IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

IN AND FOR NEW CASTLE COUNTY

CAROLINE JONES,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 07C-01-420-SER
	)	
ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, KBI SUB INC., ASTRAZENECA AB, ASTRA USA, INC. and ASTRAZENECA PLC,	)	
	)	
Defendants.	)	

Date Submitted: January 7, 2010
Date Decided: March 31, 2010

MEMORANDUM OPINION.
*Upon Consideration of Defendants' Motion in Limine To Exclude The Medical Causation Testimony of Dr. Susan Zweig and Motion for Summary Judgment***.**
GRANTED.

Linda Richenderfer, Esquire, and Jennifer Patone Cook, Esquire, KLEHR HARRISON HARVEY BRANZBURG & ELLERS, Wilmington, Delaware. Robert W. Cowan, Esquire, and Fletcher V. Trammell, Esquire, BAILEY PERRIN BAILEY, Houston, Texas. Paul J. Pennock, Esquire, WEITZ & LUXENBERG, New York, New York. Attorneys for Plaintiff.

Michael P. Kelly, Esquire, and Noriss Cosgrove Kurtz, Esquire, MCCARTER & ENGLISH, LLP, Wilmington, Delaware. Jane F. Thorpe, Esquire and Scott A. Elder, Esquire, ALSTON & BIRD, Atlanta, Georgia. Donald Scott, Esquire and Sean W. Gallagher, Esquire, BARTLIT, BECK, HERMAN, PALENCHAR & SCOTT, Chicago, Illinois. Attorneys for Defendants.

SLIGHTS, J.

I.

The latest trial setting in the Delaware mass tort litigation involving the prescription medication Seroquel® has yielded another round of motion practice in which the defendants, Astrazeneca Pharmaceuticals LP, Astrazeneca LP and Zeneca, Inc. (collectively "AZ"), invoke the well-settled directions of *Daubert v. Merrell Dow Pharm., Inc.*[1] to challenge the admissibility of plaintiff's proffered expert testimony that Seroquel® has proximately caused her to develop Type II diabetes. The Court previously has addressed a similar challenge in an extensive opinion in which it summarized the procedural history of this litigation and articulated at some length its view of the gatekeeping responsibilities imposed upon it by *Daubert*.[2] In the interests of brevity and efficiency, those views, endorsed here, will not be repeated again except as necessary to emphasize a point. Since it appears that *Daubert* motion practice will be a regular feature of this litigation, the Court will make every effort going forward to compose its opinions on this topic succinctly and directly.

The Court's decision in *Scaife* naturally served as the backdrop of the motion *sub judice.* Given the outcome of that case, it is not surprising that the plaintiff in this

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[1] 509 U.S. 579 (1993).

[2] *See generally Scaife v. Astrazeneca Pharm., LP*, 2009 WL 1610575 (Del. Super. June 9, 2009) (holding that plaintiff's specific causation expert had not offered a sufficiently reliable opinion to pass muster under *Daubert*).

case, Caroline Jones, went to great lengths to distinguish her case from *Scaife*. AZ, of course, argued that this case was distinguishable from *Scaife* only to the extent that it presented an even stronger case for *Daubert* exclusion of the specific causation expert.

After carefully reviewing the record and the parties' extensive briefing, the Court agrees with Ms. Jones that she (and her expert) have presented a case factually distinguishable from *Scaife* in several significant respects. Nevertheless, notwithstanding these distinguishing characteristics, the specific causation opinions offered by her expert have much in common with those offered in *Scaife*, particularly with regard to the methodology, or lack thereof, employed by both experts to reach their respective conclusions. Like the specific causation expert in *Scaife*, Ms. Jones' expert failed to articulate the methodology she employed to reach her specific causation opinion in a manner that would allow the Court meaningfully to exercise its *Daubert* gatekeeping function. Although repeatedly pressed to do so at deposition, the expert simply refused to expand the explanation of her methodology beyond her mantra that she had read "everything" relating to the case and had applied her extensive training and experience to consider these materials and reach the conclusion that Seroquel® had caused Ms. Jones to develop Type II diabetes. Without more, this evidence does not satisfy Ms. Jones' burden under *Daubert* to prove the reliability of

her expert's opinions. Consequently, AZ's Motion *In Limine* To Exclude Medical Causation Testimony of Dr. Susan Zweig must be **GRANTED.** And because Ms. Jones lacks sufficient competent evidence to create a genuine issue of fact regarding a *prima facie* element of her claims (proximate cause), AZ's Motion for Summary Judgment must also be **GRANTED.**

II.

A. Caroline Jones

Ms. Jones is a 22-year old woman from Boston, Massachusetts who has been diagnosed at various times in her medical history with mental health issues. In November, 2003, when Ms. Jones was sixteen years old, a nurse practitioner prescribed Seroquel®, a so-called atypical anti-psychotic medication developed and manufactured by AZ, to treat Ms. Jones' anxiety, depression and insomnia.[3] Ms. Jones remained on Seroquel® until approximately April, 2004. She alleges that, as a result of her exposure to Seroquel®, she developed Type II diabetes, first detected by an elevated blood glucose reading in July, 2005.

[3] Ms. Jones alleges that she was prescribed Seroquel® by a nurse practitioner even though she did not suffer from any condition for which the FDA had approved its use, and even though the FDA had not approved Seroquel® for use in children. It does not appear, however, that this fact, even if true, played any significant role in the formulation of Dr. Zweig's specific causation opinions. *See* Appendix to Plaintiff Carolyn Jones' Memorandum of Law In Answer To AZ's Motion *In Limine* To Exclude Medical Causation Testimony of Dr. Susan Zweig (Transaction ID. ("Tr. ID.") 28238772) Ex. 5 [hereinafter PX].

The record is unclear, and the parties dispute, whether any of Ms. Jones' treating physicians has actually diagnosed her as suffering from diabetes. Each of the treating physicians at deposition testified that they had not diagnosed diabetes.[4] Nevertheless, records from her primary care physician, Dr. Brian Battista, and her treating endocrinologist, Dr. Mary Delany, indicate that Ms. Jones' doctors, as of July, 2005, apparently suspected that she had Type II diabetes and began treating her for the condition.[5]

Ms. Jones was at some increased risk for developing Type II diabetes prior to her exposure to Seroquel®.[6] For instance, the record suggests that there was a family history of diabetes which, according to the American Diabetes Association's consensus statement, "is strongly associated with Type 2 diabetes in children."[7] She smoked, exercised little, at times ate poorly and was (at least medically speaking)

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[4] *See* Appendix to AZ's Opening Brief in Support of its Motion *In Limine* To Exclude Medical Causation Testimony of Dr. Susan Zweig (Tr. ID. 27885601) Ex. C at 99 [hereinafter DX]; Ex. F at 60, 129, 174-75; Ex. G at 114-18.

[5] *See* PX 10 at 149-50, 169-70; PX 11 at 39-40, 96.

[6] *See* DX K at 383-84 (American Diabetes Association consensus statement).

[7] *Id.* at 384. *See also* DX J (medical record noting that all four grandparents suffered from diabetes, "2 of whom needed insulin"). Ms. Jones disputes the accuracy of this record and now states that she is aware of no family history of diabetes. Jones Dep. 14, Apr. 17, 2008.

overweight.[8] Her last recorded weight prior to starting on Seroquel® was 143 lbs.[9] There are no recorded weights during the time she took Seroquel®. Ms. Jones, however, reports gaining as much as 20 lbs while on the drug.[10] The next recorded weight, 140 lbs, was taken on November 10, 2004, approximately five months after Ms. Jones stopped taking Seroquel®.[11] By June, 2005, more than a year post-Seroquel®, she weighed 172 lbs.[12]

In addition to the risk factors noted above, the record indicates that Ms. Jones may have suffered from and was treated by her gynecologist for polycystic ovarian syndrome ("PCOS"), a gynecological condition associated with, *inter alia*, weight gain and increased risk for diabetes (both diseases are marked by increased resistance to insulin).[13] According to Ms. Jones, however, AZ's specific causation expert has questioned whether the PCOS diagnosis was appropriate.[14] Whether the diagnosis was appropriate or not, the record reflects that Ms. Jones was treated for PCOS and

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[8] DX C at 116-17; DX F at 24-25; DX J; DX M (medical record indicating that as of June, 2003, Ms. Jones was 5' 3" and weighed 143 lbs).

[9] DX M.

[10] PX 7 at 63-64.

[11] DX D.

[12] DX N.

[13] DX A at 342; DX K at 382; DX O at 76.

[14] *See* PX 3 at 74.

that the diagnosis was a prominent feature of her medical picture.

B. Susan Zweig, M.D.

Ms. Jones has designated Susan Zweig, M.D., as her specific causation expert. Dr. Zweig is an endocrinologist with a busy private practice in New York City. She received her medical degree from the Sackler School of Medicine of Tel Aviv University in 1997, and completed her internship and residency at the Columbia University hospital system in New York in 2000. She completed a fellowship in Endocrinology at the Beth Israel Medical Center, Albert Einstein College of Medicine, and is Board Certified in Internal Medicine and Endocrinology, Metabolism and Diabetes. In addition to her private practice, Dr. Zweig is on the faculty of the New York University School of Medicine. She has authored a chapter in a medical text book on PCOS, and has engaged in and published results from diabetes-related research.[15] AZ has acknowledged that Dr. Zweig is highly qualified to render expert opinions regarding diabetes, and the Court agrees. The outcome of this motion will not turn on the expert's qualifications.

1. Dr. Zweig's Report

On September 19, 2008, Dr. Zweig issued an eleven page expert report in which

[15] DX Q at 1-2.

she summarized her experience, her review of Ms. Jones' medical records and history, and her "assessment" of the case.[16] In her "assessment," she identified common risk factors for diabetes, a disease which she acknowledged affects approximately 8% of Americans (around 24 million people) and is a "major cause of morbidity and mortality in the United States."[17] She described the criteria for diagnosing diabetes. She then referred generally to the "many studies showing that a cause of [Type II diabetes] is the use of atypical antipsychotics, such as Seroquel."[18] In this regard, Dr. Zweig referred specifically to unidentified epidemiological studies that, according to her review, support an association between atypical antipsychotics and weight gain and diabetes.[19] Later, she referred specifically to studies that discuss weight gain as a "well-documented metabolic side effect with atypical antipsychotics."[20]

Turning specifically to Ms. Jones, Dr. Zweig concluded unequivocally that Ms. Jones does not have PCOS.[21] Her opinion with respect to whether Ms. Jones suffered from Type II diabetes, however, was less certain. She stated that "[i]nitially it was

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[16] *See generally id.*

[17] *Id.* at 4.

[18] *Id.* at 5.

[19] *Id.*

[20] *Id.* at 7.

[21] *Id.* at 3. *See also* DX A at 274.

difficult to make a strict diagnosis of diabetes mellitus." She then went on to refer to an undocumented glucose tolerance test disclosed to her by Ms. Jones that "indicated type 2 diabetes," and she confirmed that the reported reading from that test "is in diabetic range."[22]

Dr. Zweig next addressed the literature reporting the increased relative frequency of diabetes in younger patients taking quetiapine (Seroquel®). Based on this literature, she opined that Ms. Jones, at age 20, was "at a higher risk for diabetes, compared with older quetiapine-treated patients."[23] She then mentioned Ms. Jones' purported weight gain ("roughly 20 pounds") during the time she was on Seroquel®, and followed this observation with a summary of literature linking atypical antipsychotics with weight gain. She made no effort at this point to link her observation of Ms. Jones' weight gain while on Seroquel® to the medical literature regarding weight gain to which she referred in her report.[24] In particular, she made no effort to rule out other causes for the weight gain she believed occurred in Ms. Jones while on Seroquel®.

After discussing generally the health risks posed by diabetes, Dr. Zweig offered her conclusion that "Ms. Jones's Seroquel use significantly contributed to her

[22] DX Q at 6.

[23] *Id.*

[24] *Id.* at 7.

development of diabetes."[25] She acknowledged that "the time between ingestion of a drug and commencement of a disease is not absolute definitive evidence of causation," but then went on to conclude that, in this case, "the time sequence is certainly persuasive proof that Seroquel was a substantial contributing factor."[26] She determined that the mechanism by which Ms. Jones developed diabetes was her weight gain, presumably while taking Seroquel®. According to Dr. Zweig, the diagnosis of diabetes was made more difficult in Ms. Jones because she was taking medication (Metroformin) for an incorrectly diagnosed condition (PCOS) that masked her symptoms and made her blood glucose levels lower than they otherwise would have been without the medication.[27]

The explanation of her "methodology" focused exclusively on her training and experience:

> The preceding report was based on my review of Caroline Jones's records including but not limited to her doctor's and psychiatrist's progress notes, lab reports, pharmacy notes, phone interview with the patient, and a review of depositions [unspecified]. My opinions were made based on my many years of medical training including, my fellowship studies in endocrinology at Beth Israel Medical Center, Albert Einstein College of Medicine, my work on many research projects, publications, and essays [unspecified] that were directly related to metabolism and diabetes, the numerous journals, lectures, conferences

[25] *Id.* at 8.

[26] *Id.*

[27] *Id.*

and seminars with which I'm involved on a regular basis [unspecified], and literature that I read for this case [again, unspecified].[28]

2. Dr. Zweig's Deposition

Dr. Zweig's deposition comprises 446 pages and was clearly taken with an eye toward *Daubert* motion practice. After briefly reviewing her experience, and how she became involved in this litigation, Dr. Zweig discussed in great detail the criteria she employs to diagnose diabetes. She then turned to the diagnosis of diabetes in Ms. Jones and confirmed that the medical records do not reveal a clear diagnosis of diabetes but do confirm that she was being treated for the disease.[29] She attributed the ambiguity in the medical records to the fact that "not everybody practices the way we do here."[30] Dr. Zweig relied upon her conversation with Ms. Jones, including Ms. Jones' description of the glucose tolerance test that appears nowhere in the medical records, to clarify the medical picture and ultimately to conclude that Ms. Jones, in fact, has diabetes.[31]

Next, Dr. Zweig was questioned about the materials she reviewed prior to reaching her opinion. Although she acknowledged that she was not an expert in

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[28] *Id.* at 8-9.

[29] Zweig Dep. 90-100, Oct. 9, 2009.

[30] *Id.* at 100.

[31] *Id.* at 102-07.

epidemiology, she did review epidemiological studies (including, she thinks, observation epidemiology) prior to issuing her report.[32] She also reviewed medical records and selected depositions supplied to her by Ms. Jones' attorneys. She does not believe that she had reviewed data from AZ's clinical trials of Seroquel®prior to issuing her report,[33] and did not list any reports of clinical trials among the nine "references" listed in her report.[34] She acknowledged that she had engaged in a more extensive review of the medical literature and clinical trials after she had reached her opinions in the case as she was preparing for her deposition.[35]

The substance of Dr. Zweig's opinion, for the most part, remained unchanged from her report to her deposition. She continued in her belief that Ms. Jones' medical presentation justified a diagnosis of diabetes.[36] She also continued in her belief that Ms. Jones presented virtually no risk factors for diabetes prior to her exposure to Seroquel®. She reiterated her view that the medical literature "overwhelming[ly]" supported an association between exposure to Seroquel® and the development of

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[32] *Id.* at 127-31. As will be discussed below, Dr. Zweig's inability to recall specifics regarding information she had reviewed, including medical records, was a consistent theme of her deposition.

[33] *Id.* at 118-19, 153-54.

[34] PX 19 at 10-11.

[35] Zweig Dep. 114, 117.

[36] *Id.* at 251-52.

diabetes.[37] With regard to the mechanism by which Seroquel® caused diabetes, however, Dr. Zweig's opinion changed dramatically from her report to her deposition.[38] In her report, Dr. Zweig subscribed to the theory the Seroquel® caused patients, including Ms. Jones, to gain weight which, in turn, put the patient at higher risk of developing Type II diabetes. This is what she believed occurred to Ms. Jones, at least as of the time she disclosed her specific causation opinion in her report.[39] In her deposition, however, when confronted with medical records she had not seen before which revealed that Ms. Jones weighed the same in November, 2004 (months after stopping Seroquel®) as she did when she began taking Seroquel® in November, 2003, she conceded that she could not conclude that weight gain from Seroquel® had caused Ms. Jones to develop Type II diabetes.[40] Having abandoned the weight gain theory,[41] Dr. Zweig at deposition moved on to a theory that Seroquel® had a "direct

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[37] *Id.* at 154.

[38] Of course, the mechanism by which Seroquel® causes diabetes, generally and in a specific patient, is particularly important given the very high background rate of diabetes, a disease which Dr. Zweig admits has reached "epidemic" status in this country. *Id.* at 250.

[39] *See* PX 19 at 8 ("As a result of this weight gain [while on Seroquel®], Ms. Jones developed diabetes.").

[40] Zweig Dep. 204 (when shown the medical record documenting the November 2004 weight, Dr. Zweig acknowledged "[t]his actually does not look familiar to me"), 210 ("Q: So, if she weighed 140 pounds in November of 2004, you couldn't draw the conclusion that Seroquel caused diabetes from weight gain alone; is that fair? A: I'd say that's likely fair.").

[41] *Id.* at 227-28 (confirming that she was no longer endorsing the "weight gain" mechanism of specific causation).

effect" on the body's metabolism making the body more susceptible to diabetes.[42] When pressed to explain the basis of her "direct effect" theory, Dr. Zweig was unable to point to any supporting literature and ultimately retreated for support to the temporal proximity of Ms. Jones' alleged diabetes diagnosis to her exposure to Seroquel®.[43]

As might be expected in a *Daubert*-driven deposition, much of the discussion focused on Dr. Zweig's methodology in formulating her opinions. The deposition discussion of methodology was particularly important in this case since Dr. Zweig provided no indication whatsoever in her report regarding the process(es) she followed to review the materials that had been supplied to her, including the medical records, medical literature, and scientific studies, or the means by which she assimilated this information in order to reach her specific causation opinions. At deposition, she repeatedly explained that she believed her methodology was "inherent in the report" or "inherent in how I practice medicine and interpret medical data."[44] When asked to explain the methodology that was inherent in her report, she testified

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[42] *Id.* at 214, 233, 323-24, 330.

[43] *Id.* at 213 ("Q: And describe for me what evidence you believe there exists in this case that Seroquel had a metabolic effect on Miss Jones separate and apart from weight gain? A: Well, she didn't have diabetes before the drug and she developed diabetes after."), 233 (admits that she is aware of no studies that support her "direct effect" opinion).

[44] *See, e.g., id.* at 132-33, 141, 144, 181, 212, 404.

that she had not followed a "differential diagnosis" or "differential etiology" approach and that her "methodology doesn't have one specific name."[45] When pressed to offer specifics regarding her methodological approach, time and again Dr. Zweig repeated simply that she had "put everything [or "it all"] together" to construct the foundation of her opinion, and then applied her training and experience to formulate the opinions themselves.[46]

In apparent hopes of piercing through the repeatedly vague explanations of her methodology, the questions at deposition frequently directed Dr. Zweig to offer specifics in the medical records, medical literature, scientific studies, or clinical trials that either she relied upon in formulating her specific causation opinion or that would otherwise support her opinions. All to no avail - - Dr. Zweig consistently explained(often apologizing) that she was not prepared at deposition to discuss specifics and that she would have to "get back to [counsel]" after reviewing additional information or re-reviewing what had already been supplied to her.[47] Her lack of memory made exploring her methodology practically impossible.[48]

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[45] *Id.* at 157-58, 405-08.

[46] *See, e.g.*, *id.* at 101-02, 132-34, 143-44, 151-53, 154, 235, 266-68, 281-82, 310, 360, 362, 407.

[47] *Id.* at 118-19.

[48] *See, e.g.*, *id.* at 106-09, 125, 127, 131, 134, 136, 142-43, 145, 149, 156-57, 169-71, 174, 179-80, 184, 186, 194, 201-02, 215-16, 224-25, 227-33, 239, 257-58, 274-76, 316-17, 331-32, 337,

III.

AZ contends that Dr. Zweig's opinion is inadmissible under *Daubert* for several reasons: (1) she failed to articulate any reliable methodology by which she reached her opinions; (2) she failed to identify a verifiable mechanism by which Seroquel® caused Ms. Jones to develop Type II diabetes; (3) she improperly relied upon the temporal connection between Ms. Jones' exposure to Seroquel® and her development of Type II diabetes; (4) she failed reliably to rule out other causes of Ms. Jones' diabetes; and (5) she failed to make a reliable diagnosis of diabetes.

Ms. Jones responds that Dr. Zweig's methodology was more than adequate to pass muster under *Daubert*. First, she argues at some length that her case is factually distinguishable from *Scaife* in significant respects that make the outcome there unjustified here. Specifically, Ms. Jones argues that, unlike the plaintiff in *Scaife*, when she began taking Seroquel® she was not otherwise predisposed to develop Type II diabetes. Thus, when Dr. Zweig considered the specific causation question in this case, her analysis was not confounded by other risk factors that may alone have caused Ms. Jones to develop diabetes. And, according to Ms. Jones, Dr. Zweig systematically considered all known risks for Type II diabetes in the context of Ms. Jones' medical presentation at the time she began taking Seroquel® and specifically

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343-47 (counsel's frustration over the expert's lack of recall discussed), 348, 369, 379-80, 397, 401, 403.

ruled out those risks as contributing factors in Ms. Jones' development of Type II diabetes. Notwithstanding her expert's deposition testimony in which Dr. Zweig apparently retreated from her initial views regarding the mechanism of injury, Ms. Jones contends that Dr. Zweig has consistently maintained that Seroquel® caused Ms. Jones' weight to spike which, in turn, caused her to develop diabetes. This opinion, according to Ms. Jones, is well supported in the medical literature. Finally, Ms. Jones argues that Dr. Zweig diagnosed her diabetes in the same manner, and using the same criteria, as she would employ in her own medical practice.

IV.

"No one will deny that the law should in some way effectively use expert knowledge wherever it will aid in settling disputes."[49] Nevertheless, as this Court has observed,

> [O]ur scepticism of such compensated advocacy is high and we no longer rest on the mere proper credentials of the expert witnesses or even on being satisfied as to the general relevancy of the expert's opinion. The basis of the opinion must have "good grounds" when judged by experts in the same general field as the witness. The Trial Judge must determine whether the reasoning and methodology is valid by the professional standards of the scientific, professional, or business field of the expert. And the Trial Judge must determine whether the expert's reasoning or methodology can be applied to the facts at issue. The burden is a heavy one and one that will tax even the best Trial Judges, a hearty breed who pride themselves as decision-making pragmatists in the

[49] Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 40 (1901).

> field of battle. But there can be no question that the burden has been imposed.[50]

The "burden" to which my predecessor referred is the Court's obligation to act as "gatekeeper" each time a party to litigation seeks to make or bolster its case with the testimony of a witness who is purportedly expert in a field relevant to the controversy.[51] The progression of Delaware law setting forth the parameters of this "gatekeeping" responsibility, and the requisite judicial dissection of expert testimony necessary to discharge the responsibility, has been well documented by Delaware

[50] *Minner v. Am. Mortgage & Guar. Co.*, 791 A.2d 826, 846 (Del. Ch. 2000).

[51] *See Daubert*, 509 U.S. at 579, 589 n.7 (the United States Supreme Court's seminal decision announcing the trial court's responsibilities under the Federal Rules of Evidence to scrutinize the qualifications, methodology, and ultimate conclusions of the expert and characterizing this exercise as the court's "gatekeeping" function). *See also* D.R.E. 104(a) (identical to its Federal counterpart, this rule requires the Court to determine preliminarily such matters as the "qualification of a person to be a witness" and "the admissibility of evidence").

courts and will not be repeated at length again here.[52] Suffice it to say, a motion *in limine* challenging the admissibility of expert testimony implicates the extensive review process mandated by *Daubert*.

Boiled to its essence, *Daubert* requires the Court to answer two fundamental questions before admitting expert testimony: (1) is the testimony relevant?; and (2) is the testimony reliable?[53] The party offering the testimony bears the burden of establishing both prongs of the *Daubert* analysis, i.e., relevancy and reliability, by a preponderance of the evidence.[54]

The parties here have focused on the "reliability" component of *Daubert*'s mandated inquiry. The reliability of the expert's opinion obviously depends, in part, upon her competency within her field of expertise, i.e., the expert must be qualified to render the opinions she intends to offer at trial.[55] In addition, by referring specifically to "scientific, technical or other specialized knowledge," Delaware Rule

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[52] *See, e.g.*, *Gen. Motors Corp. v. Grenier*, 981 A.2d 524, 529-31 (Del. 2009) (remanding to trial court for more careful and thorough review of the experts' proffered opinions under *Daubert*); *M.G. Bancorp., Inc. v. Le Beau*, 737 A.2d 513, 521-22 (Del. 1999) (applying *Daubert* to non-scientific expert testimony); *Crowhorn v. Boyle*, 793 A.2d 422, 427-31 (Del. Super. 2002) (tracing the history of Delaware's approach to the admissibility of expert testimony); *Minner*, 791 A.2d at 833-46 (tracing the history of American jurisprudence regarding the admissibility of expert testimony).

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

[54] *Id.*

[55] *Nelson v. State*, 628 A.2d 69, 73-74 (Del. 1993).

of Evidence 702 implicitly requires "a grounding [of the opinion] in the methodology and procedures" of the proffered expert's specialized discipline.[56] And the reference to "knowledge" in Rule 702 "connotes more than subjective belief or unsupported speculation."[57]

Certain factors may guide the Court's analysis of the "reliability" of the expert's testimony, including "'testing, peer review, error rates, and 'acceptability' in the relevant scientific community.'"[58] These factors, however, are neither exclusive nor exhaustive. The Rule 702 review is a "'flexible one,'"[59] and the "gatekeeping inquiry must be tied to the particular facts"[60] Regardless of its ingredients, the key to the "reliability" inquiry is to ensure that "an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."[61]

Before turning to the analysis, the Court must address one additional

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

[57] *Id.*

[58] *M.G. Bancorporation*, 737 A.2d at 521 (quoting *Kuhmo Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999)).

[59] *Kuhmo Tire*, 526 U.S. at 150 (quoting *Daubert*, 509 U.S. at 594).

[60] *Id.* (citing *Daubert*, 509 U.S. at 591); *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985).

[61] *Kuhmo Tire*, 526 U.S. at 152.

preliminary matter - the adequacy of the *Daubert* hearing conducted in this case. *Daubert* instructs: **"**[when f]aced with a proffer of expert [] testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to: (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact at issue."[62] "And, with that statement, the so-called *Daubert* hearing was born."[63] *Daubert* did not, however, set the parameters for the evidentiary process it had created. Confusion among the circuits followed. It was not until *Kuhmo Tire* that the Court definitively addressed whether a full evidentiary hearing is required before the Court can adequately perform its gatekeeping function. It is not.[64] A full evidentiary hearing must be conducted only if "special circumstances" warrant.[65] Otherwise, it is sufficient if the Court considers the expert's report, the expert's deposition testimony, and any supporting affidavits.[66]

Here, the Court offered to conduct a *Daubert* hearing but the parties declined

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[62] *Daubert*, 509 U.S. at 592 (footnote omitted). *See also Minner*, 791 A.2d at 843.

[63] *Minner*, 791 A.2d at 844.

[64] *Kuhmo Tire*, 526 U.S. at 152 ("[W]e conclude that the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.").

[65] *Minner*, 791 A.2d at 846.

[66] *Id.*

the invitation. Instead, the parties agreed that Dr. Zweig's report and deposition were sufficient to allow the Court to perform its gatekeeping function with regard to Dr. Zweig's opinions.[67] Although the Court ultimately has found Dr. Zweig's report and deposition testimony to be lacking in the detail necessary to allow Ms. Jones to sustain her *Daubert* burden, the Court is satisfied that the process by which the parties submitted the *Daubert* issue to the Court was more than adequate to facilitate the Court's gatekeeping responsibility.[68]

V.

A. This Case Is Factually Distinguishable From *Scaife*

As stated, the parties went to great lengths in their submissions and at oral argument to compare this case to *Scaife* - AZ to argue that this case presents a more compelling case for *Daubert* exclusion than *Scaife*; Ms. Jones to argue that this case presented none of the *Scaife* grounds for exclusion. Because *Scaife* marks this Court's first effort to address the plaintiff's burden under *Daubert* to present competent expert testimony on specific causation in the Seroquel® litigation, it is appropriate to begin the analysis with *Scaife* as a reference point.

At the outset, the Court agrees with Ms. Jones that her case does present several

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[67] Hr'g Tr. 28-30, Dec. 15, 2009 (Tr. ID. 30241803).

[68] *See Minner*, 791 A.2d at 846 (nearly identical process employed).

significant factual differences from *Scaife.* First, the record suggests that Ms. Jones apparently was at a lower relative risk of developing Type II diabetes than Ms. Scaife prior to their respective exposure to Seroquel®. In this regard, Ms. Jones is substantially younger than Ms. Scaife; she was just a teenager when she began taking Seroquel®.[69] The risk of developing Type II diabetes increases with age.[70] In addition, while Ms. Jones was overweight and, therefore, at increased risk for developing diabetes, unlike Ms. Scaife, she was not morbidly obese.[71] Morbid obesity is a prime risk factor for Type II diabetes.[72] Next, when read in a light most favorable to Ms. Jones, the record reveals that, unlike Ms. Scaife, Ms. Jones had a less significant family history of diabetes - another prime risk factor for developing the disease.[73] Both were smokers, a known risk factor, although Ms. Jones smoked less and for a shorter duration.[74]

Ms. Jones also asserts that Dr. Zweig, as compared to the expert in *Scaife*, was generally more familiar with Ms. Jones and her medical history at the time she

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[69] PX 19 at 2.

[70] DX KK at S15.

[71] Zweig Dep. 340-41, 396-97.

[72] *Id*. at 180-81.

[73] PX 17 at 293-94; Zweig Dep. at 111.

[74] PX 3 at 67-69; PX 7 at 115-16.

rendered her specific causation opinion in this case. Again, the Court concurs, although the Court must note that the expert in *Scaife* set the bar quite low.[75] As noted above, Dr. Zweig's level of familiarity with the specifics of Ms. Jones' medical records (and the specifics of medical and scientific literature/data upon which she relied) during her deposition was less than impressive.[76] Ms. Jones also points to the fact that Dr. Zweig's opinions have not been subjected to the extensive revisions and alterations that plagued her counterpart's opinions in *Scaife*. Again, the Court agrees. In *Scaife,* plaintiff's expert appeared to alter or amend her opinion with every new *Daubert* ruling in the Federal multi-district Seroquel® litigation, or with every new attack mounted against her opinion by AZ.[77] Aside from the arguable revision of her mechanism of injury opinion, which appears to have morphed from a "weight gain" to "direct metabolic effect" theory, Dr. Zweig's opinions have otherwise remained consistent from initial report through deposition. This too distinguishes Ms. Jones' case from *Scaife*.

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[75] *See Scaife*, 2009 WL 1610575, at *4-6 (noting certain deficiencies in Dr. Peck's ability to recall plaintiff's medical history).

[76] Certainly, the Court does not mean to suggest that an expert must command total recall of all pertinent facts or data each time the expert sits for deposition. But, if the expert's deposition is to form the sole or primary basis of the evidentiary record submitted in support of an expert in the face of a *Daubert* challenge, then the expert's ubiquitous lack of recall will necessarily impact the Court's determination of whether the expert's sponsor has met her burden of proof under *Daubert*.

[77] *See Scaife*, 2009 WL 1610575, at *17 n.250.

Having reviewed the factual distinctions presented by this case and *Scaife*, the Court must acknowledge that Ms. Jones has presented a stronger case for the admission of her expert's specific causation opinion than was presented in *Scaife*. Her medical profile presents fewer of the known risk factors for Type II diabetes. And her specific causation expert has not presented the "moving target" that epitomized the specific causation opinions in *Scaife*. Nevertheless, as discussed below, while these factual distinctions cannot be ignored, they do not overcome the lack of evidence of Dr. Zweig's methodology and the ultimate revelation of her opinion as mere *ipse dixit*.

B. Dr. Zweig Properly Diagnosed Ms. Jones' Diabetes

Before turning to Dr. Zweig's specific causation opinion, the Court first addresses AZ's contention that Dr. Zweig's diagnosis of diabetes for Ms. Jones is not supported by the medical evidence and is the product of flawed methodology. Specifically, AZ questions Dr. Zweig's considerable reliance upon Ms. Jones' report of an oral glucose tolerance test, not noted in her medical records, and her report of results which were suggestive of Type II diabetes.[78] But for the elevated blood glucose level, Dr. Zweig admitted that she would be unable to reach a diagnosis of

[78] *See* Zweig Dep. 66-74.

diabetes.[79] AZ also points to significant evidence in the record suggesting that Ms. Jones has never been diagnosed with diabetes by any of her treating physicians.[80] For her part, Dr. Zweig testified that she made her diagnosis of Type II diabetes based on criteria and information she regularly relies upon in her own medical practice. She routinely relies upon history provided to her by her patients and had no reason to discount Ms. Jones' report of the oral glucose tolerance test.[81] Moreover, she notes that while Ms. Jones' medical records may not reveal a formal diagnosis of diabetes, they do reveal that Ms. Jones' doctors were treating her for diabetes.[82]

With regard to methodology, the Court notes that there is a basis under *Daubert* and its progeny to distinguish between an expert's approach to reaching a medical diagnosis and the approach taken to determine the etiology of disease from among several possible causes (particularly a disease with a high background rate). As this Court has held:

> 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' [sic] generally are not appropriate for assessing the evidentiary reliability

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[79] *Id.* at 270, 380.

[80] *Id.* at 254-58.

[81] *Id.* at 254-70.

[82] *Id.* at 254.

> of a proffer of expert clinical medical testimony . . . . 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 [examination] with the results of extensive laboratory tests." *Daubert* is not an easy fit under these circumstances. And courts must be mindful of this dynamic when subjecting clinical medical testimony . . . to a *Daubert* analysis.[83]

Dr. Zweig testified persuasively that she employed the same criteria, with the same level of scrutiny, to diagnose Ms. Jones as she does for patients she treats in her clinical practice. She found Ms. Jones to be a reliable medical historian and her medical records to be reflective of ongoing treatment for the disease.[84] She squared her diagnosis with criteria from the American Diabetes Association.[85] The Court is satisfied that this record offers sufficient evidence to carry plaintiff's burden under *Daubert* to establish that Dr. Zweig made a reliable diagnosis of Type II diabetes for Ms. Jones.

C. Dr. Zweig Failed To Articulate A Reliable Methodology For Her Causation Opinion

Among *Daubert*'s many directives, its focus on the expert's methodology in

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[83] *See State v. McMullen,* 900 A.2d 103, 114 (Del. Super. Ct. 2006) (citing *Moore v. Ashland Chem.*, 126 F.3d 679, 688-90 (5th Cir. 1997), *vacated on other grounds*, 151 F.3d 269 (5th Cir. 1998); quoting Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* 465 (2d ed. 2000)) (footnotes omitted).

[84] Zweig Dep. 99, 102, 105.

[85] *Id.* at 58. *See also* DX KK at S14.

reaching an opinion is most instructive here. "To determine whether expert testimony is admissible requires a trial court to examine 'whether the reasoning or methodology underlying the testimony is scientifically valid . . . ."[86] In the second opinion of the so-called "*Daubert* trilogy," the United States Supreme Court clarified its expectations regarding the trial court's scrutiny of an experts methodology:

> [C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a . . . court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.[87]

Specifically with regard to an expert's opinion on specific causation, this Court has held that "[c]ausation of injury must be supported by more than the word of [the expert]."[88] And an expert's impressive qualifications alone will not serve as a license to express *ipse dixit* rather than properly supported expert opinion.[89] Stated differently,"'an expert's failure to explain the basis for an important inference

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[86] *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1233 (10th Cir. 2004) (quoting *Daubert*, 509 U.S. at 592-93).

[87] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

[88] *Minner*, 791 A.2d at 851.

[89] *See id.* at 846 ("we no longer rest on the mere proper credentials of the expert witness"). *See also Dodge v. Cotter Corp.*, 328 F.3d 1212, 1227 (10th Cir. 2003) (same).

mandates an [sic] exclusion of his or her opinion.'"[90]

At oral argument on the *Daubert* motion, counsel for Ms. Jones explained Dr. Zweig's methodology at great length, including her systematic incorporation of the general causation literature, and her methodical review and exclusion of each of the known risk factors for Type II diabetes, leaving only Seroquel® as the sole cause of Ms. Jones' Type II diabetes.[91] According to counsel, Dr. Zweig then addressed the mechanism by which Seroquel® caused diabetes in Ms. Jones. Notwithstanding Dr. Zweig's deposition testimony, in which she moved from her "weight gain" to a "direct metabolic effect" mechanism of injury theory, counsel maintained that Dr. Zweig has remained constant in her view that Seroquel® caused Ms. Jones to gain weight which, in turn, caused her to develop Type II diabetes.[92]

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[90] *Gen. Motors Corp.*, 981 A.2d at 529 n.14 (quoting *Hudgens v. Bell Helicopters*, 328 F.3d 1329, 1344 (11th Cir. 2003)). *See also Scaife*, 2009 WL 1610575, at *19 n.279 ("In the absence of this explanation, the expert's opinion becomes nothing more than inadmissible *ipse dixit*, and the fact finder is left to accept it *ad authoritatum*.") (citing *Alderman v. Clean Earth*, 2007 WL 1334565, at *7 (Del. Super. Apr. 30, 2007) and *Minner*, 791 A.2d at 851); *Quinn v. Woerner*, 2006 WL 3026199, at *3 (Del. Super. Oct. 23, 2006) ("While it is not the function of the Court to make a determination as to whether Dr. McCracken's conclusions are correct by weighing the objective evidence, the Court is charged with the duty to ensure that her opinions are based on some articulable and objective standard. In reaching her opinion, however, Dr. McCracken failed to articulate her use of 'methods and procedures of science' to reach her conclusion. The methodology actually employed by Dr. McCracken consisted of 'looking back' in an effort to determine what could be included and excluded as a cause for Quinn's pre-term delivery . . . . As applied here, however, this 'looking back' method does not impart an objective methodology used to reach a medical conclusion and, as such, does not meet the reliability threshold required by *Daubert*. Dr. McCracken's opinion is, therefore, unreliable.").

[91] *See* Hr'g Tr. 95-99.

[92] *Id.* at 98.

If the record supported counsel's adaptation of Dr. Zweig's methodology, then the Court might well have grounds to open the gates of the courtroom to Dr. Zweig. It does not. Dr. Zweig was asked over and over again to explain her methodology in sufficient detail to allow AZ to test it, and to allow the Court to exercise its gatekeeping responsibilities. Each time she declined to walk through her methods, and instead repeatedly intoned that she had reviewed all of the information she was supplied, applied her training and experience, and "put it all together." She specifically denied employing a "differential diagnosis" methodology and declined to characterize her approach beyond her abstruse "put it all together" explanation.[93] Apparently frustrated by the press for more specifics, Dr. Zweig ultimately exclaimed "[l]isten, I'm a double board certified physician. I don't need to, you know, justify how I make a decision."[94] Actually, in order for plaintiff to carry her burden under

[93] Zweig Dep. 403-08. The Court acknowledges that Dr. Zweig's specific causation opinion has recently been admitted in a Seroquel® case in New Jersey. The Court notes, however, that in addition to the fact that New Jersey applies an admissibility standard that is more "relaxed" than the *Daubert* or the *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), "general acceptance"standards, the decision in *Baker v. AstraZeneca Pharm., L.P.*, Docket No. L-1099-07, slip. op. (N.J. Super. Feb. 5, 2010), is also distinguishable because the court there specifically found that Dr. Zweig employed a differential diagnosis methodology to reach her opinions in the case. *Baker*, Docket No. L-1099-07, slip. op. at 11. As stated, Dr. Zweig specifically renounced that methodology here. *See* Zweig Dep. 403-08. *See also Scaife*, 2009 WL 1610575, at *15 n.232 (explaining that the "differential diagnosis" (or "differential etiology") methodology involves the expert considering and ruling out potential causes of a medical condition in order to reach a conclusion regarding causation by the process of scientific elimination).

[94] Zweig Dep. 272.

Daubert, this is precisely what Dr. Zweig "needed" to do.[95]

The Court must reject plaintiff's argument that cross-examination will place Dr. Zweig's opinions in proper context. While it is true that cross-examination can, in certain instances, effectively expose a soft expert opinion, the cross-examination of an expert whose opinion is based solely on her *ipse dixit* is tantamount to wasted breath. Under these circumstances, the skilled expert witness is virtually untouchable on cross-examination. Accordingly, before the Court will allow a "shaky" expert opinion to pass through the courtroom "gate" on the expectation that cross-examination will serve as an equalizer, the Court must be satisfied that cross-examination can be "vigorous."[96] Vigorous cross examination simply is not possible when neither counsel, the Court, nor the expert herself can discern the process or method by which the expert's opinion was generated.

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[95] *See Joiner*, 522 U.S. at 146-47 (expert must demonstrate that she employed a methodology to "fit" her conclusions within the data she reviewed); *Gen. Motors Corp.*, 981 A.2d at 529 (holding that "an expert's methodology must be not only reliable intrinsically but also reliably applied to the facts of the specific case"). *See also United States v. Fredette*, 315 F.3d 1235, 1239-40 (10th Cir. 2003) ("[A] witness 'relying solely or primarily on experience' must 'explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.'")(quoting Fed. R. Evid. 702)); *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.").

[96] *See Daubert*, 509 U.S. at 595-96 ("**Vigorous** cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." (emphasis added)). *See also Bowen v. E.I. du Pont de Nemours & Co., Inc.*, 2005 WL 1952859, at *11 (Del. Super. June 23, 2005) (noting that cross examination cannot adequately test *ipse dixit*).

D. In The Absence of Competent Expert Testimony On Specific Causation, Ms. Jones Is Unable To Meet Her Prima Facie Burden To Establish Proximate Cause

Under Massachusetts law, Ms. Jones must establish proximate causation as a requisite element of each of her claims against AZ.[97] Having determined that Dr. Zweig's specific causation testimony must be stricken under *Daubert*, the record is devoid of any competent evidence that Ms. Jones' exposure to Seroquel® proximately caused any injury to her. Consequently, in the absence of proof that would create a genuine issue of material fact with regard to a *prima facie* element of plaintiff's claims, the Court must grant AZ's motion for summary judgment.[98]

VI.

Based on the foregoing, AZ's Motion *In Limine* To Exclude The Medical Causation Medical Testimony of Dr. Susan Zweig and Motion for Summary Judgment must be **GRANTED**.

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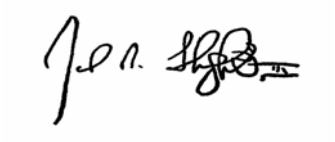
[97] *See, e.g.*, *Kent v. Massachusetts*, 771 N.E.2d 770, 777 (Mass. 2002) ("In addition to being the cause in fact of the injury, the plaintiff must show that the negligent conduct was a proximate or legal cause of the injury as well.")(citing *Wallace v. Ludwig*, 198 N.E. 159, 161 (Mass. 1935)).

[98] *See Oliver B. Cannon & Sons, Inc. v. Dorr-Oliver, Inc.*, 312 A.2d 322, 325 (Del. Super. 1973).

IT IS SO ORDERED.



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