IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

IN AND FOR NEW CASTLE COUNTY

NINA SCAIFE,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. NO. 06C-04-218 SER
	)	
ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP and ZENECA, LP,	)	
	)	
	)	
Defendants.	)	

Date Submitted: March 27, 2009
Date Decided: June 9, 2009

MEMORANDUM OPINION.

Upon Consideration of Defendant AstraZeneca's Motion In Limine to Exclude Expert Testimony of Valerie Peck, M.D.
GRANTED.
Upon Consideration of Defendant AstraZeneca's Motion for Summary Judgment.
GRANTED.

Linda Richenderfer, Esquire and Jennifer Patone Cook, Esquire, KLEHR, HARRISON, HARVEY, BRANZBURG & ELLERS, LLP, Wilmington, Delaware; Lawrence J. Gornick, Esquire and Dennis J. Canty, Esquire, LEVIN, SIMES, KAISER & GORNICK, San Francisco, California; Paul J. Pennock, Esquire, WEITZ & LUXENBERG, New York, New York. Attorneys for Plaintiff.

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SLIGHTS, J.

I.

In this opinion, the Court discharges its evidentiary "gate keeping" responsibility by reviewing the relevancy and reliability of proffered expert testimony on the question of whether Seroquel, an atypical antipsychotic medication manufactured by the defendants, Astrazeneca Pharmaceuticals, LP, Astrazeneca LP, and Zeneca, Inc. (collectively "AZ"), proximately caused the plaintiff, Nina Scaife, to develop Type II diabetes mellitus ("diabetes"). AZ has moved the Court to exclude the medical causation opinions of Ms. Scaife's expert witness, Valerie Peck M.D., on the ground that the opinions are not scientifically reliable. The Court's review has been guided by the settled directives of *Daubert v. Merrell Dow Pharm., Inc.,*[1] and its Delaware and federal progeny, that have led the Court down well-worn paths of inquiry into the methodologies employed by the expert to reach her medical causation opinions in this case. The Court has made every effort to follow the *Daubert* directives and to scrutinize the proffered expert testimony accordingly.

After carefully reviewing the expert's report, supplemental affidavit, deposition testimony, *Daubert* hearing testimony, and the extensive briefing submitted by the parties, the Court concludes that Dr. Peck's opinions do not satisfy the *Daubert* imperatives because, in reaching her differential diagnosis that plaintiff suffers from

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[1]509 U.S. 579 (1993) (hereinafter "*Daubert*").

diabetes caused by Seroquel, she: (1) failed adequately to "rule out" other likely causes of the plaintiff's diabetes; (2) improperly relied upon the temporal proximity of the plaintiff's exposure to Seroquel and the onset of her diabetes in forming her opinion that Seroquel proximately caused the diabetes; and (3) failed to correlate the information she purportedly reviewed to support the diagnosis into a meaningful analytical framework from which to draw a scientific conclusion. Consequently, AZ's Motion *In Limine* To Exclude The Medical Causation Expert Testimony of Dr. Valerie Peck must be **GRANTED.** Because Ms. Scaife is unable to support her claims against AZ with competent expert testimony regarding specific causation, AZ's motion for summary judgment must also be **GRANTED.**

II.

A. Seroquel

AZ manufactures and sells a prescription drug known chemically as quetiapine fumarate and marketed as Seroquel.[2] The Food and Drug Administration approved Seroquel in 1997 for use in the United States. It is one of a class of medications known as "second-generation" or "atypical" antipsychotics, and it is prescribed to

[2]*See* Transaction ID. ("Tr. ID.") 23384929, at Ex. E (Nov. 1997 Seroquel labeling, reproduced in 1999 Physicians' Desk Reference).

treat certain manifestations of psychotic disorders, as well as a number of "off-label" conditions.[3]

Over the past several years, reports have appeared in the medical literature and elsewhere suggesting a possible association between exposure to Seroquel and the development of diabetes and related metabolic disorders.[4] Litigation followed in which patients who have been prescribed Seroquel allege that AZ failed adequately to warn them of the risk that Seroquel might cause them to develop diabetes, and further allege that Seroquel has, in fact, caused them to develop diabetes. These cases have been filed in state and federal courts throughout the country, including the approximately 700 such cases filed in this Court. The plaintiff here, Nina Scaife, is the first of the Delaware plaintiffs to have her claims reviewed on the merits through dispositive motion practice.

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[3] *See id.*, at Ex. D (FDA approval letter from FDA to AZ, Sept. 1997), Ex. E (1997 Seroquel labeling, reproduced in 1999 Physicians' Desk Reference). *See also* Ex. B (Deposition of Samuel Lehman, M.D., at 41:1-42:11 (hereinafter "Lehman Dep.")).

[4] *See, e.g.*, Tr. ID. 24398358, at Ex. 5 (John B. Buse et al., *A Retrospective Cohort Study of Diabetes Mellitus and Antipsychotic Treatment in the United States*, 56 J. CLINICAL EPIDEMIOLOGY at 164-70 (2003)), Ex. 10 (Michael J. Sernyak, *Association of Diabetes Mellitus With Use of Atypical Neuroleptics in the Treatment of Schizoprenia*, 159:4 AM. J. PSYCHIATRY at 561-66, (Apr. 2002)), Ex. 11 (Leslie Citrome et al., *Relationship Between Antipsychotic Medication Treatment and New Cases of Diabetes Among Psychiatric Inpatients*, 55:9 PSYCHIATRIC SERVICES at 1006 (Sept. 2004)), Ex. 12 (Daniel A. Ollendorf et al., *Rate of New-Onset Diabetes Among Patients Treated With Atypical or Conventional Antipsychotic Medications for Schizophrenia*, 6(1) MEDSCAPE GENERAL MED. (2004), http://www.medscape.com/viewarticle/466800_print).

B. Nina Scaife

Ms. Scaife is a 46 year-old African American woman who lives in Kansas City, Kansas. She suffers from hypertension and degenerative joint and disk disease.[5] Since the age of 16, she has undergone seven knee surgeries and a total knee replacement.[6] Ms. Scaife's health problems generally have caused her to suffer from chronic pain and sleeplessness over many years.[7] Her lower extremity injuries in particular have caused her to live a relatively sedentary lifestyle - she has experienced difficulty standing and walking long distances since the first of her several knee surgeries, and has required crutches, casts and canes at various points starting in the 1980's and continuing through the 1990's.[8]

Over the years, Ms. Scaife has been treated with a wide variety of medications to provide relief from her many ailments including, *inter alia*, painkillers, sleep aids, steroids, hormone therapies, anti-inflammatories, anti-depressants and anti-anxietals.[9] She has smoked approximately a half a pack of cigarettes per day since the age of 23,[10] and has never followed a regular exercise routine.[11] In addition, Ms. Scaife's

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[5] Tr. ID. 23384929, at Exs. V & X.
[6] *Id.*, at Ex. A. (Deposition of Nina Scaife, at 18:23-19:7, 59:4-16, 109:25-110:8 (hereinafter "Scaife Dep.")).
[7] *Id.* at 110:16-117:6. *See also id.,* at Ex. U (Deposition of John Greenwood at 20:23-25, 21:4-16, 22:4-5, 63:3-8 (hereinafter "Greenwood Dep.")).
[8] Scaife Dep. at 110:1-8.
[9] Greenwood Dep. at 17:22-25, 18:8-10, 29:21-33:19, 47:8-13, 50:13-20, 55:9-19, 57:1-16, 58:12-25, 67:8-24, 72:9-10, 84:8-14.
[10] Scaife Dep. at 83:12-25.
[11] *Id.* at 91:20-25.

medical records reveal a history of chronic obesity and difficulty maintaining a healthy body mass index ("BMI"), i.e., a healthy weight in proportion to height (Ms. Scaife is 5'4" tall).[12]

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[12]

Weight	Date	Record
136	08/06/1983	Tr. ID. 23386323 at Ex. HH, Univ. of Kansas Med. Cntr.
190	03/04/1992	Tr. ID. 23386323 at Ex. II, Providence Med. Cntr.
200	10/05/1995	Tr. ID. 23386323 at Ex. II, Providence Med. Cntr.
205	10/09/1995	Tr. ID. 23386323 at Ex. II, Providence Med. Cntr.
210	12/04/1998	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
210	02/03/1999	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
215	03/12/1999	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
206	04/19/1999	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
206	05/14/1999	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
206	06/24/1999	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
206	08/11/1999	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
204.5	04/14/2000	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
199	06/14/2000	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
198	08/16/2000	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
185	09/21/2001	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
208	11/15/2001	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
190	09/16/2002	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
215	09/30/2002	Tr. ID. 23386323 at Ex. LL, Overland Park Reg. Med. Cntr.
197	09/15/2003	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
198	10/11/2004	Tr. ID. 23386323 at Ex. OO, Headache & Pain Cntr.
216	05/17/2004	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.
212	03/02/2005	Tr. ID. 23386323 at Ex. KK, Olathe Med. Cntr.

In addition to her many physical problems, Ms. Scaife has suffered from several mood disorders, as well. Her medical records reflect that she was diagnosed with affective disorder, which includes depression and anxiety disorder, in June 1999.[13] Medical records from September 2001 indicate that Ms. Scaife continued to be treated for depression,[14] and that she was treated for anxiety disorder in October 2001.[15] Her significant pain caused her to develop a sleeping disorder.[16] In May 2002, she sought treatment for sleep deprivation and fatigue at Olathe Medical Services.[17] Her treating doctor noted that over the last couple of years Ms. Scaife's condition was marked by "crying, tearful, anxious, poor sleep, decreased energy, [and] mood swings."[18] In the same month, Ms. Scaife also visited her primary care physician, who noted that her depression, anxiety and affective disorder were being exacerbated by menopausal symptoms.[19]

198	08/17/2005	Tr. ID. 23386323 at Ex. EE, Dr. Greenwood's Med. Rec.
179.6	01/30/2006	Tr. ID. 23386323 at Ex. PP, Shawnee Mission Med. Cntr.
160	12/29/2006	Tr. ID. 23386323 at Ex. MM, Plaintiff Fact Sheet (by Nina Scaife)

[13]Greenwood Dep. at 34:1-10.
[14]Scaife Dep. at 109:1-18.
[15]*Id.* at 110:9-15.
[16]*Id.* at 111:6-25.
[17]*Id.* at116:17-117:1.
[18]*Id.* at 117:3-4.
[19]Greenwood Dep. at 56:13-23.

In May 2003, Ms. Scaife complained of headaches, as well as pain in her lower back, cervical area and left arm.[20] In addition, she told her doctor that she was "unable to be around people" and that she was "a walking ball of anxiety."[21] She slept poorly. In response, her doctor prescribed Seroquel in August, 2003.[22] She started taking the drug in low doses (25 milligrams once at night).[23] Two weeks later her doctor increased the dosage to 100 milligrams per night.[24] Ms. Scaife continued to take Seroquel at this dosage for five months, until early October 2003, when her doctor increased the dosage to 200 milligrams per night, instructing her that if she could not tolerate the higher dosage, she should return to taking 100 milligrams per night.[25] Subsequent pharmacy records beginning later that month indicate that Ms. Scaife continued to fill her prescription for sixty 100 milligram Seroquel tablets every other month, consistent with a 100 milligram per night dosage.[26]

Ms. Scaife was diagnosed with diabetes in May 2004,[27] but continued to take Seroquel until September 2004.[28] Prior to this diagnosis, Ms. Scaife's diet consisted

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[20]Scaife Dep. at 150:7-12.
[21]*Id.* at 150:14-15.
[22] Lehman Dep. at 46:2-4.
[23]Lehman Dep. at 46:4.
[24]*Id.* at 50:18-25.
[25]*Id.* at 52:14-53:7.
[26]Tr. ID. 23386323, at Exs. AA & BB (Pl.'s Pharmacy Records from Walgreens and CVS). *See also* Tr. ID. 23908607, at Ex. 1 (Deposition of Dr. Valerie Peck, at 93:13-94:23 (discussing Ms. Scaife's testimony regarding a return from 200 mg. to 100 mg.) (hereinafter "Peck Dep.")).
[27]Greenwood Dep. at 78:10-80:21.
[28]Lehman Dep. at 56:12-58:12.

mainly of pasta, rice, doughnuts, slurpies, fish and fries from McDonalds and Burger King, chicken shrimp, and "[a] lot of Chinese food."[29] After stopping Seroquel in March 2005, Ms. Scaife reported that her pain level was interfering with her sleep more than ever, and she felt "like [she] had gone all the way backwards."[30]

C. Diabetes

Diabetes is a disease with an extremely high background rate. According to Dr. Peck, 10% of the adult population in this country will develop diabetes.[31] Data from the Centers for Disease Control ("CDC") estimates that approximately 1.6 million Americans are diagnosed with diabetes every year.[32] The CDC has characterized the rapid increase in diabetes as an "epidemic."[33] Some data suggests that African American women with a BMI in the range of Ms. Scaife's (BMI > 33) are at a 54x increased risk of developing diabetes.[34] In addition, other data suggests that "98 percent of diagnoses of diabetes" in women with a BMI in the range of Ms. Scaife's "are attributable to obesity."[35]

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[29] Scaife Dep. at 56:1-58:12.
[30] *Id.* at 174:25-175:4.
[31] Peck Dep. at 708:17-21.
[32] Tr. ID. 23476147, at Ex. A (Affidavit of Jeffrey P. Koplan, M.D., M.P.H., at ¶ 8 (citing figures from: http://www.cdc.gov/nccdphp/publications/aag/pdf/diabetes.pdf) (hereinafter "Koplan Aff.")).
[33] *Id.*
[34] *Id.* at ¶ 31.
[35] Graham A. Colditz, et al., *Weight as a Risk Factor for Clinical Diabetes in Women*, 132:3 AM. J. OF EPIDEMIOLOGY 501, 504 (1990).

It is in this context that Dr. Peck attempted to formulate her specific causation opinion in this case.

D. Valerie Peck, M.D.

Ms. Scaife has designated Valerie Peck, M.D. as an expert witness who will opine at trial that Ms. Scaife's exposure to Seroquel caused her to develop diabetes. Dr. Peck's opinions in this case have been disclosed in many forms and have evolved substantially over time, particularly in response to AZ's *Daubert* arguments in this case and decisions from the court in the federal Multi-district Seroquel Litigation in which the court struck plaintiffs' specific causation experts on *Daubert* grounds.[36] A chronological summary of her opinions, as appears below, illustrates the point.

1. The Credentials

Before discussing her opinions, it is appropriate first to summarize Dr. Peck's credentials to serve as an expert. By any measure, they are impressive. She currently maintains a private endocrinology practice at New York University (NYU) Medical Center, where she also serves as a clinical associate professor of medicine.[37] After graduating from NYU's School of Medicine in 1974, Dr. Peck completed a residency in internal medicine and a fellowship in endocrinology at Bellevue Hospital in New

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[36]*See Haller v. Astrazeneca Pharm. LP,* 598 F. Supp.2d 1271, 1299 (M.D. Fla. 2009); *Guinn v. Astrazeneca Pharm. LP*, 598 F. Supp.2d 1239, 1243 (M.D. Fla. 2009).

[37]Tr. ID. 24398358, at Ex. 34 (Expert Endocrine Opinion and Case Review of Nina Scaife at 1 (hereinafter "Peck Expert Rpt.")).

York.[38] Since 1979, she has been board certified in endocrinology and metabolism.[39] She was the Co-Director of the Bellevue Hospital Endocrinology Clinic for many years, and she is still deeply involved in that Clinic's operations.[40] She also helped to establish and then run a medical weight loss clinic at NYU Medical Center where she focused on treating patients with medical issues related to obesity.[41]

2. The Report

On November 10, 2008, Dr. Peck generated a report in which she summarized the information she reviewed, her findings from that information and her ultimate opinions in the case. She began her report by discussing certain features of Ms. Scaife's medical history. To gather this history, she conducted a telephone interview of Ms. Scaife, reviewed Ms. Scaife's medical records and reviewed both Ms. Scaife's deposition in this case and those of her doctors.[42] Dr. Peck described Ms. Scaife as an African American woman in her mid-40's who, at the time of the report, had been chronically obese for at least the past ten years.[43] Dr. Peck noted that Ms. Scaife has a family history of diabetes, smokes half a pack of cigarettes a day, has hypertension, has been on over a dozen prescription medications and suffers from chronic pain.[44]

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[38] *Id.* at 1.
[39] *Id.*
[40] *Id.*
[41] Tr. ID. 24195977, at 8:13-9:12 (*Daubert* Hearing Transcript, Mar. 12, 2009, AM Session (hereinafter "Hr'g Tr. AM")).
[42] Peck Expert Rpt. at 2.
[43] *Id.* at 2.
[44] *Id.* at 2-3.

The chronic pain caused sleeping difficulties, which prompted her treating doctor to prescribe Seroquel for her in May 2003.[45] Dr. Peck incorrectly stated that Ms. Scaife took Seroquel at a dose of 200mg per day throughout most of the time she was on the drug,[46] and she discussed Ms. Scaife's rather substantial weight fluctuations while on Seroquel.[47] Dr. Peck noted that Ms. Scaife was diagnosed with diabetes in May 2004.[48]

Next, Dr. Peck described the most common risk factors associated with the development of diabetes, including: genetics, obesity, sedentary lifestyle, ethnicity, family history of diabetes and "Drugs, e.g. antipsychotics."[49] She noted that Ms. Scaife had some of these risk factors, including "morbid obesity, family history, and the use of Seroquel."[50] She did not mention ethnicity or sedentary lifestyle as risk factors for Ms. Scaife, although both clearly apply to her.

Dr. Peck then described her "extensive" review of the pertinent medical literature.[51] She highlighted four studies in particular[52] and, after mentioning each, concluded that "Seroquel is [in] a drug class now known to be a cause of weight gain

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[45]*Id*. at 2.
[46]*Id*. at 2. As discussed above, the dosage actually was 100mg per day.
[47]*Id*. at 2.
[48]*Id*. at 2-3.
[49]*Id*. at 3-4.
[50]*Id*. at 5.
[51]*Id*. at 1, 4-5.
[52]*Id*. at 4-5. The studies, *supra* note 4, mentioned by Dr. Peck were: Buse *et al*. (2003), Olendorf *et al*. (2004), Citrome *et al*. (2004), Sernyak *et al*. (2002).

and diabetes," and that "Seroquel has an associated risk of diabetes" that is similar to other drugs in its class.[53] At the end of her report, Dr. Peck stated her conclusion:

> [Plaintiff] developed type 2 diabetes mellitus after taking Seroquel for 12 months. Other risk factors for her development of diabetes include obesity and family history. I thus conclude to a reasonable degree of medical probability that Seroquel was more likely than not a significant contributing factor in the development of type 2 diabetes in [Plaintiff].[54]

With this summary of her opinion, Dr. Peck ended her report without having provided any description of the methodology she employed to reach her conclusion.

3. The Deposition - Part One

Dr. Peck's first deposition lasted a full day and produced a transcript in excess of 400 pages. Early in her deposition, Dr. Peck was careful to delineate the boundaries of her expertise as an endocrinologist generally, and in treating patients with diabetes specifically. For instance, when asked to differentiate between "medical causation" and "association," Dr. Peck declined and stated that she was not an epidemiologist and did not know their terminology.[55]

As of the time of her deposition, Dr. Peck had reviewed thirty-one items of medical literature from various sources and of various forms, all of which had been provided to her by plaintiff's counsel.[56] She confirmed that she had not conducted any

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[53]Peck Expert Rpt. at 4.
[54]*Id*. at 6.
[55]Peck Dep. at 75:14-77:23.
[56]*Id.* at 23:3-24.

of her own research to reach her opinions; she reviewed only what Ms. Scaife's lawyers gave her.[57] She also acknowledged that she chose not to review data that had been supplied to her from AZ's clinical trials,[58] and further acknowledged that she was not aware of any prospective, controlled, randomized trials relating to Seroquel at the dosage levels implicated by Ms. Scaife's use of the drug.[59] Dr. Peck admitted that she had never met Ms. Scaife, although she did conduct a telephone interview of her.[60] She had not reviewed Ms. Scaife's pharmacy records and formed her understanding of the dosage of Seroquel Ms. Scaife took from a reference (which she could not give) in Ms. Scaife's medical records.[61]

When questioned about the risk factors that may lead to the development of diabetes, Dr. Peck agreed that Ms. Scaife's chronic obesity put her at risk of developing diabetes before she began taking Seroquel.[62] When asked to quantify or compare the seriousness of each risk factor for diabetes, Dr. Peck stated that she was unable to do so.[63] When asked if all of Ms. Scaife's pre-existing risk factors would have led her eventually to develop diabetes, Dr. Peck responded: "She might have

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[57] *Id*. *See also id*. at 27:10-25, 41:20-23.
[58] *Id*. at 37:3-40:10.
[59] *Id*. at 79:20-25.
[60] *Id*. at 250:3-8.
[61] *Id*. at 93:13-101:25.
[62] *Id*. at 145:18-146:2.
[63] *Id*. at 310:3-314:4, 310:19-23 (Q: "Do you know how the risk of a BMI of 30 to 35 for five years or more compares to the risk of taking Seroquel for less than a year at 200 milligrams?" A: "I've never seen those numbers."), 629:18-631:24.

eventually gotten it, but more likely than not she wouldn't have got it in this time frame."[64]

Dr. Peck was then asked to address the significant fluctuations in Ms. Scaife's weight. Dr. Peck stated that Seroquel most likely caused Ms. Scaife's nineteen pound weight gain from September 2003 to May 2004.[65] She based that conclusion on the fact that Seroquel was "the one risk factor that was changed"[66] prior to the weight gain, but then conceded that she is unaware of a method to determine if her weight gain was due to Seroquel or some other cause such as Ms. Scaife's diet or lack of exercise.[67] Notwithstanding this concession, however, Dr. Peck went on to opine that Ms. Scaife's weight gain, as caused by Seroquel, was a "contributing factor" in the development of her diabetes.[68] Dr. Peck surmised that weight gain associated with Seroquel might be caused by a metabolic effect of the drug, although she was unable to point to literature that substantiated this claim.[69]

Next, Dr. Peck was asked if she had an opinion regarding the mechanism by which Seroquel caused Ms. Scaife's diabetes. In response, she opined that the most likely mechanism is "insulin resistance."[70] When pressed to explain, however, she

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[64]*Id*. at 312:24-313:11.
[65]*Id*. at 174:2-24.
[66]*Id*. at 221:11-25.
[67]*Id*. at 156:4-10.
[68]*Id*. at 138:5-139:10, 328:2-11.
[69]*Id*. at 181:2-24.
[70]*Id*. at 267:15-268:4, 286:8-20, 267:25-268:4. ("It's my understanding that, yes, that Seroquel, independent of weight gain, has an effect on insulin resistance and therefore causes diabetes.").

conceded that the "details and mechanisms are not absolutely clear,"[71] and that she could not point to any peer reviewed literature to substantiate her opinion.[72] Dr. Peck then listed other possible mechanisms, including effects on the metabolic system, liver, and brain, but stated that the details were not proven and she was unable to point to any literature that supported these hypotheses.[73] Repeatedly asked whether short term weight gain was a possible mechanism whereby Seroquel caused diabetes,[74] Dr. Peck responded that it may be, but she could not point to particular supporting literature and conceded that the scientific evidence on this point was unclear.[75]

When asked to explain the process by which she reached her opinion, Dr. Peck testified:

> I was basing my opinion not just - - since I was doing this reviewing a case, and my main goal was to determine whether, in this patient, Seroquel was the cause of her diabetes, I used my past knowledge, my conferences, the accepted medical knowledge on Seroquel and diabetes and then supplemented it with a certain number of articles that I reviewed in preparation for this.[76]

She made no effort, however, to explain specifically what "past knowledge" she relied upon, nor did she explain the specific manner in which she applied the

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[71] *Id*. at 268:13-14.
[72] *Id*. at 294:2-295:8.
[73] *Id*. at 280:15-281:25, 299:11-13. *See also id*. at 63:2-65:15 (declining to point to any one study that generally supported her opinion that Seroquel causes an increase in glucose levels).
[74] *See e.g. id*. at 256:3-8, 266:19-290:25.
[75] *Id*.
[76] *Id.* at 47:18-48:3.

"evidence" from medical conferences, literature, and "accepted knowledge" to the process she employed to reach her opinion. After discussing at some length the information she reviewed, Dr. Peck's opinion boiled down to the following: "She had numerous risk factors, all of which were there for a lot of years. Then she was given a drug and developed [diabetes] in a time sequence related to that. So that's definitely a factor."[77] According to Dr. Peck, the Seroquel was a "very significant factor" in the causation analysis "because it was added on and tipped [Ms. Scaife] over the edge."[78] With this said, the deposition was adjourned shortly thereafter with plans to resume at a later date.

4. The Deposition - Part 2

Dr. Peck's deposition resumed on January 31, 2009. Like the first deposition, the continued deposition lasted an entire day and consumed nearly 400 pages of transcript. Prior to the deposition, Dr. Peck had been supplied with additional information from plaintiff's counsel, including medical records and other records relating to Ms. Scaife. Most of the deposition, however, covered old ground, meaning

[77] *Id.* at 321:10-14.
[78] *Id.* at 312:15-18.

topics already explored in the first deposition. This time, however, it appears Dr. Peck offered somewhat more responsive and detailed answers.[79]

Dr. Peck was asked to explain the basis for her conclusion that Ms. Scaife did not have diabetes before she started on Seroquel but developed it afterwards. She acknowledged that she could not rule out the possibility that Ms. Scaife had diabetes before taking Seroquel, but concluded "that more likely than not, she did not have it until then."[80] In this regard, Dr. Peck was less than responsive:

> Q. Doctor, are there any glucose readings you can point me to that show that she had normal glucose levels before she took Seroquel [i.e., readings that she did *not* have diabetes before Seroquel]?[81]
>
> * * *
>
> A. To the - - it's my opinion that with the glucoses that I have available that were most likely postprandial, that I had no evidence she *had* diabetes.[82]

* * *

Counsel tried again:

> Q. What readings, more likely than not, showed that she *didn't have* diabetes before?
> A. We don't have - - these are presumably random postprandials, because most of her glucoses were, when done; and therefore we don't have any glucoses that define her as *having* diabetes.

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[79]The first deposition transcript is replete with exchanges between defense counsel and Dr. Peck where Dr. Peck was either asking for questions to be repeated or for questions to be rephrased. These instances are too numerous to cite. Perhaps after seven hours of testimony, she had become more familiar with defense counsel and the deposition process by the time her deposition resumed.
[80]*Id.* at 476:10-18.
[81]Blood glucose testing is the preferred method by which clinicians diagnose diabetes. *See* **http://www.diabetes.org** (website for the American Diabetes Association).
[82]Peck Dep. at 473:10-13, 474:14-17 (emphasis supplied).

Q. And you don't have any that showed that she *didn't* have diabetes?
A. Right. I said you can't be definitive.[83]

Ultimately, after sparring with counsel over the meaning and significance of pre-Seroquel glucose readings, Dr. Peck testified that her opinion that Ms. Scaife did not have diabetes before taking Seroquel was based on glucose readings that did not meet the American Diabetes Association criteria for diagnostic significance, and based on the timing of the treating physician's diagnosis of diabetes.[84]

Similarly, Dr. Peck acknowledged that glucose testing results were not clear in their indication of diabetes after Ms. Scaife began taking Seroquel.[85] To make her diagnosis of diabetes, therefore, Dr. Peck relied upon the blood glucose levels along with the treating doctor's diagnosis and treatment of diabetes, as well as diabetes-related symptoms that she believed Ms. Scaife exhibited after the diagnosis was made.[86]

Dr. Peck was asked to revisit her views regarding risk factors for diabetes. She agreed that, as a rule, obesity was a more significant risk factor for diabetes than exposure to Seroquel.[87] Indeed, she agreed that obesity alone can cause diabetes,[88]

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[83] *Id.* at 475:13-476:2 (emphasis supplied).
[84] *Id.* at 471:23-499:24. *See also id.* at 539:12-540:4, 544:8-22.
[85] *Id.* at 527:17-528:7, 529:19-530:3.
[86] *Id.* at 530:9-18.
[87] *Id*. at 629:25-630:3, 639:9-12.
[88] *Id*. at 798:19-20.

that diabetes is a progressive disease that develops over time,[89] and that the risk from obesity can increase the longer a person remains obese.[90] She was unaware, however, of any data that attempted to "quantitate" chronic obesity as a risk factor for diabetes, and she did not attempt to compare or contrast that risk factor with the risk associated with Seroquel.[91] According to Dr. Peck, such comparisons are not possible.[92] She did, however, acknowledge that Ms. Scaife was probably in the "highest category" of obesity, as measured by body mass index.[93] But she did not research whether short term weight gain (purportedly attributable to Seroquel)[94] "can or can't make a difference in [the] development of diabetes."[95]

When the questioning turned to Dr. Peck's previously expressed opinion that Seroquel causes diabetes by somehow increasing the body's resistance to insulin, Dr. Peck ultimately acknowledged that insulin resistance could not be measured.[96] Thus, she acknowledged that "the exact mechanism by which Seroquel causes [insulin resistance and then diabetes] is not well defined."[97] So, to support her "mechanism" theory, Dr. Peck fell back on a temporal association methodology:

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[89] *Id.* at 332:6-11.
[90] *Id*. at 320:17-20.
[91] *Id.* at 620:22-631:2.
[92] *Id.* at 631:15-24.
[93] *Id.* at 635:17-19.
[94] *Id.* at 156:4-20.
[95] *Id.* at 640:17-642:18. *See also id.* at 646:4-23.
[96] *Id*. at 563:6-564:21, 579:21-580:4.
[97] *Id.* at 557:7-18.

Q. That's my question. Do you know what Ms. Scaife's level of insulin resistance was before she took Seroquel?
A. One can make a presumption that she had some degree of insulin resistance, as most obese people do, but one doesn't measure, can't measure it.
Q. And do you know what her level of insulin resistance was after taking Seroquel?
A. I know that she developed diabetes after taking Seroquel, so presumably there was some degree of insulin resistance that she couldn't compensate for. But you can't quantitate that, and it isn't quantative.[98]

* * *

Q. As a generality, will patients who have a variety of risk factors for diabetes, and do not do anything to control those risk factors, progress over time?
A. Some do; some don't.
Q. Is there any way you can tell me that Ms. Scaife would not have progressed over time?
A. Nobody can tell you whether or not she would have progressed over time. We're just focusing on the fact that she progressed in this period of time where Seroquel was added.[99]

* * *

Q. I want to know whether you know if her progression was more rapid while on Seroquel than it had been previously?
A. Well, I know that it went from her not having clinical diabetes to having diabetes, so it did something different. But as we - - you already asked me whether we can measure insulin resistance, and we can't.[100]

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[98] *Id.* at 557:19-558:9.
[99] *Id.* at 560:24-561:12.
[100] *Id.* at 561:20-562:3.

Dr. Peck reiterated her causation opinion several times during her deposition, albeit in various renditions.[101] Near the end of her lengthy testimony, she summarized her opinion as follows:

> So based upon the fact that she had several risk factors before and did not have diabetes, had the same risk factors with the additive risk factor of the Seroquel and then developed diabetes, my opinion is that more likely than not the Seroquel was the cause of her diabetes.[102]

In this regard, her opinion did not change from the first to second deposition.[103]

5. The Affidavit

Dr. Peck submitted a sworn affidavit on February 24, 2009,[104] which she characterized as a response to AZ's *Daubert* motion and the "combative and sometimes harassing" deposition to which she had been subjected.[105] In her affidavit,

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[101] *Id*. at 324:9-13 ("[S]he had preexisting risk factors, Seroquel was added to the picture, and she developed diabetes; and most likely than not it caused that."); 326:12-17 ("No, that all her risk factors for diabetes were there. We add one more thing, and in that time frame she develops diabetes. Therefore it's more likely than not that that's the additional risk factor that pushed her to that diagnosis."); 634:7-12 ("Once again, I'm not exactly wording it that way. She had several risk factors for diabetes. There was a point in time where Seroquel was added, which, in my opinion, is the risk factor that took her from not having diabetes to having diabetes.").

[102] *Id*. at 685:17-23.

[103] *Compare id.* at 312:21-23 ("[Seroquel] was added, so more likely than not it's the thing that brought [the diabetes] on.") *with* 473:5-9 ("She did not have evidence of diabetes before, she had evidence of diabetes after. That's what the records show, when that was added, and that's how I concluded that caused it.").

[104] Tr. ID. 23908607, at Ex. 2 (Affidavit of Valerie Peck, M.D., at ¶ 1 (hereinafter "Peck Aff.")). AZ filed its Daubert motion regarding Dr. Peck on Jan. 26, 2009 (Tr. ID. 23476147).

[105] *Id.* at ¶ 13. Aside from AZ's motion to exclude Dr. Peck's testimony, it is likely that Judge Conway's *Daubert* and summary judgment decision in the Seroquel federal Multi-District Litigation also played a role in prompting Dr. Peck's affidavit. *See Haller,* 598 F. Supp. 2d at 1296-98 (decided between the second Peck deposition and the Peck affidavit, granting summary judgment to AZ after excluding on *Daubert* grounds plaintiff's specific causation expert who, like Dr. Peck, relied heavily upon a temporality methodology to reach his opinions).

Dr. Peck defended her analysis and methodology.[106] She reiterated her belief that Ms. Scaife did not have diabetes before taking Seroquel,[107] discussed her review of the medical literature,[108] described how she concluded that Seroquel caused diabetes in Ms. Scaife[109] and discussed Ms. Scaife's other risk factors.[110]

The affidavit suggested that Dr. Peck had taken account of the criticisms leveled against her in AZ's *Daubert* motion and intended to fill any gaps in her methodology that may have been revealed there. Although she generally was unable to recall specific articles in the medical literature at her deposition, in her affidavit, Dr. Peck discussed at some length the findings of selected articles,[111] case reports and challenge/dechallenge reports that she reviewed.[112] She discussed clinical trials for the first time, having previously stated that she had not reviewed them.[113] And, she revised her description of the dosage of Seroquel that Ms. Scaife took leading up to the diagnosis of diabetes, apparently recognizing that her deposition testimony on this important fact had been inaccurate.[114]

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[106]*Id.* at ¶ 1.
[107]*Id*. at ¶¶ 16-26.
[108]*Id*. at ¶¶ 27-39.
[109]*Id*. at ¶¶ 40-51.
[110]*Id*. at ¶¶ 52-64 (reiterating her belief that obesity and ethnicity contributed to Ms. Scaife's development of diabetes and, *inter alia*, ruling out smoking as a risk because the literature is "unclear").
[111]*Id*. at ¶¶ 28-30, 33.
[112]*Id*. at ¶¶ 37-38.
[113]*Id*. at ¶¶ 31, 34.
[114]*Id*. at ¶ 43.

Significantly, Dr. Peck revised her causation theory from an indirect mechanism to direct mechanism theory. In the wake of Judge Conway's rejection of the indirect mechanism theory in the Seroquel MDL, Dr. Peck backed away from her previous opinion that Seroquel caused weight gain in Ms. Scaife that, in turn, contributed to her diabetes. Now, Dr. Peck advised that she would opine that medical literature might support the notion that Seroquel directly causes metabolic changes in the body that lead to the development of diabetes.[115]

Most significantly, Dr. Peck took issue with AZ's assertion that her opinion was "based on timing alone."[116] Dr. Peck agreed that the temporal relationship between Ms. Scaife's exposure to Seroquel and the onset of her diabetes was an important factor in her causation opinion.[117] But she adamantly maintained that her methodology went beyond temporal association to incorporate a detailed review and application of the data contained in the published medical literature to the facts of this case.[118]

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[115] *Id*. at ¶¶ 33.
[116] *Id*. at ¶ 40.
[117] *Id*. at ¶ 46 ("The onset timing is an important consideration in analyzing whether Seroquel contributed to her diabetes, because it is consistent with the timing for diabetes diagnosis that has been reported in epidemiologic literature.").
[118] *Id*. at ¶¶ 47-48, 50.

6. The *Daubert* Hearing Testimony

In reviewing AZ's *Daubert* motion, and the response thereto, both of which contained substantial excerpts from Dr. Peck's report, deposition and affidavit, the Court was struck by the extent to which her expert opinion had evolved as the litigation progressed. Her initial report disclosed a conclusory causation opinion with little indication of foundation or methodology. When pressed at her deposition to explain her methodology, Dr. Peck revealed that she based her opinion almost entirely upon the temporal relationship between Ms. Scaife's exposure to Seroquel and the onset of her diabetes.[119] When AZ's *Daubert* motion exposed her opinion as lacking in reliable methodology and admissible foundation, Dr. Peck issued an affidavit in which she expanded and modified her opinion once again in an effort to respond to AZ's criticisms and make fast her drifting opinions to *Daubert*'s now-settled mooring. Because her opinions had been difficult to tie down, the Court determined that Dr. Peck should appear in Court to clarify her opinions at a *Daubert* hearing.

The hearing occurred on March 12, 2009. After reviewing her credentials, Dr. Peck turned directly to explaining her methodology.[120] She explained that she first drew on her general knowledge of the association between atypical antipsychotics and

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[119]*See e.g.* Peck Dep. at 554:22-555:3 ("Seroquel was the new factor that is a known risk factor during this period of time that she developed diabetes. Therefore, it is my opinion that the Seroquel was the additional risk factor that caused her to have diabetes.")

[120]Hr'g Tr. AM at 10:20-23.

diabetes from her own practice, as well as her impression of the generally accepted literature on the issue.[121] Next, she reviewed medical literature and studies that dealt with atypical antipsychotics and diabetes,[122] including epidemiological studies, case studies, clinical trials and National Institute of Health ("NIH") clinical prospective trials.[123] This, of course, was in marked contrast to her deposition testimony where she acknowledged having received medical literature but testified that she had not read critical data.[124] At the hearing, however, Dr. Peck explained that she had not only read the literature but carefully considered whether there was "consistent reproducible data that . . . actually lead to the conclusion that Seroquel caused diabetes."[125] Since her deposition, she also looked for studies that might reveal a "mechanism that was theoretical or reasonable to explain" how Seroquel caused diabetes.[126] Dr. Peck stated that her last step was to consider the specifics of Ms.

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[121] *Id.* at 11:10-17.
[122] *Id*. at 11:17-19.
[123] *Id*. at 11:21–12: 2.
[124] *See* Peck Dep. at 7:15-25 (Q: "Now, you brought two shopping bags of materials with you today. Are you representing that these two shopping bags are the entirety of what you looked at in connection with the preparation of your report in the Scaife case?" A: "Yes, but I never looked at – the things you mentioned, those disks of trials, they're in there, but I never looked at them. I'm not sure why I had them. They were given to me, but I didn't look at them."). *See also Id.* at 41:20-23 (Q: "You didn't do any independent research on the subject of quetiapine and weight gain or diabetes, correct?" A: "Not in preparation for this.").
[125] Hr'g Tr. AM at 12:2-12.
[126] *Id*. at 12:13-18.

Scaife's case and then "to put the literature together to [determine] whether in her, in fact, Seroquel was a major contributing factor or caused her diabetes."[127]

After generally describing her methodology, Dr. Peck began a rather thorough review of the medical literature she had now carefully studied, starting with the epidemiological literature. Dr. Peck described how she approached the literature, stating that she looked at the structure, populations, and controls of each study when considering how much weight to give to the study's conclusions.[128] She testified that she also considered each study's limitations and "confounding factors."[129] Dr. Peck concluded that most of the studies she reviewed "pointed toward a . . . definite effect of Seroquel on diabetes,"[130] although she admitted that the studies were by no means uniform in that conclusion.[131]

Dr. Peck focused most of her attention on the "low dose" studies. For instance, she highlighted the Feldman study[132] and the Buse study[133] because they both considered patients taking Seroquel at dosages similar to the dosages prescribed to Ms. Scaife.[134] The mean dosage in Feldman study was 64.6mg, with 95% of the

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[127]*Id*. at 13:4-14.
[128]*Id*. at 25:21-26:6.
[129]*Id*. at 30:21-31:12, 36:2-37:6.
[130]*Id*. at 29:9-11.
[131]*Id*. at 28:22-29:7.
[132]Tr. ID. 24398358, at Ex. 9 (Feldman *et al*., *Retrospective Cohort Study of Diabetes Mellitus and Antipsychotic Treatment in a Geriatric Population in the United States*, 5 J. AM. MED. DIRECTORS ASS'N 38-46 (Jan.-Feb.2004)).
[133]*Id.* at Ex. 5 (Buse *et al*. (2003)).
[134]Hr'g Tr. AM at 39:18-40:2.

patients taking less than 250mg.[135] According to Dr. Peck, the study showed a statistically significant increased risk of developing diabetes of 1.9, as compared to the general population.[136] She then described the Buse study, which had a higher mean dosage level of 203mg, and showed a statistically significant hazard ratio of 3.1.[137] Due to the higher mean dosage level, however, Dr. Peck was only able to state "more likely than not" that some of the patients who developed diabetes in the study were on a dose lower than 203mg.[138] According to Dr. Peck, these two studies provide "reasonable evidence that, in fact," Seroquel can cause diabetes.[139]

Dr. Peck next addressed her consideration of the "obviously important" issue of mechanism.[140] Dr. Peck stated that she looked at four peer reviewed articles that discussed plausible mechanisms by which Seroquel can cause diabetes at the cellular level.[141] In her mind, it was not necessary for her to reach an opinion regarding a definite mechanism; only a "reasonable"[142] or "plausible"[143] explanation was required as she formulated her causation opinion. Nevertheless, she explained that the

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[135]*Id*. at 41:5-42:10.
[136]*Id*. at 41:7-14, 42:18-20.
[137]*Id*. at 43:3-8.
[138]*Id*. at 43:20-44:2.
[139]*Id*. at 46:4-11.
[140]*Id*. at 63:12-18.
[141]*Id*. at 63:12-65:5.
[142]*Id*. at 65:1-23.
[143]*Id.* at 66:10-11. *See also* Tr. ID. 24196574 (Hearing Transcript, Mar. 12, 2009, PM Session (hereinafter "Hr'g Tr. PM") (explaining that a mechanism is not necessary to rule out other risk factors)).

mechanism of injury was "close to being fully defined but still in the research phase."[144] She explained that Seroquel's effects on insulin resistance, glucose metabolism, brain function and liver function are all possible mechanisms "being looked into."[145]

Dr. Peck discussed one possible mechanism in detail -- Seroquel's effect on glucose metabolism. She testified that in order "to have diabetes one has to have an effect on glucose metabolism."[146] Dr. Peck reviewed studies analyzing data from prospective trials conducted by the NIH, which discussed glucose metabolism.[147] She highlighted two studies in particular, but concluded that one of them was not helpful because of the high rate at which subjects discontinued their participation in the study and also the study's reliance upon an unreliable measure of glucose.[148] According to Dr. Peck, the other study (the "Meyer" study[149]) showed health changes in patients after they took Seroquel for three months.[150] The Meyer data revealed that fasting glucose levels had risen above 100 in 4% of the patients taking Seroquel and there was

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[144]Hr'g Tr. AM at 65:23-66:2; Hr'g Tr. PM at 68:6-18, 124:5-15.
[145]Hr'g Tr. AM. at 66:19-67:3.
[146]*Id*. at 47:3-4.
[147]*Id*. at 52:1-13. The NIH trials were conducted to determine the efficacy of Seroquel, but the trials produced data that could be analyzed for metabolic effects, including glucose metabolism. *Id.*
[148]*Id.* at 52:20-54:14.
[149]Tr. ID. 24401484, at Ex. 35 (Meyer *et al*., *Change in Metabolic Syndrome Parameters with Antipsychotic Treatment in the CATIE Schizophrenia Trial: Prospective Data From Phase I*, Schizophrenia Research (2008), doi:10.1016/j. schres, 2007.12.487, at 2).
[150]Hr'g Tr. AM at 55:17-56:10.

a 4% increase in metabolic syndrome.[151] Dr. Peck testified that based on this study, it was now her opinion to a reasonable degree of medical probability that Seroquel "causes effects on glucose metabolism . . . [which] adds to the development of diabetes."[152]

Dr. Peck then addressed the issue of "temporality." In a dramatic shift from her first deposition testimony, and even her second deposition testimony, Dr. Peck now maintained that "[t]emporality clearly has to come into this, but it's clearly not the whole analysis."[153] She testified that temporality was important to determine where to start her analysis, and that she needed to know that Ms. Scaife did not have diabetes before taking Seroquel.[154] Her review of Ms. Scaife's medical history satisfied her that Ms. Scaife did not have diabetes before she began taking Seroquel, but developed it after.[155] This, according to Dr. Peck, was the starting point.

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[151] *Id*. at 58:11-59:1. A fasting plasma glucose level below 100 mg/dL is normal. A fasting plasma glucose level above 100 mg/dL but below 126 mg/dL is indicative of an impaired glucose tolerance, or pre-diabetes. Patients with pre-diabetes have a high risk of developing diabetes. A fasting glucose level equal to, or above, 126 mg/dL, which is confirmed by repeat testing on a separate day, will result in a diagnosis of diabetes. *See also* Tr. ID. 23386323, at Ex. CC (Amer. Diabetes Ass'n, *Diagnosis and Classification of Diabetes Mellitus*, 31:1 DIABETES CARE S55, S59 (2008)).

[152] *Id*. at 46:18-20.

[153] *Id*. at 76:12-13, 114:9–12.

[154] *Id*. at 76:13-16.

[155] *Id*. at 78:18-79:1. Dr. Peck's conclusion was based on records of doctor visits, glucose tests outside of the diabetic range, the absence of pre-diabetes, and a lack of symptoms. *Id.* at 77:1-6. Dr. Peck rejected defense counsel's suggestion that Ms. Scaife's record of glucose levels, specifically three high, random, non-fasting measurements, showed that Ms. Scaife may have had diabetes before taking Seroquel. *Id.* at 126:5-131:10. She further stated that "a conglomeration of many glucoses that are not in the diabetic range and not consistent with [Ms. Scaife] having diabetes" led her to conclude that Ms. Scaife did not have diabetes before taking Seroquel. *Id.* at 123:23-124:3.

Next, Dr. Peck compared Ms. Scaife's case with the literature she reviewed to see if Ms. Scaife "fit" within the studies.[156] Specifically, Dr. Peck compared Ms. Scaife's dosage levels and the length of time she was on Seroquel with the test data from particular studies.[157] Dr. Peck explained that Ms. Scaife's Seroquel dosage ranged from 25mg to 200mg, with 100mg being the most consistent dosage level for the "short period of time" Ms. Scaife took the drug.[158] Dr. Peck then testified that she compared Ms. Scaife's information to data that emerged from the low dose studies and concluded that ". . . everything about the way [Ms. Scaife] took [Seroquel] and the timing definitely fit within the literature of what we know about Seroquel causing diabetes."[159]

Dr. Peck then discussed Ms. Scaife's other risk factors for diabetes. Dr. Peck acknowledged that Ms. Scaife's long-term obesity and her ethnicity were "contributing risk factors."[160] She then ruled out a series of other recognized risk factors because she did not believe they were implicated in Ms. Scaife's case - - age, family history and alcohol abuse.[161] Dr. Peck then, in remarkably categorical fashion,

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[156]*Id*. at 80:12-13, 81:17-82:19.
[157]*Id*. at 80:14-81:20.
[158]*Id*. at 80:18-81:12.
[159]*Id*. at 83:2-4.
[160]*Id*. at 84:10-13.
[161]*Id*. at 86:2-6, 87:5-6, 90:9-91:10. Age was not a risk factor because Ms. Scaife, who is in her mid-40's, was not yet in the at-risk age group. Family history was not a risk factor because Ms. Scaife does not have a first-degree relative with diabetes. There was no evidence that Ms. Scaife abused alcohol. *Id*.

ruled out a series of other risk factors that *were* implicated in Ms. Scaife's case but, in her opinion, did not contribute to Ms. Scaife's development of diabetes, including Ms. Scaife's diet and sedentary lifestyle (Dr. Peck considered these to be a part of the obesity risk),[162] her ongoing hypertension (Dr. Peck testified that the data on hypertension as a risk factor was "a little bit unclear"),[163] her treatment with steroids in the mid-1990's (because the dose was not high enough, the treatment occurred a long time ago, and afterwards there had been no sign of diabetes), and her smoking up to half a pack of cigarettes per day (Dr. Peck characterized the relationship between diabetes and smoking as "one of the difficult ones"[164] because "the data is not that clear that it's a clear risk factor").[165]

Dr. Peck then returned to the two significant risk factors, obesity and ethnicity, that she "ruled in" as contributing causes of Ms. Scaife's diabetes. In this regard, Dr. Peck testified that "there's no doubt"[166] and "it's clear and accepted"[167] that obesity is a "very major significant risk factor for diabetes."[168] Dr. Peck stated that obese people have a 5-10% increased risk of developing diabetes.[169] She noted that Ms.

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[162]*Id.* at 85:20-23.
[163]*Id*. at 86:15-16, 101:18-23.
[164]*Id*. at 86:7-8.
[165]*Id*. at 86:8-10, 102:19–103:2; Hr'g Tr. PM at 92:5-92:16 ("As I said, I am not sure how good the data is in actually showing that smoking is a risk factor.").
[166]Hr'g Tr. AM at 94:14.
[167]*Id*. at 93:2.
[168]*Id*. at 93:3.
[169]*Id*. at 93:6-94:16.

Scaife had been obese most of her life, and was obese at least ten years prior to taking Seroquel.[170] Dr. Peck concluded, therefore, that Ms. Scaife's obesity was a significant risk factor that had to be "ruled in" as a cause of her diabetes.[171] Also, Dr. Peck stated that based on the Krishnan study of black women's health,[172] she believed that African Americans had a 2 or 2.5 times increased risk of developing diabetes.[173] Accordingly, she "ruled in" ethnicity as a cause of Ms. Scaife's diabetes as well.[174] Significantly, Dr. Peck was not asked directly to address in her direct testimony whether obesity and/or ethnicity alone could have caused Ms. Scaife to develop diabetes. A discussion of this crucial issue had to await cross examination.

Defense counsel's cross-examination started where Dr. Peck herself started and ended when explaining her opinions on the first day of her deposition - - discussing the temporal association between Ms. Scaife's exposure to Seroquel and the onset of her diabetes. Dr. Peck again reiterated her direct testimony that a temporal relationship "[is] necessary, but not sufficient for causation."[175] She never addressed, however, how or why she had moved beyond her deposition testimony revealing that

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[170]*Id*. at 95:3-6.
[171]*Id*. at 94:17-22, 101:10-11.
[172]Tr. ID. 24395045 at Ex. 14 (Krishnan et al., *Overall and Central Obesity and Risk of Type 2 Diabetes in U.S. Black Women*, 15 OBESITY1860 (2007)).
[173]Hr'g Tr. AM at 100:15-22.
[174]*Id*. at 101:12-13.
[175]*Id*. at 114:9-12.

the temporal association was the primary methodology upon which her specific causation opinion rested.

Next, defense counsel returned Dr. Peck to Ms. Scaife's risk factors for diabetes. Dr. Peck reiterated her concern about the data that showed an increased risk of diabetes because of smoking.[176] According to Dr. Peck, the data was equivocal. Of course, she already acknowledged that the data regarding the association between Seroquel and diabetes was likewise unsettled.[177] Nevertheless, Dr. Peck agreed that she was comfortable ruling out smoking as a contributing risk factor just as she was "comfortable ruling in Seroquel."[178]

With respect to Ms. Scaife's obesity, Dr. Peck agreed that Ms. Scaife had been obese twenty years before developing diabetes,[179] and conceded that obesity is "probably a stronger [risk] factor [for diabetes]" than Seroquel.[180] She further acknowledged that "the longer one is obese, it would increase the risk [of developing

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[176]Hr'g Tr. PM at 8:14-18, 18:2-3.
[177]*Id*. at 120:2-17.
[178]*Id.* at 9:18-22; Hr'g Tr. AM at 102:11-16 ("[S]moking I ruled out as a significant factor. Again, that's another one of these risk factors that it's not clear it's a direct risk factor for diabetes and not associated. It's clear it worsens diabetes and is an increased risk for complications from it.").
[179]Hr'g Tr. PM at 11:10-12.
[180]*Id*. at 13:16-23.

diabetes]."[181] Given these concessions, Dr. Peck was asked repeatedly whether she had ruled out obesity as the lone cause of Ms. Scaife's diabetes.[182] The following exchange is illustrative:

> Q. There are patients who have diabetes just from obesity, right?
> A. Well, obesity could be their only risk factor, but many patients with obesity don't have diabetes.
> Q. You agree there are patients who have diabetes just from obesity?
> A. With obesity the only risk factor, yes.
> Q. You cannot, and have not ruled out that obesity alone, or obesity plus other risk factors that Ms. Scaife had before taking Seroquel caused her to have diabetes, right?
> A. Your sentence is hard for me. So she clearly had those risk factors, had them for many years. She then - - there is no evidence that she would have developed diabetes in the time frame she did, or even in a time frame soon to that with those risk factors alone. So I am not quite - - you may be asking the reverse of that. I am not sure.
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> * * *
>
> Q. You cannot and have not ruled out that obesity alone [that] Ms. Scaife had before she took Seroquel caused her to have diabetes?
> A. So I can't rule out that obesity alone - - could not have led - - with her other risk factors - - could not have led to her diabetes, but I think it's more likely than not that it wouldn't have in the time frame she developed diabetes since she had all of these risk factors for ten years, up until that point, and did not have diabetes, or any evidence of pre-

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[181] *Id*. at 14:23–15:1. In this regard, Dr. Peck was asked about the "Colditz" study, Tr. ID. 24401484 at Ex. 34 (Graham A. Coldlitz *et al. Weight As a Risk Factor For Clinical Diabetes in Women*, 132(3) AMER. J. EPIDEMIOLOGY 501-13 (1990)), which showed that as among the test subjects with diabetes and with a body mass index comparable to Ms. Scaife's, 98% of such diagnoses were attributable to obesity. *Id*. at 23:4-24:1. Dr. Peck discounted the study, however, because the comparison group was "94 percent white people . . . [with] an ideal 22 BMI, " Hr'g Tr. AM at 93:20-22, and concluded that the risk numbers from that study were "very large number[s] compared to most people's experience with obesity and diabetes." Hr'g Tr. PM at 25:16-17.

[182] *Id.* at 33:20–37:4.

> diabetes. Could not rule out - - you can't - - it's not impossible that she would have developed it.[183]

When asked to explain her use of the term "unlikely" when opining that it was unlikely obesity alone or obesity coupled with other risk factors caused Ms. Scaife's diabetes, Dr. Peck explained:

> [T]he "unlikely" is [] the fact that she had all these - - had [obesity] as a risk factor for at least ten years until she developed diabetes, and hadn't had any evidence she had diabetes, or even pre-diabetes. So in the - - that is where the temporality becomes important again in this framework, in the time frame she developed diabetes something changed, and that adds to the thinking that all these things were the same, for ten years she does not develop diabetes, then in a time frame where we add an additional risk factor, she develops diabetes.[184]

Dr. Peck was then questioned about her reliance upon the low dose epidemiological studies.[185] With regard to the Buse study, she conceded that the data regarding the age group closest to Ms. Scaife showed a relative risk of one[186] which, in essence, meant that subjects taking Seroquel in that age group faced no increased risk of developing diabetes from taking the medication.[187] She also conceded that the Feldman study, upon which she relied so heavily during her direct testimony, likewise was not on point. Specifically, the Feldman study involved a population of patients

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[183] *Id.* at 33:13-35:7.
[184] *Id.* at 37:16-38:3.
[185] *Id*. at 39:12-13. Dr. Peck explained that at the time of her deposition she still thought Ms. Scaife had taken Seroquel at a dosage of 200mg, so she was unable immediately to recall the low dose studies during the deposition. *Id.* at 44:17-47:17. *See generally id.* at 39-45.
[186] *Id*. at 49:3-5.
[187] *Id*. at 48:8-18. *See also* Hr'g Tr. AM at 43:3–44:2 (Dr. Peck addressing limitations of the Buse study).

who were substantially older than Ms. Scaife,[188] and showed that patients who were 60 to 75 years old did not reveal a statistically significant risk of developing diabetes while on Seroquel.[189] She also conceded that it was only the age 75 and older group of patients that had a statistically significant risk.[190]

Dr. Peck was asked to revisit the portions of the Meyer study she relied upon to conclude that Seroquel affects glucose metabolism.[191] After some back and forth in cross examination, she conceded that portions of the study upon which she relied had no reference to statistical significance, and agreed that she "would not rely on that [as] establishing anything about glucose . . . ."[192]

Dr. Peck also briefly touched on the issue of weight gain and Seroquel.[193] Asked to describe how she ruled out certain risk factors, Dr. Peck responded that ruling out a risk factor with "a reasonable degree of medical certainty . . . is very different from saying one is absolutely certain that something couldn't have

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[188]Hr'g Tr. PM at 51:7-10.
[189]*Id*. at 51:7-15.
[190]*Id*. at 51:16-22. Nevertheless, Dr. Peck testified that she could rely on the results of the study because there was a statistically significant risk of 1.9 in the whole group and that "clearly some of the people in [the younger group] had also developed diabetes, just not enough to segregate out that group, and end up with a statistically significant number." *Id*. at 51:20-52:7. Later, in her redirect testimony, she discussed the Sernyak study, *supra* note 4, and a "whole spectrum of age group studies (never identified)," that suggested a link between Seroquel and diabetes. *Id*. at 88:21-89:3.
[191]*Id*. at 56:2-16.
[192]*Id.* at 57:4-9. Not to be undone, however, Dr. Peck testified that she could use that data and "put it together with . . . all the other [undefined] data [she] reviewed." *Id*. at 57:10-12.
[193]*Id*. at 111:3-12. Dr. Peck testified that it was likely Seroquel caused Ms. Scaife's weight gain, but then emphasized that it was her opinion that "[Seroquel] was a significant contributing factor to her diabetes with or without the component of the weight gain." *Id*. at 11:10-12.

contributed."[194] She explained further that there is a distinction between "impossible and what's most likely, or more likely than not to have been the situation."[195]

While Dr. Peck hinted that she might offer a fixed summary of her methodology and her resulting opinion earlier in the hearing,[196] she did not attempt to do so until the end of her re-direct testimony:

> [I]n an organized way, [I] looked at the literature, analyzed the literature, looked at Ms. Scaife's medical records in detail, then taking that information and her glucoses and diagnosis, and then looking back at the literature and seeing whether it actually fit in this case with what happened to her, and putting together all the literature that I talk about, the epidemiology, case studies, mechanism studies, clinical trials, all that information with her data, all the details of her records, putting it all together in an organized way to come to the conclusion that Seroquel was a significant contributing factor in her case, in her development of diabetes.[197]

Unfortunately, the Court never heard any explanation of the "organized way" in which she assimilated the available data in accordance with the demands of science and the scientific method.

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[194] *Id*. at 102:18-103:5.

[195] *Id*. at 103:14-17. Dr. Peck also testified that the process she used to rule out Ms. Scaife's risk factors is the same she has used in her 30 years of medical practice. *Id*. at 104:12-15.

[196] Hr'g Tr. AM at 84:10-23. "And in looking sort of in a general way, she for at least ten years had her -- had this other contributing risk factors for diabetes of obesity and ethnicity. Those things were constant over ten years. She had not yet before being on Seroquel, despite those risk factors going on those years, we have no -- she had not developed diabetes. There's no evidence she had diabetes. And there's no evidence she even had prediabetes. So that's a background to now saying, well, she has other risk factors. And then that leads into the analysis of let's look at the other risk factors so that I can be comfortable that Seroquel was actually a significant contributing factor in this." *Id.*

[197] Hr'g Tr. PM at 111:19-112:9.

III.

A. The *Daubert* Motion

"No one will deny that the law should in some way effectively use expert knowledge wherever it will aid in settling disputes. The only question is as to how it can do so best."[198] Judge Quillen, in *Minner v. American Mortgage & Guar. Co.*,[199] used this basic yet sage observation from Judge Learned Hand as a springboard to launch a thorough and thoughtful review of the use of experts in the courtroom and the evolution of the legal standards by which the admissibility of expert testimony has been measured. His discussion is noteworthy both in its thoroughness and in its melding of both Delaware and federal law on the subject. Suffice it to say, the import of Judge Quillen's review is that, despite a history of skepticism, trial courts now encourage the use of expert testimony if it will be of assistance to the trier of fact and if the opinions of the expert are reliable and rest on "good grounds."[200] But the expert's access to the courtroom is not unfettered. "The polestar must always be scientific or other validity and the evidentiary relevance and reliability of the principles that underlie a proposed submission."[201]

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[198]Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV. L. REV. 40 (1901).
[199]791 A.2d 826, 833 (Del. Super. 2000).
[200]*Id.* at 841.
[201]*Id.* at 843.

A prominent feature of modern civil litigation is the central role that science and other technical disciplines play in the adversarial search for the truth.[202] In recognition of this phenomenon, Delaware's Uniform Rules of Evidence provide:

> 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.[203]

Prior to *Daubert,* the Supreme Court of Delaware recognized the importance of the Rules of Evidence in determining the admissibility of 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. 402, 702); and
> 5) The evidence does not create unfair prejudice, confuse the issues, or mislead the jury (D.R.E. 403).[204]

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[202]Steven J. Breyer, *Introduction to Reference Manual on Scientific Evidence*, Fed. Jud. Ctr. 2d ed., at 2 (2000)(hereinafter "Reference Manual").
[203]*See* D.R.E. 702 ("Rule 702").
[204]*Minner*, 791 A.2d at 842-43 (citing *Nelson v. State*, 628 A.2d 69, 74 (Del. 1993)).

Then, in 1999, our 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.[205] Thus, "under *Daubert*, *Kumho*, and *M.G. Bancorporation*,[206] the Trial Judge acts as the gatekeeper to ensure that the scientific testimony is not only relevant but reliable."[207] 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.[208] These factors do not function as a "definitive checklist or test."[209] Rather, Delaware trial courts should apply the factors, as set forth in both *Nelson* and *Daubert*, in a flexible manner that takes into account the particular specialty of the expert under review and the particular facts of the underlying case.[210]

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[205]*M.G. Bancorporation v. Le Beau*, 737 A.2d 513, 521 (Del. 1999).
[206]*Daubert,* 509 U.S. 579 (1993); *Kumho Tire Co. v. Carmichael,* 526 U.S. 137 (1999); *M.G. Bancorporation*, 737 A.2d 513.
[207]*Minner*, 791 A.2d at 843 (citations omitted).
[208]*Daubert*, 509 U.S. at 593-94.
[209]*Kumho,* 526 U.S. at 150 (quoting *Daubert*, 509 U.S. at 593).
[210]*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."[211] 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."[212] And "knowledge" is more than unsupported beliefs; it must be derived from supportable facts.[213] 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."[214]

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."[215] If proffered testimony is not related to the case, then it will not aid in clarifying a contested fact and is, therefore, not relevant.[216] Accordingly, the "helpfulness" standard requires that evidence have "a valid scientific connection to the pertinent

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[211] *Id.* (emphasis in original).
[212] *Daubert*, 509 U.S. at 589 (emphasis in original).
[213] *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.").
[214] *Daubert*, 509 U.S. at 590.
[215] *Id.* at 591 (quoting Rule 702).
[216] *Id.*

inquiry as a precondition to admissibility."[217] As stated recently by our Supreme Court, "an expert's methodology must be not only reliable intrinsically but also be reliably applied to the facts of the specific case."[218] *Daubert* characterized this requirement as one of "fit."[219] Of course, the party proffering the expert testimony carries the burden of establishing that it is admissible.[220]

1. The Peck Opinion – First Cut

The first glimmer of Dr. Peck's opinion appeared in her November 10, 2008, expert report. There, after describing what she reviewed and offering a brief summary of Ms. Scaife's medical history, Dr. Peck summarily stated her conclusion that Seroquel "was more likely than not a significant contributing factor in the development of [Ms. Scaife's] diabetes."[221] In doing so she offered not even a hint of her methodology.

Dr. Peck's first deposition followed her report by a little more than a month, on December 19, 2008. Despite the fact that the deposition lasted an entire day, Dr. Peck offered little insight into her methodology. She did no independent research.[222] She was provided with data from the clinical trials for Seroquel but did not look at them

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[217] *Id.* at 592.
[218] *General Motors Corp. v. Grenier,* 2009 WL 267665, at * 4 (Del.) (en banc).
[219] *Daubert*, 509 U.S. at 591.
[220] *Bowen v. E.I. DuPont de Nemours & Co.*, 906 A.2d 787, 795 (Del. 2006).
[221] Peck Expert Rpt. at 6.
[222] Peck Dep. at 15:4-6, 41:20-23, 230:10-17.

and "was not sure why [she] had them."[223] She did not know how Seroquel causes diabetes generally or how it purportedly caused it in Ms. Scaife.[224] She had a fundamental misunderstanding of the dosage of Seroquel Ms. Scaife took throughout her course with the drug.[225] She did not know when Ms. Scaife stopped taking Seroquel.[226] She did not know Ms. Scaife's eating habits, her sleeping habits, her exercise habits or her medication history.[227] And yet, when asked whether she had an opinion as to whether Seroquel caused Ms. Scaife's diabetes, Dr. Peck did not hesitate to offer her definitive word on the subject - more likely than not, Seroquel caused Ms. Scaife's diabetes.[228]

Although she might not have known it at the time, from the outset of her engagement, Dr. Peck's methodology was to formulate a differential diagnosis for Ms. Scaife's diabetes with an eye towards determining whether *vel non* Seroquel was the cause. That is, in keeping with the Kansas law on concurrent causation,[229] she

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[223]*Id.* at 7:21-25.
[224]*Id.* at 267:9-20, 268:9-15, 281:4-10, 299:9-18.
[225]*Id.* at 92:18-93:21.
[226]*Id.* at 205:20-23.
[227]*Id.* at 263:11-25.
[228]Peck Dep. *passim.*
[229]*Burton v. R.J. Reynolds Tobacco Co.*, 181 F. Supp.2d 1256, 1268 (D. Kan. 2002) (addressing Kansas law on concurrent causation - - there can be more than one cause of injury, but there is no concurrent causation if a factor is the sole cause of injury).

attempted to "rule in" Seroquel as *a* cause,[230] and then to "rule out" other known risk factors as *the* cause.[231] This "rule in" "rule out" process is the essence of the differential diagnosis,[232] and the methodology is recognized as valid in Delaware if properly employed.[233]

In some cases, either the disease process itself or the circumstances surrounding the exposure to a toxic substance will substantially narrow the inquiry leading to the differential diagnosis. For instance, when the background rate of disease is low and the risk factors for disease are limited, such as in the case of a so-called "signature

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[230] *Warren v. Topolski*, 2008 WL 836022, at *3 (Del. Super.) ("referring to the differential diagnosis idea. . . [the expert] needs to 'rule in' the cause he suspects"); *Meister v. Medical Eng'g Corp.*, 267 F.3d 1123, 1129 (D.C. Cir. 2001) (holding that expert's opinion based on a differential diagnosis was flawed because expert failed to rule in asserted cause as capable of causing plaintiff's injury; "That methodology rests on the assumption that whatever factors remain after other alternative causes have been eliminated is at least capable of causing the disease in question."); *Caraker v. Sandoz Pharm. Corp.*, 188 F. Supp.2d 1026, 1030 (S.D. Ill. 2001) (holding that when differential diagnosis methodology "is used in the practice of science . . . it must *reliably* "rule in" a potential cause.").

[231] *Minner*, 791 A.2d 826 at 854 (holding that expert's methodology was flawed because "she refused to adequately consider, and eliminate, other possible causes of the Plaintiffs' illnesses through a definitive scientific process."). *See also* Mary Sue Henefin, et al., *Reference Guide on Epidemiology, in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 444 (Federal Judicial Center, 2d ed. 2000) (collecting cases on differential diagnosis/etiology and emphasizing the importance under *Daubert* of insuring that the expert employs a reliable process to rule out potential causes of disease).

[232] In a case such as this, where the expert is opining on one of several potential specific causes of a disease, the more accurate terminology is "differential etiology." *See Bowers v. Norfolk S. Corp.* 537 F. Supp.2d 1343, 1361-63 (N.D. Ga. 2007) (explaining differences between "differential diagnosis" and "differential etiology"). Because most of the cases addressing admissibility under *Daubert* do so in the context of "differential diagnosis" (as opposed to "differential etiology"), and the *Daubert* analysis is essentially the same in either context, the Court will refer to Dr. Peck's methodology as a differential diagnosis.

[233] *See Long v. Weider Nutrit. Group, Inc.,* 2004 WL 1543226, at *6 (Del. Super.); *State v. McMullen*, 900 A.2d 103, 116-17 (Del. Super. 2006).

disease," the diagnosis will turn on whether the plaintiff, in fact, has the disease and whether he was, in fact, exposed to the known risk factor(s).[234] In these cases, the differential diagnosis is simplified by the fact that the known risk factors for the disease are few and the incidence of disease is relatively rare. On the other hand, when the disease at issue has a high background rate, like diabetes, the differential diagnosis process takes on added complexity that requires the expert carefully to employ a "definitive scientific process" to rule in and rule out the many potential causes of the disease before reaching a diagnosis.[235]

Throughout her deposition, Dr. Peck iterated over and over again, in various configurations, that the analysis leading to her differential diagnosis was simple and sequential: Ms. Scaife took Seroquel and then, in sequence, things began to happen to her - - she gained weight; she developed diabetes. Thus, notwithstanding Ms. Scaife's long history of weight fluctuation prior to taking Seroquel, her weight gain after taking Seroquel was, according to Dr. Peck, caused by Seroquel "[b]ecause she

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[234] *See e.g., In re Asbestos Litig.,* 900 A.2d 120, 132, 134 (Del. Super. 2006) (addressing the signature disease of mesothelioma known uniquely to be associated with exposure to asbestos and to be associated with a background rate of "basically zero").

[235] *See Minner*, 791 A.2d at 854. *See also Haller,* 598 F. Supp.2d at 1295, 1297 (discussing the need methodically to rule out the several known risk factors for diabetes before concluding that the disease was caused by Seroquel).

was on Seroquel and gained that weight while on Seroquel."[236] Similarly, notwithstanding Ms. Scaife's long history of clinical (if not morbid) obesity, Dr. Peck concluded that Seroquel caused Ms. Scaife's diabetes "[b]ecause all the other risk factors were there. She didn't have it, and then she took Seroquel and did have it. So more likely than not, it was a factor."[237] She postulated two mechanisms by which Seroquel might have caused Ms. Scaife's diabetes: (1) it somehow caused to her to gain weight which, in turn, caused diabetes; or (2) it somehow created a direct metabolic effect that increased her resistance to insulin.[238] Ultimately, however, she acknowledged that the mechanism of injury "is not entirely worked out."[239]

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[236]Peck Dep. at 156:4-20. *See also id.* at 174:6-12 ("Q: Why do you conclude that Seroquel likely caused 19 pounds of weight gain in Mrs. Scaife? A: Because she gained 19 pounds between September '03 and May '04, during the time she was on it, so it is most likely due to that."). A later exchange at deposition remarkably illustrates Dr. Peck's commitment to the temporal association methodology. Dr. Peck acknowledged that Ms. Scaife gained a significant amount of weight before ever taking Seroquel, and that the rate of weight gain did not appreciably change after taking Seroquel. When confronted with the obvious question, then, of how she could attribute weight gain to Seroquel, Dr. Peck stated: "I can say she gained weight at other times (before Seroquel), but that at this time she gained this weight on Seroquel and I think they're related." Peck Dep. at 617:9-20. Of course, at the *Daubert* hearing, Dr. Peck backed away from this opinion entirely. Hr'g Tr. PM at 113:3-7.

[237]*Id.* at 313:25-314:4. *See also id.* at 473:5-9 ("She did not have evidence of diabetes before, she had evidence of diabetes after. That's what the records show, when that was added, and that's how I concluded that caused it."); 554:22-555:3 ("She - in 2004, Seroquel was the new factor that is a known risk factor during this period of time that she developed diabetes. Therefore, it is my opinion that the Seroquel was the additional risk factor that caused her to have diabetes.").

[238]*Id.* at 267:9-20, 299:9-18.

[239]*Id.* at 267:16-20.

The case law is legion that an expert may not rely upon temporal proximity alone as a basis to reach a specific causation opinion.[240] As Judge Quillen explained in *Minner,* the temporal proximity approach to causation strays from accepted scientific methods because it fails to "follow a logical, scientific, and deductive process to exclude other causative factors."[241] But this is precisely the approach initially taken by Dr. Peck here. She acknowledged that "[o]besity is a major risk factor for diabetes,"[242] and that she did not believe that Seroquel was a greater, or even

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[240]*Minner*, 791 A.2d at 855 (quoting *Schmaltz v. Norfolk & Western Ry. Co.*, 878 F. Supp. 1119, 1122 (N.D. Ill. 1995) ("It is well settled that a causation opinion based solely on a temporal relationship is not derived from the scientific method and is therefore insufficient to satisfy the requirements of [F.R.E. 702]."). *See also McClain v. Metabolife Intern., Inc*., 401 F.3d 1233, 1243 (11th Cir. 2005) ("[P]roving a *temporal* relationship between taking [a drug] and the onset of symptoms does not establish a *causal* relationship. In other words, simply because a person takes drugs and then suffers an injury does not show causation. Drawing such a conclusion from temporal relationships leads to the blunder of the *post hoc ergo propter hoc* fallacy."); *Roche v. Lincoln Prop. Co.*, 278 F. Supp.2d 744, 750 (E.D. Va. 2003) (excluding the expert opinion of a physician who relied solely on the temporal relationship between the exposure to mold and injury); *Cuevas v. E.I. DuPont de Nemours & Co.*, 956 F. Supp.1306, 1311 (S.D. Miss.) (excluding the opinions of several experts because they "all based their opinion on the temporal relationship between the alleged exposure to the [product] and the exacerbation of [the plaintiff's] medical problems"); *Nat'l Bank of Commerce v. Dow Chem. Co.*, 965 F. Supp.1490, 1506, (E.D. Ark. 1996) (excluding testimony of a physician and a chemist whose opinions were founded primarily upon the temporal connection between the exposure to a pesticide and injury); *Porter v. Whitehall Labs., Inc.*, 9 F.3d 607, 611 (7th Cir. 1993) (excluding expert testimony of two experts whose opinions were based solely on the temporal relationship between the ingestion of Ibuprofen and injury).

[241]*Minner*, 791 A.2d at 855. *See also Warren v. Topolski,* 2008 WL 836022, at *3 (Del. Super.) (finding it to be methodologically unsound, the court held that "temporal relationship is insufficient to establish a causal link"); *Allison v. McGhan Med. Co,,* 184 F.3d 1300, 1321 (11th Cir. 2005) (describing temporal relationship as mere "coincidence").

[242]Peck Dep. at 312:8-14; 320:15-16.

an "equally potent" risk factor.[243] Yet, throughout her deposition testimony it was clear that she employed no scientifically-driven course to rule out obesity or other known risk factors in Ms. Scaife as the sole cause of Ms. Scaife's diabetes.[244] This lack of process is particularly troubling given the high background rate for diabetes and Ms. Scaife's particular susceptibility to the disease long before she ever took Seroquel.[245] Thus, as of the conclusion of her deposition, Dr. Peck's specific causation opinion was not sufficiently reliable to pass through the *Daubert* filter.[246]

2. The Peck Opinion - Second Cut

As one follows the time line tracking the evolution of Dr. Peck's opinion, three significant events occurred after her first deposition that bear mentioning. First, on January 26, 2009, AZ filed its thirty five page brief (with appendices) in support of its motion *in limine* to exclude Dr. Peck's testimony in this case under *Daubert.*[247] Next, on January 30, 2009, the day before her deposition was to resume, Judge Conway struck plaintiff's specific causation expert in the federal Seroquel MDL on

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[243]*See Id.* at 312:8-14 ("Certainly there is [sic] risk factors greater than others. Obesity is a very major risk factor for diabetes. Family history is a very major risk factor. I'm not saying that Seroquel is an equally potent risk factor. I'm saying it's a significant risk factor that was added to her picture.").
[244]*Id.* at 156:4-20, 174:6-12, 221:17-24, 312:21-23, 313:25-314:4, 321:10-14, 464:3-9, 473:5-9, 554:16-555:3, 685:17-23.
[245]*Haller,* 598 F. Supp.2d at 1295.
[246]*See Id.* at 1297-99 (excluding specific causation expert under *Daubert* upon concluding that expert improperly relied upon the temporal relationship between the plaintiff's exposure to Seroquel and the onset of diabetes); *In re Zyprexa Prod. Liab. Litig.,* 2009 WL 1357236, at *3-4 (E.D.N.Y.) (excluding specific causation expert in the Zyprexa litigation on the same ground).
[247] Tr. ID. 23476147.

Daubert grounds in the *Guinn* case.[248] And finally, on February 6, 2009, Judge Conway struck plaintiff's specific causation experts in the *Haller* case, again on *Daubert* grounds.[249]

The Court is not privy to the factors that animated the evolution of Dr. Peck's opinion and will make no assumptions here. Suffice it to say, the opinion was refined (to be generous) after it was initially disclosed, and the amendments, in part, addressed core flaws in her methodology as expressed in Judge Conway's *Daubert* opinions and in AZ's *Daubert* motion in this case.[250] In an effort to cure the flaws, Dr. Peck attempted to ground her subjective differential diagnosis to objective data she found in the medical literature addressing general causation, *i.e.,* data suggesting that Seroquel can cause diabetes. The effort was too little too late.

As discussed above, Dr. Peck initially reached her differential diagnosis by ruling out other known risk factors for diabetes based solely upon the timing of Ms.

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[248]*Guinn,* 598 F. Supp.2d at 1243.

[249]*Haller*, 598 F. Supp.2d at 1299.

[250]Needless to say, the elusive nature of Dr. Peck's evolving methodology is cause for questions and concerns. *See e.g. id.* at 1296-97 (finding that expert's attempt to bolster his initial opinion in an attempt to avoid exclusion under *Daubert* "illustrate[d] that he reached his initial conclusions prematurely and based on incomplete data, [and] then later gathered what additional information he could to shore up his initial opinions."). *See also Miller v. Pfizer*, 356 F.3d 1326, 1329-30 (10th Cir. 2004) (affirming the exclusion of an expert witness whose opinion was characterized as a "moving target" because it had evolved so much during the course of the litigation); *Lantec, Inc. V. Novell, Inc.*, 306 F.3d 1003, 1025 (10th Cir. 2002) (affirming district court exclusion of an expert who changed his opinion from the opinion he gave in an earlier expert report because such a change, among other things, was evidence that the opinion lacked foundation and was unreliable); *Kirstein v. Parks Corp.*, 159 F.3d 1065, 1067-68 (7th Cir. 1998) (affirming the exclusion of an expert opinion where the expert's theory was described as "protean," and the court was unable to "pin down" the expert's opinion).

Scaife's exposure to Seroquel. While the initial construct of her differential diagnosis methodology was appropriate - - she attempted to "rule in" and "rule out" known risk factors - - her means of implementing it (temporal association) was not. When faced with AZ's *Daubert* challenge, Dr. Peck turned to where perhaps she should have started - - the medical literature and other data regarding the association between Seroquel and diabetes. At deposition, Dr. Peck could not recall the details of the literature she had reviewed. She simply did not want to get pinned down to the literature.[251] In her lengthy post-deposition affidavit, however, she prominently featured her literature review.[252] And, at the *Daubert* hearing, much if not most of the time with Dr. Peck was consumed by discussion of general causation data on Seroquel.

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[251]The examples of this are too numerous to cite here. To follow is a sampling: Peck Dep. at 65:8-20 (Q: "Tell me which of the studies you've looked at identifies patiennts by the criteria you've given me, either fasting blood glucose levels or nonfasting blood glucose levels, in coming to a conclusion that Seroquel cases diabetes?" A: "I would have to look through these now." Q: "Go ahead." A: "If you are asking me, I will tell you right now. If you want me to tell you scientific stuff from articles, you give me time by myself to relax to look at them."), 89:14-23 (Q: "Is there any study in any of the materials you looked at, where you identify that patients taking Seroquel at 200 milligrams or below experienced a rise in their glucose level of any particular magnitude?" A: "Once again, I've told you, I can pull anything you want out of articles, if you give me time to look at them and find it for you. Do I have it in my head, no."), 90:8-21 ("I am prepared to – I am not prepared to scientifically analyze all those articles. I was not asked to do that. I was asked to anlayze a case and have background information to form my opinion that I am very comfortable with. Specifics about what article said what at what dose I am happy to look up for you. I haven't read many of these articles for months, I was not asked to rereview them for today, and they are not all scientifically in my head. But any data you need me to find, I'm happy to find.") 118:22-25, 119:6-120:24, 125:21-126:11, 183:11-24, 184:12-18.

[252]*See* Peck Aff. at ¶¶ 27-39.

The fatal flaw in Dr. Peck's eleventh hour literature review is that she employed absolutely no process in doing it. For the same reason an expert may not rely solely upon temporal relationships when formulating a specific causation opinion, the expert cannot simply "look back" subjectively to selected features of the plaintiff's history so that she can randomly plug them into selected findings from the medical literature in order to cobble together a specific causation opinion;[253] again, the methodology must be grounded in a "definitive scientific process."[254] Subjectively selecting items from the medical literature without explanation of the process for selection or the methods by which the literature is evaluated is by no means a "definitive scientific process." [255] In this regard, the United States District Court for the District of New Jersey offers useful guidance:

> [A] weight-of-the-evidence approach requires that different types of data be evaluated together. This may include toxicology and chemical/structural studies, epidemiological studies, animal studies and comparison and toxicity benchmarks. . . . Importantly, because the weight-of-the evidence methodology involves substantial judgment on the part of the expert, it is crucial that the expert supply his method for weighing the studies he has chosen to include in order to prevent a mere listing of studies and jumping to a conclusion. How else can one expert's choice of "weight" be helpful to a jury which may be called on to assess a battle of weighers?[256]

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[253]*Quinn*, 2006 WL 3026199 at *3.
[254]*Minner,* 791 A.2d at 854.
[255]Of course, in this instance, Dr. Peck's sampling of medical literature was almost entirely selected for her by plaintiff's counsel.
[256]*Magistrini v. One Hour Dry Cleaning,* 180 F. Supp.2d 584, 601, 602 (D. N.J. 2002).

Simply stated, the expert cannot accept some but reject other data from the medical literature without explaining the bases for her acceptance or rejection.[257] And the expert must, as a *Daubert* requisite, fill the analytical gap between the premise of the studies (and the implications of the data) and the specific facts of the case in which the expert's conclusion has been reached.[258] Stated differently, the expert's review of the medical literature and other data must "fit" the facts of the case she is reviewing.[259] Otherwise, the opinion purportedly drawn from the literature "will [not] assist the trier of fact to understand the evidence," but instead "will [ ] create unfair prejudice [and] confuse or mislead the jury."[260]

In her affidavit, and again at the *Daubert* hearing, Dr. Peck made clear that she was no longer pressing the "indirect weight gain" theory as a mechanism by which Seroquel caused diabetes.[261] Nor was she pressing the "direct effect" theory, although she said the science was progressing in this regard.[262] After reviewing the literature,

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[257]*See Bowen,* 906 A.2d at 797 (noting that expert cannot ignore unfavorable studies); *In re Bextra & Celebrex Prod. Liab. Litig.,* 524 F. Supp.2d 1166, 1176 (N.D. Cal. 2007) (criticizing expert for "cherry-picking studies").
[258]*Minner,* 791 A.2d at 854 (noting that "too many analytical gaps" existed in the specific causation expert's temporal association methodology to allow its admission); *General Elec. Co. v. Joiner*, 522 U.S. 136, 143-47 (1997) (excluding causation expert's opinion where there was "simply too great an analytical gap between the data [relied upon] and the opinion proffered."); *Schudel v. General Elec. Co.*, 120 F.3d 991, 997 (9th Cir. 1997) (excluding experts who failed to make a weighted extrapolation from studies relied upon), *abrogated on other grounds*, *Weisgram v. Marley Co.*, 528 U.S. 440, 445 (2000); *Eskin v. Carden*, 842 A.2d 1222, 1232 (Del. 2004) (affirming exclusion of biomechanical testimony that did not tie general scientific data to the facts of the case).
[259]*Daubert,* 509 U.S. at 591.
[260]*Bowen*, 906 A.2d at 795.
[261]Hr'g Tr. PM at 113:3-7.
[262]Hr'g Tr. AM at 66:16-67:3.

Dr. Peck was of the view that the scientific community is not yet able to identify a mechanism, if any, by which Seroquel causes diabetes.[263] Her now definitive view on this subject is that "you don't have to have mechanism" in order to rule out other risk factors, including obesity, in the specific causation determination.[264]

In the absence of an identified mechanism and in the case of a disease with such a high background rate, it was all the more important for Dr. Peck to articulate clearly the means by which she "ruled in" and "ruled out" causative factors for her differential diagnosis.[265] "[T]he mere statement by an expert that he or she applied differential diagnosis does not *ipso facto* make the application scientifically reliable or admissible."[266]

For purposes of this analysis, the Court will assume *arguendo* that Dr. Peck properly ruled in Seroquel as a risk factor for diabetes even though she admitted that one of the studies upon which she relied, the Buse study, did not show an increased risk of developing diabetes from taking Seroquel in the age group nearest to Ms. Scaife,[267] and the Feldman study, upon which she also relied, did not show a statistically significant increase in the risk for developing diabetes among patients

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[263]Hr'g Tr. PM at 124:5-15, 126:11-127:1.
[264]*Id.* at 126:14-127:1.
[265]*See Warren*, 2008 WL 836022, at *3-4; *Mancuso v. Con. Ed. Co.*, 967 F. Supp. 1437, 1451 (S.D.N.Y. 1997) (holding that "failure to exclude other possible causes is particularly disturbing in light of the common nature of the plaintiffs' complaints.").
[266]*McMullen*, 900 A.2d at 116-17.
[267]Hr'g Tr. PM at 48:8–18.

taking Seroquel.[268] Her refusal to rule in other known risk factors for diabetes, such as Ms. Scaife's sedentary lifestyle, ongoing hypertension and smoking, however, cannot be given the same deference. Dr. Peck declined to rule in these risk factors purportedly because the literature with regard to association was unclear.[269] She acknowledged without hesitation, however, that the literature upon which she relied to rule in Seroquel likewise was not clear.[270] Her inconsistency in this regard reveals a flawed and perhaps contrived methodology.[271]

More troubling is Dr. Peck's insistent reliance upon a "temporal relationship" as opposed to an "objective measure" to rule out other potential causes of Ms. Scaife's diabetes.[272] Even after the flaws in this approach were exposed through the *Daubert* decisions in the federal Seroquel MDL, and AZ's motion *in limine* to exclude her testimony here, Dr. Peck could not help at the *Daubert* hearing but to fall back on the temporal relationship between Ms. Scaife's exposure to Seroquel and the onset of her diabetes when explaining why she ruled out Ms. Scaife's chronic obesity as the sole cause of the disease.[273]

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[268]*Id.* at 51:11–15.
[269]*See e.g., id.* at 93:6-15, 95:8-14, 96:12-14.
[270]*Id.* at 102:19, 120:2-121:17.
[271]*See Carlson v. Overstrom*, 675 N.W.2d 89, 105 (Neb. 2004) (excluding differential diagnosis when expert failed reliably to explain failure to rule in known causes).
[272]*See Quinn v. Woerner*, 2006 WL 3026199, at *3 (Del. Super.).
[273]*See* Hr'g Tr. PM at 34:8-38:3, 70:3-71:19.

As noted, the new twist to Dr. Peck's opinion at the *Daubert* hearing was her reliance upon medical literature to bolster her temporal analysis. But these serendipitous references to the medical literature supplied to her by Ms. Scaife's attorneys, almost none of which she confirmed or even accented with her own research, do not make her reliance upon temporal proximity more scientific.[274] In this regard, the Court cannot ignore the fact that Dr. Peck did not reference any findings from the medical literature in her report, could not meaningfully discuss the medical literature at either of her discovery depositions, chose not to review data from clinical trials of Seroquel until her opinion was criticized, and chose to incorporate the medical literature into her opinion only after *Daubert* motion practice was initiated.[275] Even then, Dr. Peck still inexplicably chose not to address relevant data, including studies that reveal a mean weight loss in obese patients taking Seroquel, and other studies that she acknowledged show no causal relationship between Seroquel and diabetes.[276]

At the end of the day, Dr. Peck simply could not articulate the manner in which she considered the data from the medical literature, how she weighed it in her

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[274]*See Magistrini,* 180 F. Supp.2d at 602; *Haller,* 598 F. Supp.2d at 1297-98.

[275]Hr'g Tr. PM at 52:12-62:5. *See e.g.* Peck Dep. at 7:21-25, 15:4-6, 23:22-24, 24:8-11, 41:20-23, 230:10-17, 243:3-8, 275:15-24.

[276]*See* Peck Dep. at 46:12-20 (Q: "Do you know whether there are observational studies, in addition to the ones you've looked at, where Seroquel does not appear any different from placebo?" A: "I did not see any article that showed that to a statistical significance, I haven't seen one. There might be articles on it, but I never saw one that showed it to be statistically clear and a good study."), 119:19-120:3, 126:12-127:4, 185:21-186:18; Hr'g Tr. PM at 57:6-12, 59:17-61:3, 62:7-22, 114:1-115:2.

analysis, relied upon it or discounted it, fit Ms. Scaife's case within the data points, or otherwise utilized it to support her ultimate conclusion. It is not enough for her simply to say she referred to medical literature and then to state generally that it supports her conclusion.[277] *Daubert* demands that she employ intellectual rigor in the consideration of scientific data, including in the evaluation and discounting of studies that are not supportive of her opinion.[278] And it demands that she adequately explain that process.[279] This has not occurred here.

The Court as gatekeeper is left to wonder exactly how Dr. Peck was able methodically to rule out other potential risk factors, including and particularly Ms. Scaife's chronic obesity, in making her specific causation opinion. Like the experts in *Guinn* and *Haller,* Dr. Peck stated that the relative contribution of individual risk factors to Ms. Scaife's diabetes "cannot be quantified in any numerical way."[280] When one considers that Dr. Peck acknowledged that obesity is a more significant risk factor for diabetes than Seroquel, that the risk of diabetes increases the longer one is obese, and that Ms. Scaife was chronically (and likely morbidly) obese, it is difficult to follow in sequence her opinion that Seroquel, not chronic obesity, is the most likely

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[277]*See* Peck Dep. at 739:23-740:2 ("I didn't go back and look, but I know that it's stated at conferences, at scientific meetings and conferences that I go to."); Hr'g Tr. PM at 64:22-65:6, 66:1-15.
[278]*Bowen,* 906 A.2d at 797; *Crowhorn v. Boyle*, 793 A.2d 422, 431 (Del. Super. 2002).
[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*. *See Minner*, 791 A.2d at 851; *Alderman v. Clean Earth*, 2007 WL 1334565, at * 7 (Del. Super.).
[280]Hr'g Tr. PM 20:14-20.

sole cause of the onset of Ms. Scaife's diabetes.[281] And, of course, Dr. Peck offered nothing meaningful by way of explanation of her methodology other than the refrain of her inadmissible temporal relationship theory. Without any insight into Dr. Peck's methodology for ruling out known, prominent risk factors, the Court must conclude that Ms. Scaife has failed to meet her burden to establish the reliability of her specific causation evidence under *Daubert.*[282]

B. The Motion for Summary Judgment

Having concluded that Dr. Peck's testimony is not admissible under *Daubert,* the Court must now determine whether Ms. Scaife can sustain her claims of negligence, strict products liability and fraud in the absence of competent expert testimony on specific causation, a requisite element of each of her claims. To do so, the Court must reach AZ's motion for summary judgment.

The Court's principal function when considering a motion for summary judgment is to examine the record to determine whether genuine issues of material fact remain for trial.[283] Summary judgment will be granted only if no genuine issues of material fact exist and the moving party is entitled to judgment as a matter of law.[284] In this regard, "Rule 56(c) mandates the entry of summary judgment against a party

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[281] *Id.* at 13:18-23, 14:15-23.
[282] *See Paoli II*, 35 F.3d at 763 (excluding testimony of specific causation expert who "provided no reason to explain" why he ruled out other known risk factors).
[283] *Oliver B. Cannon & Sons, Inc. v. Dorr-Oliver, Inc.*, 312 A.2d 322, 325 (Del. Super. 1973).
[284] *Id.*

who fails to establish the existence of an element essential to that party's case."[285]

The Kansas Product Liability Act ("KPLA") governs all product liability claims in Kansas. The KPLA clearly provides that a plaintiff must prove that the defective product proximately caused injury, regardless of the tort theory upon which plaintiff seeks recovery.[286] To establish causation, plaintiff must present evidence from which a reasonable juror could find (1) Seroquel, in general, can cause diabetes, and (2) Seroquel more likely than not was the specific cause of Ms. Scaife's diabetes.[287] In pharmaceutical cases such as this, involving complex scientific evidence, a plaintiff must present expert witnesses to provide evidence of both general and specific causation.[288] For her part, Ms. Scaife has relied exclusively upon the testimony of Dr. Peck to establish specific causation. Having determined that Dr. Peck does not survive *Daubert* scrutiny, Ms. Scaife has no competent evidence of specific causation. Consequently, as a matter of law, she cannot meet her *prima facie* burden of proving medical causation under the KPLA. AZ is entitled to summary judgment.

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[285]*Celotex Corp. v. Catrett,* 477 U.S. 317, 322 (1986).
[286]*See* K.S.A. § 60-3302 (including, but not limited to, "any action based on strict liability in tort, negligence . . . breach of, or failure to, discharge a duty to warn or instruct . . . or under any other substantive legal theory"); *Samarah v. Danek*, 70 F. Supp. 2d 1196, 1206 (D. Kan. 1999) (requiring more than just proof of an injury to establish proximate cause).
[287]*See Vanderwerf v. SmithKline Beecham, Corp.*, 529 F. Supp. 2d 1294, 1306 (D. Kan. 2008).
[288]*See Miller v.* Pfizer, 196 F. Supp.2d 1095, 1125 (D. Kan. 2002); Smith *v. Pfizer*, 2001 WL 968369, at *4-5 (D. Kan.).

IV.

In the wake of *Guinn, Haller, In re Zyprexa Prod. Liab. Litig.,* and now this case, each striking on *Daubert* grounds plaintiffs' specific causation experts in cases involving the alleged link between atypical antipsychotic medications and diabetes, in a particular plaintiff, the Court is left to wonder what is to become of its docket of more than 700 Seroquel cases. Trial groups have been formed well into the future and the parties are expending significant resources to prepare for these trials. The Court is expending resources too. Under these circumstances, it is appropriate to wonder aloud.

During closing arguments in the *Daubert* hearing, the Court asked counsel for AZ whether a Seroquel plaintiff's specific causation expert can ever pass muster under *Daubert* given the current state of the science. Counsel responded, in essence, that science has not caught up with the litigation or, perhaps, the litigation is racing ahead of the science.[289] Certainly, Delaware courts have confronted instances where "the precepts of science have not caught up with all of the claims of the plaintiff."[290] In such instances, our trial courts steadfastly guard the gates of the courtroom and demand that the science, if it is to advance, be enriched in the laboratories, hospitals, universities or other research centers where serious scientists consider such matters.[291]

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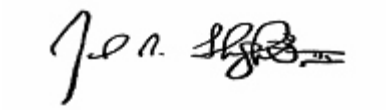
[289]Hr'g Tr. Closing Remarks at 27:19-29:22.
[290]*Minner*, 791 A.2d at 848.
[291]*E.g. Id.*

Thus far, AZ has been careful to focus its specific causation attack case-by-case. It has yet to argue in motion papers that plaintiffs' (collectively) specific causation case cannot withstand *Daubert* scrutiny in *any* case given the state of the existing science and the consistent physical and medical presentations of the plaintiffs in this litigation. Perhaps, for all concerned, it is time to call that question.[292]

Returning to this case, based on the foregoing, AZ's Motion *In Limine* To Exclude Medical The Medical Causation Testimony of Dr. Valerie Peck is **GRANTED.** Because the plaintiff has no competent evidence of medical/specific causation, AZ's Motion for Summary Judgment must also be **GRANTED**.

IT IS SO ORDERED.



Judge Joseph R. Slights, III

Original to Prothonotary

[292]The Court notes that it does not necessarily share the sentiment that the science has not caught up with this litigation. Any number of scenarios might have altered the outcome here, *e.g.,* a medical history not so dominated by chronic obesity and other known risk factors for diabetes and/or an earlier, more methodical and more thorough review and application of a fair cross section of the general causation data to the plaintiff's specific medical and Seroquel history.