *Daubert* dictates that Rule 702 is the governing standard for the admissibility of scientific evidence by specifying that "*if scientific*, technical, or other specialized knowledge *will assist the trier of fact* to understand the evidence or to determine a fact in issue," then the expert "may testify thereto."[44] The *Daubert* interpretation of the phrase "scientific knowledge" in Rule 702 is the genesis of the so-called "reliability" requirement. The adjective "scientific" linked with "knowledge" "implies a grounding in the methods and procedures of science."[45] And "knowledge" is more than unsupported beliefs; it must be derived from supportable facts.[46] Although scientific opinions need not be "[held] to a certainty" to be offered at trial, they must be grounded in the scientific method to qualify as "scientific knowledge."[47]

Rule 702 also requires that expert testimony be relevant by requiring that it "assist the trier of fact to understand the evidence or to determine a fact in issue."[48] If proffered testimony is not related to the case, then it will not aid in clarifying a contested fact and is, therefore, not relevant.[49] Accordingly, the "helpfulness" standard requires that evidence have "a valid scientific connection to the pertinent inquiry as a precondition to admissibility."[50] *Daubert* characterized this requirement as

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[44] *Id.* (emphasis in original).

[45] *Daubert*, 509 U.S. at 590.

[46] *Id.* (The Court quoted the definition of "knowledge" from WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1252 (1986), noting that the term "applies to any body of ideas inferred from such facts or accepted as truths on good grounds.").

[47] *Id.*

[48] *Id.* at 591.

[49] *Id.*

[50] *Id.* at 592.

one of "fit."[51]

B. The Burden of Proof

[51] *Id*. at 591.

The "proponent of the proffered testimony bears the burden of establishing the relevance [and] reliability ... by a preponderance of the evidence."[52] The proponent's focus in establishing the scientific validity of expert testimony should be on the methodology applied by the expert rather than the conclusions he generates.[53] "Proponents do not need to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of the evidence that their opinions are reliable."[54] When assessing whether the proponent has met its burden, the trial court does not choose between competing scientific theories, nor is it empowered to determine which theory is stronger.[55] *Daubert* requires only that the trial court determine whether the proponent of the evidence has demonstrated that scientific conclusions have been generated using sound and reliable approaches.[56]

V.

[52] *Minner*, 791 A.2d at 843.

[53] *Daubert*, 509 U.S. at 595.

[54] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994).

[55] *Minner*, 791 A.2d at 848.

[56] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 744.

"'Even with all the advances of medical science, the practice of medicine remains an art.'"[57] This pointed observation perhaps best illustrates the often vexing challenge confronting the judicial gatekeeper when applying a *Daubert* analysis to the discipline of clinical medicine as opposed to the practice of "hard science." As aptly articulated by the United States Court of Appeals for the Fifth Circuit in *Moore v. Ashland Chem.*:[58]

> Because the objectives, functions, subject matter and methodology of hard science vary significantly from those of the discipline of clinical medicine, as distinguished from research or laboratory medicine, the hard science techniques or methods that became the '*Daubert* factors' generally are not appropriate for assessing the evidentiary reliability of a proffer of expert clinical medical testimony.
> First, the goals of the disciplines of clinical medicine and hard or Newtonian science are different. In hard science, the usual motive is inquiring: to gain a new understanding of some mechanism of nature. In contrast, the care and treatment of the individual patient is the ultimate, specific act that characterizes a clinical physician. The clinical physician, therefore, must take account of the immediacy of the problem confronting her for she bears an essential relationship to each patient. Additionally, she has many human values to consider-ethics, compassion, and must

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[57] *Easum v. Miller*, 92 P.3d 794, 803 (Wyo. 2004) (quoting *Coastal Tankships, U.S.A., Inc. v. Anderson*, 87 S.W.3d 591, 604-605 (Tex. App. 2002)). *See also State Bd. of Registration for the Healing Arts v. McDonagh*, 123 S.W.3d 146, 160 (Mo. 2004) (Wolff, J., concurring in part and dissenting in part) ("[M]edicine is not readily regulated by a standard cookbook or set of rules."); Barry R. Furrow, *Incentivizing Medical Practice: What (If Anything) Happens To Professionalism*, 1 Widener L. Symp. J. 1, 2 (1996) (cautioning that doctors may be forced to engage in "cookbook" medicine due to imposed practice guidelines from managed care organizations).

[58] 126 F.3d 679, 688-690 (5th Cir. 1997), *vacated*, *on reh'g en banc,* 151 F.3d 269 (5th Cir. 1998).

have a willingness to take responsibility in the face of the unknown. The pursuit of these different goals of hard science and clinical medicine serves to shape the distinct objectives of the scientific experiment and the clinical treatment of a patient[.]

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Second, the subject matter and conditions of study are different. 'In laboratory work, the experimental material is an intact animal, a part of a person or of an animal, or an inanimate system; in clinical treatment, the material is an intact human being.' The hard scientist initiates the experiment at a time of his own convenience and chooses the material usually without regard to its desire or consent for participation. In clinical medicine, the patient initiates the treatment, choosing the time, place, duration, and clinician. 'The physician is not studying the properties of chemical compounds in a test tube; he cannot postpone dealing with cancer in a patient for fifty years because he hopes by then to have a much clearer insight into the nature of the disorder.'

Finally, clinical medicine and hard science have markedly different methodologies. A clinician observes at least three types of data for each patient who undergoes treatment: A disease in morphologic, chemical, microbiologic, physiologic, or other impersonal terms; the host in whom the disease occurs and his environmental background, including his personal properties (such as age, race, sex, and education) and external surroundings (such as geographic location, occupation, and financial and social status) before the disease began; and the illness that occurs in the interaction between the disease and its environmental host, consisting of clinical phenomena: the host's subjective sensations, or 'symptoms,' and 'signs,' which are findings discerned objectively during the physical examination.

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In sum, hard or Newtonian scientific knowledge does not comprehend all subjects that theoretically might be subjected to its methodology. It is knowledge of a particular and limited kind, gathered or tested by a particular and characteristic method. Although clinical medicine utilizes parts of some hard sciences, clinical medicine and many of its subsidiary fields are not hard sciences. The purposes, criteria, values and methods of hard or Newtonian science and clinical medicine are far from identical. *Consequently, the Daubert factors, which are hard scientific methods selected from the body of hard scientific knowledge and methodology generally are not appropriate for use in assessing the relevance and reliability of clinical medical testimony.*[59]

[59] *Id.* (citations omitted) (emphasis added).

Although the Fifth Circuit ultimately vacated its opinion in *Moore* -- presumably because it incorrectly held that *Daubert* was not applicable and, "[i]nstead, the trial court as gatekeeper should determine whether the doctor's proposed testimony as a clinical physician is soundly grounded in the principles and methodology of his field of clinical medicine"[60] -- its discussion of the significant differences between the disciplines of "hard science" and clinical medicine still holds true. Simply stated, a diagnosis in the practice of clinical medicine "is not an exact science. ... [P]hysicians make probabilistic judgments on a day-to-day basis, even when they can supplement a patient's history and physical with the results of extensive laboratory tests."[61] *Daubert* is not an easy fit under these circumstances. And courts must be mindful of this dynamic when subjecting clinical medical testimony (as presented in this case) to a *Daubert* analysis.

Throughout the discipline of clinical medicine, it is standard practice to make a diagnosis of a patient through the use of a technique called "differential diagnosis."[62] Differential diagnosis refers "to the process of determining which of two or more

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[60] *Id.* at 689-690.

[61] REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 465.

[62] *Smith v. Wyeth-Ayers Laboratories Co.*, 278 F. Supp. 2d 684, 692 (W.D.N.C. 2003). *See also Terry v. Ottawa Cty. Bd. of Mental Retardation*, 2006 WL 456769, at *10 (Ohio Ct. App. Feb. 24, 2006) (Differential diagnosis is "a 'standard diagnostic tool' in medicine.").

diseases with similar symptoms and signs the patient is suffering from, by means of comparing the various competing diagnostic hypotheses with the clinical

findings."[63] It "involve[s] the testing of a falsifiable hypothesis ... through an attempt

[63] REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 481. A step-by-step approach to conducting a differential diagnosis was outlined by the New Jersey Supreme Court in *Creanga v. Jardal*, 886 A.2d 633, 639 (N.J. 2005) (alteration in original) (citations omitted):

> The first step in properly conducting a differential diagnosis is for the expert to 'rule[ ] in' all plausible causes for the patient's condition by compiling 'a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration.' At this stage, the issue 'is which of the competing causes are generally capable of causing the patient's symptoms or mortality.' A differential diagnosis that 'rules in a potential cause that is not so capable' or fails to consider a plausible hypothesis that would explain the condition has not been properly conducted. 'Including even rare entities in the list ensures that such disorders are not overlooked.'
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> Second, after the expert 'rules in' plausible causes, the expert then must rule out those causes that did not produce the patient's condition by engaging 'in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that

to rule out alternative causes."[64] It does not, therefore, "lend[] itself to establishing a 'direct link' between an activity and an injury. ... In other words, it is a process of elimination."[65]

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particular case.' An expert 'need not conduct every possible test to rule out all possible causes of a patient's [injury], so long as he or she employed sufficient diagnostic techniques to have good grounds for his or her conclusion.'

[64] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 758.

[65] *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 262 (6th Cir. 2001).

Because the differential diagnosis implicates a methodology of exclusion, it is generally recognized that it "involves far more elements of judgment than does a scientific study attempting to test a more general scientific proposition."[66] The fact that a differential diagnosis is deemed a reliable method to reach a diagnosis in the medical community, however, does not necessarily imply that it is admissible under *Daubert*.[67] That is, "the mere statement by an expert that he or she applied differential diagnosis ... does not *ipso facto* make that application scientifically reliable or admissible."[68] The Court must "delve into the particular witness's method of

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[66] *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 758.

[67] *See Poust v. Huntleigh Healthcare*, 998 F. Supp. 478, 496 (D.N.J. 1998) ("[W]hile the method of differential diagnosis is clearly a reliable methodology in general, that does not answer the question of admissibility."); *Kenna ex rel. Kenna v. Jill-Dhara, Inc.*, 2006 WL 1266522, at *3 (W.D. Pa. May 9, 2006) ("[T]he use of differential diagnosis does not create a per se reliable conclusion.").

[68] *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 551 (W.D. Pa. 2003). *See also Creanga*, 886 A.2d at 640 (citation omitted) ("'[S]imply ... uttering the phrase 'differential diagnosis'

performing a differential diagnosis to determine if his or her ultimate conclusions are reliable."[69] Drs. DeJong and Zitelli both testified that a differential diagnosis is generally a prerequisite to diagnosing PCF. Accordingly, the Court must review both doctors' methods of performing their respective differential diagnoses to determine if their PCF diagnosis is reliable.[70]

... [does not mean] an expert can make his or her opinion admissible.'").

[69] *Poust*, 998 F. Supp. at 496.

[70] *See* D.I. 92 at 35-37, 48-64, 260-265.

A differential diagnosis is deemed reliable for *Daubert* purposes if it is rendered after the physician conducts a physical examination, takes a medical history, reviews clinical tests, including laboratory tests, and excludes *obvious* (but not all) alternative causes.[71] It is not necessary, however, for the clinician to employ all of these techniques in order for his diagnosis to be reliable.[72] For instance, "a physician may reach a reliable differential diagnosis without himself performing a physical examination, particularly if there are other examination results available."[73] In other words, it is acceptable for a physician to arrive at a diagnosis by relying on

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[71] *Bowen v. E.I. DuPont De Nemours and Co., Inc.*, 2005 WL 1952859, at *10 (Del. Super. Ct. June 23, 2005); *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999). *See also Easum*, 92 P.3d at 803 (citation omitted) (A medical expert's conclusion based on a differential diagnosis "'should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness. The alternative causes suggested by a defendant affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony.'").

[72] *Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 807 (3d Cir. 1997) (A "differential diagnosis may be reliable with less than all the types of information set out above.").

[73] *Id.*

examinations and tests performed by other medical practitioners.[74] Furthermore, a differential diagnosis is not considered unreliable simply because "no epidemiological studies, peer-reviewed published studies, animal studies, or

[74] *Id.*

laboratory data are offered in support of the opinion."[75] So long as physicians employ

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[75] *Easum*, 92 P.3d at 803. *See also Heller*, 167 F.3d at 155:

> [W]e do not believe that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness. To so hold would doom from the outset all cases in which the state of research on the specific ailment or on the alleged causal agent was in its early stages, and would effectively resurrect a *Frye*-like bright-line standard, not by requiring that a methodology be 'generally accepted,' but by excluding expert testimony not backed by published (and presumably peer-reviewed) studies.
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> In the actual practice of medicine, physicians do not wait for conclusive, or even

objective diagnostic techniques when performing a differential diagnosis, their diagnosis will be reliable under *Daubert* even if the conclusion is "novel" and not widely known in the medical community.[76]

> published and peer-reviewed, studies to make diagnoses to a reasonable degree of medical certainty. Such studies of course help them to make various diagnoses or to rule out prior diagnoses that the studies call into question. However, experience with hundreds of patients, discussions with peers, attendance at conferences and seminars, detailed review of a patient's family, personal, and medical histories, and thorough physical examinations are the tools of the trade, and should suffice for the making of a differential diagnosis even in those cases in which peer-reviewed studies do not exist to confirm the diagnosis of the physician.

[76] *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 759 n.27 ("Precedent supports our conclusion that when a doctor employs standard diagnostic techniques, his or her testimony is much more readily admissible. ... [T]he standard techniques of differential diagnosis are reliable and will allow a doctor who employs them to testify to a novel conclusion."); *Creanga*, 886 A.2d at 357 ("To be admitted, the expert witness must demonstrate ... that the proper diagnostic procedures were followed when performing the diagnosis."); *Heller*, 167 F.3d at 153 (Holding that a court "could not exclude the testimony simply because the conclusion was 'novel' if the methodology and the application of the methodology were reliable."); *Kenna ex rel. Kenna*, 2006 WL 1266522, at *3

("[T]he question is whether the overall conclusion of the expert is based on good grounds and does not have analytical gaps within its foundation.").

The "take home" point from the cases addressing the reliability of differential diagnoses is that courts must be "flexible" in the exercise of their evidentiary "gatekeeping" function. The United States Court of Appeals for the Third Circuit explained the rationale for such "flexibility" in *In re Paoli R.R. Yard PCB Litig.*:[77]

> While an important aspect of assessing scientific validity (and therefore evidentiary reliability) is the ability of other scientists to test or retest a proponent's theory, differential diagnosis involves assessing causation with respect to a particular individual. This merely makes it a different type of science than science designed to produce general theories; it does not make it unreliable science. ... [D]ifferential diagnosis generally is 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. As a result, the steps a doctor has to take to make that (differential) diagnosis reliable are likely to vary from case to case[.]
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> Thus, although differential diagnosis is a generally accepted technique, no particular combination of techniques chosen by a doctor to assess an individual patient is likely to have been generally accepted. But unlike a methodology used in conducting a scientific study, lack of general acceptance is not a sign of unreliability, it is merely a result of the fact that the medical community will rarely have considered the reliability of a particular process of differential diagnosis used in an individual case. Nor is it likely that the particular combination will have been published and subject to peer review, because a particular version of differential diagnosis will rarely be of general interest to the medical community. However, to the extent that a doctor utilizes standard diagnostic techniques in gathering this information, the more likely we are to find that the doctor's methodology is reliable. For these reasons, *we must be*

[77] 35 F.3d at 758.

flexible in conducting our Daubert inquiry.[78]

[78] *Id.* (emphasis added).

In sum, a "soundly performed" differential diagnosis *alone* satisfies the *Daubert* requirements for reliability in the context of clinical medicine.[79] Indeed, "[i]f a differential diagnosis provides a sufficient basis on which to prescribe medical treatment with potential life-or-death consequences, it should be considered reliable enough to assist a fact finder in understanding certain evidence or determining certain fact issues."[80]

[79] *Terry*, 2006 WL 456769, at *10; *Easum*, 92 P.3d at 803.

[80] *Easum*, 92 P.3d at 803.

In assessing the reliability of the State's proffered expert testimony in this case, the Court is satisfied that Drs. DeJong and Zitelli employed objective diagnostic techniques and a sound methodology when diagnosing PCF. Both doctors testified that making a diagnosis of PCF generally requires a doctor to engage in a differential diagnosis. Dr. DeJong explained that, in doing so, the doctor must collect as much medical history of the child as possible, look for specific medical explanations for the symptoms with which the child presents, and discuss the medical history with the child's primary care physician and any consultants or specialists involved in the child's care. The doctor must then either conduct medical tests or review medical tests that have already been performed in an effort to eliminate potential causes for the child's symptoms until the only reasonable explanation left for the child's illness is a diagnosis of PCF.[81] Dr. Zitelli's testimony essentially concurred with this methodology, but he also added that additional objective techniques to make a PCF diagnosis through a differential diagnosis involve looking for physiological or biological inconsistencies in the presentation of the child that can only be explained by the introduction of some outside contaminant into the body and separating the child from the suspected perpetrator(s) to see if there is subsequent recovery.[82] Both

[81] D.I. 92 at 51-53, 132.

[82] *Id.* at 260-265.

doctors testified that they complied with this methodology in making their diagnoses here.

The Court further finds that the proffered expert testimony on PCF is relevant. The testimony will assist a lay juror in understanding the State's contentions regarding Reilly's medical condition and will aid the trier of fact in clarifying contested facts.[83] For instance, testimony explaining the process Drs. DeJong and Zitelli engaged in when diagnosing PCF will assist the trier of fact in determining whether the cause of Reilly's illness was due to an intentional inducement of toxins or an explainable (or unexplainable) medical condition. Such testimony will not confuse or mislead the jury. Therefore, the expert testimony "fits" as that term is used in *Daubert*.[84]

[83] *See Daubert*, 509 U.S. at 591.

[84] *Id.* at 591.

For the reasons stated above, the State has met its burden to establish that the proffered expert testimony on PCF from Drs. DeJong and Zitelli satisfies the *Daubert* and *Nelson* criteria. The doctors are clearly qualified; both are exceptionally well credentialed pediatricians with extensive experience in diagnosing PCF.[85] The bases for their opinions are relied upon by other experts in the medical community; differential diagnosis is well known to be a reliable means to reach a diagnosis of PCF.[86] Most of the literature endorsing the diagnosis of PCF and MSBP has been subjected to peer review and publication.[87] While there is no known potential rate of error with respect to diagnosing PCF and only one (albeit unreliable) control study on MSBP and PCF,[88] it is clear that the diagnosis does not lend itself easily to an experimental design because of the likelihood of uncontrollable confounders and the obvious ethical implications of intentionally inducing illness in children in order to test the PCF diagnosis.[89] Further, the absence of epidemiological data on PCF and its relatively recent arrival in the pediatric medical community do not, per se, render the diagnosis unreliable.[90] It appears from the undisputed evidence of record that PCF has gained general acceptance in the pediatric community.[91] Lastly, the expert testimony will assist the jury in understanding the evidence and determining issues of fact and will neither confuse nor mislead them at trial. If the science employed by Drs. DeJong and Zitelli is, in fact, unsettled as McMullen alleges, then the proper manner for her to attack this "shaky but admissible evidence" is through "vigorous cross-examination,

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[85] *See* D.I. 88, Ex. 1; D.I. 92 at 27-31, 101, 179-188.

[86] *See Terry*, 2006 WL 456769, at *10 (Differential diagnosis is "a 'standard diagnostic tool' in medicine.").

[87] *See* D.I. 92 at 40, 108-115.

[88] *See* Hall, *supra* note 14.

[89] *See* D.I. 92 at 147-150, 205.

[90] *See Easum*, 92 P.3d at 803 ("Reliable differential diagnosis alone may provide a valid foundation for a causation opinion, even when no epidemiological studies, peer-reviewed published studies, animal studies, or laboratory data are offered in support of the opinion."); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 759 n.27 ("[T]he standard techniques of differential diagnosis are reliable and will allow a doctor who employs them to testify to a novel conclusion."); *Heller*, 167 F.3d at 153 (Holding that a court "could not exclude the testimony simply because the conclusion was 'novel' if the methodology and the application of the methodology were reliable.").

[91] *See* D.I. 92 at 204.

presentation of contrary evidence, and careful instruction on the burden of proof[.]"[92]

Daubert and *Nelson* do not, however, support the admission of testimony regarding PCF from the other experts. The Court cannot assess their expertise to render the diagnosis on this record, nor can the Court review their methodology, assuming one was employed at all. These experts will be permitted to testify regarding their treatment of Reilly, the medical conditions they were investigating to explain Reilly's symptoms, and their bases for concluding that such conditions were not the cause(s) of Reilly's symptoms. They may not, however, refer to MSBP or any of its derivations.

VI.

Based on the foregoing, McMullen's Motion *in Limine* to Limit the Testimony of Drs. DeJong and Zitelli is **DENIED**. McMullen's Motion is **GRANTED** as it relates to the testimony of Drs. Mann, Frantz, DiPentima, and Schaffer.

IT IS SO ORDERED.

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Judge Joseph R. Slights, III

[92] *Daubert*, 509 U.S. at 595.

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