IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

IN AND FOR NEW CASTLE COUNTY

REGINA HOPKINS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06C-01-325 SER
	)	
ASTRAZENECA	)	
PHARMACEUTICALS, LP and	)	
ASTRAZENECA LP,	)	
	)	
Defendants.	)	

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

MEMORANDUM OPINION.
*Upon Consideration of Defendants' Motion In Limine To Exclude The Medical Causation Testimony of Dr. Loren W. Greene and Motion for Summary Judgment***.**
GRANTED.

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

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

SLIGHTS, J.

I.

Plaintiff, Regina Hopkins, has joined approximately six hundred other plaintiffs in Delaware, each of whom allege that their exposure to the atypical anti-psychotic medication Seroquel®, manufactured by the defendants, Astrazeneca LP and Astrazeneca Pharmaceuticals LP (collectively "AZ"), has caused them to develop Type II diabetes. The Court has divided the several hundred plaintiffs into multiple "trial groups." Ms. Hopkins, once a part of the first trial group, comes before the Court as a member of the second trial group that had been scheduled for trial in January of this year.[1] By letter dated January 7, 2010**,** the Court advised the parties that Ms. Hopkins' trial would not go forward because the Court was granting AZ's motion to exclude Ms. Hopkins' specific causation expert and its Motion for Summary Judgment. The Court indicated that a written opinion would follow. This is that opinion.

Aside from the unsettled issues relating to her bankruptcy, Ms. Hopkins' case had been fully prepared for trial in the first trial group, and motions *in limine* regarding the admissibility of her expert witnesses' opinions had been fully briefed. The first trial group was scheduled for trial in the Spring of 2009. This group did not

[1] Issues relating to Ms. Hopkins' filing for bankruptcy protection caused her case to be deferred from the first to the second trial setting.

yield a trial-ready case, however, after Ms. Hopkins' case was deferred and the Court determined that the only other case presented for trial, *Scaife v. Astrazeneca LP*, could not proceed because Ms. Scaife had failed to present competent expert testimony that her exposure to Seroquel® proximately caused her to develop diabetes.[2] Specifically, in *Scaife*, the Court upheld AZ's "*Daubert* challenge" to a plaintiff's specific causation expert upon finding that the expert had failed adequately to explain her methodology, had relied too heavily upon the temporal proximity of Ms. Scaife's exposure to Seroquel® and her onset of diabetes, had failed to rule out other likely causes of Ms. Scaife's diabetes, and had improperly attempted to bolster her opinions with eleventh hour scientific and medical research.[3]

The motions *in limine* relating to Ms. Hopkins' experts, deferred from the first trial setting, are now ripe for decision. This opinion, one of two issued today in connection with the second trial setting, finds the Court addressing the admissibility of Ms. Hopkins' specific causation expert testimony in nearly identical factual and procedural contexts as presented in *Scaife*. Indeed, if anything, this case presents an even more compelling case for *Daubert* exclusion. Having said this, the Court appreciates that the specific causation expert opinion in this case was developed prior

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[2] *See Scaife v. Astrazeneca LP*, 2009 WL 1610575, at *21 (Del. Super. June 9, 2009).

[3] *See generally id.* (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993)).

to the Court's opinion in *Scaife*, so the expert here performed her review and analysis without the guidance to be gleaned from *Scaife*.[4] Nevertheless, as discussed below, the record *sub judice* reveals that the specific causation expert opinion in this case is inadmissible for much the same reasons as the expert opinion was excluded in *Scaife*. Consequently, AZ's Motion *In Limine* To Exclude Medical Causation Expert Testimony of Dr. Loren W. Greene must be **GRANTED.** Because Ms. Hopkins has failed to present competent evidence of proximate causation, AZ's Motion for Summary Judgment must also be **GRANTED.**

II.

A. Regina Hopkins

Regina Hopkins is a 48-year-old African-American woman who lives in Youngstown, Ohio.[5] She suffers from chronic morbid obesity and high blood pressure, both of which pre-date her exposure to Seroquel®.[6] In addition to these chronic conditions, Ms. Hopkins has been diagnosed with fibromyalgia, depression,

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[4] It has not escaped notice that the Court has yet to review the admissibility of specific causation expert testimony on a post-*Scaife* record. Thus, the question of whether the Seroquel® plaintiffs can present competent specific causation opinions under *Daubert* in any circumstance remains very much open.

[5] Hopkins Dep. 4, 7, Mar. 31, 2008.

[6] Hopkins Dep. 128 (high blood pressure); Appendix to AZ's Opening Brief in Support of its Motion for Summary Judgment (Transaction ID. ("Tr. ID.") 23378532) Ex. HH [hereinafter AZ's Summ. J. App.] (chart of Ms. Hopkins' weight measurements from 1997 to 2008), JJ (high blood pressure).

anxiety, panic disorder, chronic fatigue syndrome, panic attacks, and sleep apnea.[7] Ms. Hopkins' family history and medical presentation puts her at a substantially increased risk for developing Type II diabetes. Her risk factors include her ethnicity, family history of diabetes, age, sedentary lifestyle, poor diet, hypertension, and morbid obesity.[8]

With regard to her history of chronic obesity, Ms. Hopkins' medical records reveal her long struggle with, and inability to maintain, a healthy body mass index ("BMI"). Ms. Hopkins is 5'3" tall and her weight has fluctuated from 200 pounds in February 1987 to a high of 304 pounds in January 1999.[9] When she began taking Seroquel® in January 2003, Ms. Hopkins weighed 270 pounds. In June 2003, Ms. Hopkins weighed 277 pounds.[10] She weighed 283 pounds in August 2005, her last recorded weight before stopping Seroquel®.[11] In December 2005, less than two

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[7] Singsen Dep. 33 (fibromyalgia), June 6, 2008; Nath Dep. 11-12 (chronic fatigue syndrome), 14 (sleep apnea), Apr. 2, 2008; Tesar Dep. 17 (anxiety), 19 (panic disorder), 38 (panic attacks), May 13, 2008.

[8] *See, e.g.*, Appendix to AZ's Opening Brief in Support of its Motion *In Limine* to Exclude Medical Causation Expert Testimony of Drs. Greene and Peck (Tr. ID. 23476147) Ex. A at ¶¶ 28-45 [hereinafter AZ's *In Limine* App.] (discussing the risk factors for diabetes).

[9] *See* AZ's Summ. J. App. Ex. Y, HH, II. *See also* Greene Dep. 449-51, Nov. 14-15, 2008.

[10] *See* Plaintiff's Memorandum of Law in Answer to AZ's Motion *In Limine* to Exclude Medical Causation Testimony of Dr. Greene (Tr. ID. 28242542) Ex. 12 [hereinafter Pl.'s Answer]. *See also* Nath Dep. 26.

[11] AZ's Summ. J. App. Ex. DD.

months after stopping Seroquel®, Ms. Hopkins weighed 290 pounds, and in February 2006 she weighed 272 pounds.[12] Over the past seven years, her BMI has fluctuated from a high of 53.8 in January, 1999 to 47.8 in January, 2003.[13] Some data suggest that women with a BMI greater than 33 are at a 54X increased risk of developing diabetes.[14] Women with a BMI greater than 35 face a 93.2X greater risk for diabetes.[15] "At higher levels of BMI, the risk of developing diabetes as a result of obesity dwarfs even the risk of developing lung cancer as a result of smoking."[16]

Unfortunately, Ms. Hopkins is in strong company when it comes to her high risk of developing diabetes. "The Centers for Disease Control has characterized the rapid increase in diabetes in the United States as an epidemic."[17] The pervasiveness of diabetes in this country translates to a very high "background rate" for the disease

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[12] *Id.*

[13] Greene Dep. 453, 478.

[14] Appendix to AZ's Supplement in Support of its Motion for Summary Judgment and Motion *In Limine* to Exclude Medical Causation Expert Testimony of Dr. Greene (Tr. ID. 27887486) Ex. C at ¶ 31 [hereinafter AZ's Supplement App.].

[15] *Id.*

[16] *Id.* at ¶ 28.

[17] *Id.* at ¶ 8.

which, in turn, makes the job of determining a cause for the disease in a particular patient all the more challenging.[18]

Ms. Hopkins has had problems sleeping since the 1990s.[19] Her sleep disorders were originally treated by her rheumatologist, Dr. Berhnhard Singsen. Dr. Singsen prescribed a number of medications for Ms. Hopkins in an effort to alleviate her symptoms.[20] When Dr. Singsen was unable to find an effective medication, however, he referred Ms. Hopkins to Dr. George Tesar, a psychiatrist, for evaluation and treatment of her ongoing depression, anxiety and resulting insomnia.[21] By the end of 2002, Ms. Hopkins' symptoms had still not improved and Dr. Tesar was running out of pharmaceutical options. So, in January 2003, Dr. Tesar prescribed Seroquel® for Ms. Hopkins in hopes that it would improve her insomnia. She continued taking the medication until November 2005.[22]

Ms. Hopkins was diagnosed with Type II diabetes in October of November 2005. Her primary care physician, Dr. Ravinder Nath, based the diagnosis on clinical

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[18] *Id.* at ¶¶ 25, 28, 31.

[19] Hopkins Dep. 55.

[20] The medications that Dr. Singsen prescribed that were ineffective in alleviating Ms. Hopkins' symptoms included Trazodone, Ambien, Elavil, Doxopin, Xanax, Pamelor, Serzone, and Zyprexa. Singsen Dep. 64, 74, 77.

[21] *Id.* at 85-86; Tesar Dep. 17.

[22] Tesar Dep. 52, 61.

symptoms and an elevated hemoglobin A1c test.[23] There are no known elevated fasting glucose levels for Ms. Hopkins from either before or during the time she was taking Seroquel®.[24] Ms. Hopkins' pre-Seroquel® random glucose levels were all normal.[25] Fasting glucose levels were recorded in February 2006 and November 2007, after Ms. Hopkins had discontinued Seroquel®, and both were within the normal range.[26]

B. Loren W. Greene, M.D.

Ms. Hopkins has designated Loren W. Greene, M.D. as her specific causation expert, i.e., she proposes to testify at trial that Ms. Hopkins' exposure to Seroquel® proximately caused her to develop Type II diabetes. Dr. Greene's opinions are set forth in her expert report, dated September 19, 2008, and in her deposition, taken November 14-15, 2008. Counsel requested and was granted the opportunity to supplement Dr. Greene's report, but chose not to do so.[27] Counsel also declined to

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[23] Nath Dep. 29-30. *See also* AZ's Summ. J. App. Ex. EE.

[24] Greene Dep. 278-79, 282, 286-87; AZ's Summ. J. App. Ex. EE, II, JJ, RR.

[25] Ms. Hopkins' only abnormal random glucose level was 190 mg/dl in May 1987, after an episode of acute pancreatitis. *See* Greene Dep. 286-87 (listing the dates and results of the blood glucose readings included in Ms. Hopkins' medical records).

[26] AZ's Summ. J. App. Ex. DD, EE. At the time those readings were taken, Ms. Hopkins had already been prescribed Glucophage, a medication commonly used in treating diabetes. Nath Dep. 30, 35.

[27] AZ's Supplement App. Ex. I at 6-7, K at 21-22; Pl.'s Answer Ex. 1 at 84-85. *See also* Letter from Michael P. Kelly, Attorney for Defendant, to The Honorable Joseph R. Slights, III (Sept. 24, 2009)

present Dr. Greene for further testimony at the hearing on AZ's motion to exclude her testimony.[28]

1. Dr. Greene's Credentials

Before discussing her opinions, it is appropriate first to summarize Dr. Greene's credentials to serve as an expert. By any measure, they are impressive. Dr. Greene graduated from Barnard College and New York University School of Medicine. She did her residency in Internal Medicine and a fellowship in Endocrinology and Metabolism at NYU Medical Center and Bellevue Hospital. She is board certified in Internal Medicine and Endocrinology and Metabolism and has completed a certification program in Medical Ethics at NYU Graduate School of Nursing and Montefiore Hospital.[29]

Dr. Greene is currently a Clinical Associate Professor of Medicine at NYU School of Medicine and a Coordinator for the Osteoporosis and Metabolic Bone Disease Program of the Department of Medicine. She is also the co-coordinator of an annual CME program in Osteoporosis and the co-director of the second year

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(Tr. ID. 27236209).

[28] Hr'g Tr. 28-30, Dec. 15, 2009 (Tr. ID. 30234596).

[29] AZ's *In Limine* App. Ex. G at 1 (Expert Witness Report of Loren Wissner Greene, MD, FACE, FACP).

Endocrine course. She is the chair of the NYU School of Medicine Colloquium on Medical Ethics and on the adjunct faculty of NYU's Master's program in Bioethics.[30]

AZ has not challenged Dr. Greene's qualifications to render specific causation opinions in this case, and for good reason. She is qualified by any measure.

2. Dr. Greene's Report

On September 19, 2008, Dr. Greene generated a report in which she summarized the information she reviewed, her findings, and her ultimate conclusions in this case. The report began with a review of Dr. Greene's background and experience. The report then contained a brief discussion of the materials Dr. Greene reviewed in forming her opinion.

Dr. Greene next addressed Ms. Hopkins' medical history. She explained that she gathered the history from her physical examination of Ms. Hopkins and her review of Ms. Hopkins' medical records and laboratory tests. Dr. Greene described Ms. Hopkins as a 48-year-old woman who has been morbidly obese for "many years."[31] She noted that Ms. Hopkins had a maternal aunt who may have had diabetes, but no other recorded family history of the disease. She acknowledged that Ms. Hopkins presented with other risk factors for diabetes including chronic morbid obesity and

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[30] *Id.*

[31] *Id.* at 2.

African-American ethnicity. She emphasized that Ms. Hopkins does not smoke or use illicit drugs, and rarely drinks alcohol.[32]

Dr. Greene discussed Ms. Hopkins' history of weight fluctuation and her possible history of hypoglycemia. She indicated that "[d]espite obesity and weight fluctuation, and though she underwent many routine laboratory tests and medical examinations, Ms. Hopkins did not develop diabetes until 2005, after almost 3 years of Seroquel therapy."[33]

Next, Dr. Greene discussed Ms. Hopkins' pharmaceutical history, notably a prescription for Precose in 2001 that might have been issued in connection with a diagnosis of reactive hypoglycemia.[34] Dr. Greene also discussed the fact that Ms. Hopkins might have been on Zyprexa intermittently sometime in 2000 or 2001.[35] Lastly, Dr. Greene discussed the time line and dosage of Ms. Hopkins' Seroquel® prescriptions. She noted that Ms. Hopkins was first prescribed Seroquel® in January

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[32] *Id.*

[33] *Id.* at 3-4.

[34] *Id.* at 3.

[35] *Id.* Zyprexa was the subject of class action litigation in which plaintiffs alleged that exposure to the medication caused Type II diabetes. A multi-million dollar class action settlement with drug manufacturer Eli Lilly & Company was announced on June 10, 2005. *See* www.zyprexaclassaction.com.

2003, in a dosage of 25mg. That dose was eventually increased to 200mg, although Dr. Greene's report does not indicate the timing of that increase.[36]

Dr. Greene indicated that by June 2003, Ms. Hopkins' blood glucose was 112mg/dL, a slightly elevated value. She also indicated that Ms. Hopkins' hemoglobin A1c in December 2004 was 6.5%, and in October or November 2005 it was 6.8%. Dr. Greene noted that it was after the October or November 2005 A1c that Dr. Nath diagnosed Ms. Hopkins with diabetes.[37]

The next section of Dr. Greene's report dealt with her examination of Ms. Hopkins, which took place on September 2, 2008. During that examination, Dr. Greene took a medical history and performed a physical examination. She also ordered some laboratory tests.[38] As a result of her encounter with Ms. Hopkins, Dr. Greene was able to provide a more thorough account of Ms. Hopkins' medical history, including an extensive discussion of her many weight fluctuations and the various medications she had been prescribed over the years.[39]

Dr. Greene then devoted a short paragraph to the literature she reviewed in preparing her opinion in this case. Dr. Greene noted: "I am generally familiar with

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[36] *Id.* at 4.

[37] *Id.*

[38] *Id.*

[39] *Id.* at 4-9.

case studies, epidemiological studies, clinical studies and review articles which demonstrate a direct causal association between quetiapine and diabetes mellitus, hyperglycemia and other adverse metabolic effect."[40] This section of Dr. Greene's report does not cite or discuss a single study, nor does it indicate Dr. Greene's methodology for assessing the studies and articles and determining whether they are relevant in analyzing Ms. Hopkins' case.

The last section of Dr. Greene's report is entitled "Discussion." In this section, Dr. Greene discussed the pathophysiology of Type II diabetes, including how it is diagnosed and the most common risk factors.[41] Among those risk factors, Dr. Greene listed weight gain, obesity, genetics and family history, race/ethnicity, age, and "use of medications such as steroids, alcohol, and atypical (or second generation) antipsychotics."[42] Dr. Greene noted that "[t]hese factors may combine and contribute to further increase the risk of developing diabetes."[43] She then identified the phenomenon of "[m]etabolically healthy but obese (MHO) individuals," who are at a lower risk for diabetes. After discussing the MHO phenomenon, Dr. Greene observed that "[s]ignificantly, though Ms. Hopkins was obese, she did not develop

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[40] *Id.* at 9.

[41] *Id.* at 9-10.

[42] *Id.* at 10.

[43] *Id.*

diabetes until she ingested Seroquel."[44] This statement hinted that Dr. Greene might characterize Ms. Hopkins as MHO, but she did not elaborate on this concept, nor did she indicate what information she would rely upon to support that conclusion.

The remainder of Dr. Greene's report discussed the progressive nature of diabetes, and the negative effects of diabetes, including the available treatments, potential complications, and monetary costs of the disease.[45] Dr. Greene also made several statements about Ms. Hopkins, including that "Ms. Hopkins has diabetes" and "her ingestion of Seroquel was a substantial factor in causing her diabetes."[46] Accompanying Dr. Greene's report was a list of the seven references to which she alluded in her report.[47] None of the referenced articles were discussed in the opinion sections of the report, although they were cited in support of a number of general principles and statistics related to diabetes.[48]

3. Dr. Greene's Deposition

Dr. Greene's deposition was taken over the course of two days, November 14-15, 2008. It produced a transcript in excess of 700 pages. The first 200 pages of

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[44] *Id.*

[45] *Id.* at 10-11.

[46] *Id.* at 11-12.

[47] *Id.* at 13.

[48] *Id. See also id.* at 1-2, 9-12.

deposition transcript are devoted primarily to a discussion of the general causation literature Dr. Greene reviewed in preparing her opinion and report in this case.[49] When pressed for details regarding the literature, Dr. Greene's most frequent response was "I don't recall."[50] Dr. Greene also frequently stated that she could not answer a question without going back and rereading the specific article, study, or record to which the question referred.[51]

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[49] *See generally* Greene Dep. 38-256.

[50] *See, e.g., id.* at 51 ("I don't recall."), 63 ("I don't recall which summaries I reviewed in detail and which ones I didn't review in detail, because again, I reviewed them all and gave a cursory view to some of them and a more detailed view to other ones of them."), 65 ("I can't recall which of the review – which of the ones I've reviewed."), 67 ("I don't recall."), 84-85 ("I can't remember . . . . And I really don't recall."), 89 ("I don't recall for each individual trial."), 101 ("I don't recall."), 123 ("I don't recall."), 126 ("I don't know if it was an epidemiological study or not, so you're asking me a very specific question which I don't recall."), 131 ("I don't recall. I know I have seen case reports without associated factors, but I don't know if I've seen an epidemiological study showing that."), 134 ("I don't recall."), 146 ("I don't recall."), 160 ("Wait a second. I don't recall if I read Sacchetti for that report."), 165 ("I don't remember if any of the studies control for BMI."), 168 ("I don't recall any."), 347 ("I can't recall.").

[51] *See, e.g., id.* at 85 ("I'd have to go back to the whole trial and analyze it again, reading the methods in the trial and which subjects were excluded and how they came about this table."), 124 ("I can tell you some of the most important articles, but I can't remember whether – what they were important for, off the top of my head. I can just start reciting names of people, but I don't remember which ones answer your question. I have to go back to the original article to answer that."), 183 ("I'd have to go back and tell you because you're asking me very specific things."), 213 ("I think I could find that answer out if I studied this article in more detail, but I don't know right now without going back to studying the article again."), 283 ("I'd have to look at the data. Can I go back and look at the data? . . . I would have to go back and look at the data. I have some ideas, but I don't want to say without looking at the data."), 343 ("I'd have to look it up in the data because I don't have a number right now in my head. I know I've seen those numbers, but I don't recall the exact number and I didn't want to give you have an imprecise number."), 348 ("I have to go back and look at the literature."), 349 ("Let me go back and look at the records."), 439 ("I have to check back to the data . . . ."), 493 ("I have to go back to my chart, look over all the dates to answer your question . . . ."), 496 ("I have to go back and look at the chart and the dates and tell you these

(continued...)

Dr. Greene's theory of the mechanism by which Seroquel® caused Ms. Hopkins' diabetes was unclear, at best. When asked about how Seroquel® causes weight gain, Dr. Greene responded: "I don't know the mechanism by which [Seroquel®] causes weight gain. I'm intrigued by the fact that it causes weight gain, but I don't understand it."[52] Dr. Greene was equally unsure about the mechanism(s) by which Seroquel® could directly cause diabetes:

> I think there are a number of theories, and I don't think any one theory has been proven to be the correct theory, and I think people are actively investigating all of the atypical antipsychotics and what causes diabetes with these drugs . . . . It might be one of those theories, one of those theories might be correct. So I'm not saying that it's unknown, I'm saying we still don't know which of the theories is correct or if there's another theory by which it causes diabetes, which is more correct. I don't know which of the theories is correct, but there are many theories."[53]

At the end of the day(s), Dr. Greene was unable to give an opinion, to a reasonable degree of medical probability, as to how Seroquel® causes diabetes.[54] Apparently,

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[51](...continued)
things."), 506 ("I have to go back to the medical records to tell you the exact date and note."), 652 ("I can go back to the records and give you the date."), 685 ("I would have to go back and look at the article again to find out the answer to that."), 699 ("I don't recall the number. I would have to go back and look at the numbers."), 702 ("I would have to go back to the medical records to confirm that."), 705 ("I have to go back to the records.").

[52] *Id.* at 21.

[53] *Id.* at 21-22.

[54] *Id.* at 22.

Dr. Greene did not feel the need to understand the mechanism of injury in order to reach her specific causation opinion in this case.[55]

Throughout her deposition, Dr. Greene repeatedly was asked to explain her methodology in reaching her opinion about the cause of Ms. Hopkins' diabetes.[56] Despite several direct questions that asked for the explanation, Dr. Greene simply refused to provide any meaningful detail regarding her methodology. Instead, as the excerpt below (one of many) reveals, she insisted on broad brushed descriptions and shied away from detail:

> I went through every article I could find or that Weitz & Luxenberg found for me that would show a positive or negative effect of Seroquel and diabetes. Some were articles on Seroquel and weight; some were articles of atypicals with various metabolic parameters. And I went through as many articles as I could get through, which was quite a task. Some of the articles I really focused on more than other articles, and I know better if you were to quiz me on other ones. But I really wanted to form my own opinion . . . .

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[55] *Id.* at 154, 595.

[56] *See, e.g.*, *id.* at 492-93 ("What was your methodology for just saying that a large part of Ms. Hopkins' 24-pound weight loss was due to the fact that she went from 200 milligrams of Seroquel down to 100? . . . What other methodology did you use? . . . Other than looking over the records, what methodology did you use to determine that a large part of her 24-pound weight loss was due to the fact that she went from 200 milligrams down to 100 milligrams? . . . Can you think of any other methodology, other than looking at her records, for making that determination?"), 494 ("Other than looking at the medical records what other methodology did you use to determine that a large part of her 24-pound weight loss was due to the fact that she reduced her dose of Seroquel from 200 to 100?"), 707 ("I would like you to describe for me what methodology, if any, you employed when you took on the task of assessing whether or not Seroquel played any role in the onset of Ms. Hopkins' diabetes. Can you do that?").

> And I went on to look at any report I could find to try to evaluate what I could find. I also looked over, obviously, all the data in Ms. Hopkins' file and even asked for more data that wasn't in Ms. Hopkins' file.
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> I examined Ms. Hopkins in the same way I would examine my own patient who was sent to me having nothing to do with legal affairs, and even asked for some additional tests that I thought were necessary to rule out some other causes of diabetes besides the Seroquel, notably Cushing's syndrome. I just wanted that to be ruled out in a person who had what looked like acanthosis nigricans on her neck, and also appeared to have a more centripetal distribution of her obesity, although not entirely centripetal in terms of obesity. She is obese.
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> I spoke to people at Weitz & Luxenberg asking for more information specifically directing it to more information when I wasn't satisfied that I had enough information.
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> . . . .
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> And I just went back and forth and questioned things and I questioned things that I thought were unclear. I questioned things that I thought were questionable for any reason pro or con in her case, but also tried to learn as much as I could update my knowledge about the atypical antipsychotics and particularly Seroquel in regard to causation of diabetes or not causation of diabetes.[57]

Aside from her repeated fall back to the temporal relationship between Ms. Hopkins' exposure to Seroquel® and her development of diabetes, as will be discussed below, Dr. Greene's general explanations of "reading everything she could find on the

[57] *Id.* at 707-10.

subject," and ruling out (without explanation) other causes, were the only insights Dr. Greene was willing to provide with respect to her methodology.[58]

Dr. Greene acknowledged the general principle that obesity is an important factor to control for in any study about the causes of diabetes because "people with obesity have more diabetes."[59] Despite this, Dr. Greene never ruled out chronic morbid obesity as the sole cause of Ms. Hopkins' diabetes. In fact, Cushing's

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[58] Dr. Greene provided variations of this answer every time she was asked about her methodology. *See, e.g.*, *id.* at 184-85 ("It would sort of be, like, similar to any other methodology I would use for any other reason, including my Zyprexa case report. I would try to get all of the literature I could find which would be, you know, for it, against it, questioning it, thinking about mechanisms, is there a plausible mechanism that could cause it, is this a viable association, is it a realistic cause. I mean I don't, you know, so I would go through as much medical literature as I could get, I would read it as much as I can read it, I would review it as much as I can review it, I would try to find out the factors that would be important. I would try to look for confounding factors that would exclude it. I would go back and forth and question it . . . . And so I was really saying are we sure that this is the only reason. Can we find other reasons in this particular person . . . but I was looking for objections to what I was finding . . . ."), 187 ("I looked at as much literature as I could . . . . And I then went to look for all the objections I had to it, as well as all the support I had for it. I had to weigh the individual points of evidence, what the confounders were before I could come to an opinion in this particular case."), 188 ("Yes, I looked at them for confounding factors. I looked for them to try to find out what didn't prove it or sometimes I disagreed when they said that they didn't find a casualty and I could find reasons that I thought the studies were faulty, so I looked to the methodology of the studies, I looked for the confounders in the studies. I was looking for all kinds of things in the studies. I mean, and the case reports are kind of easier to look through quickly because with a case report you can, you know, see if they're fat, they're this, they're that, they have ten relatives with diabetes or whatever could be a confounder in the study. And the case reports it's much harder to find especially in those crossover studies."), 347 ("By looking at all of the literature it seems the preponderant literature shows a positive increase in weight in most people on Seroquel at therapeutic doses."), 600-01 ("I answered it as a physician. As a physician who is trying to look for as many points as I can to explain it, and I read articles that were negative. I read articles that were positive. I reviewed as many articles as I can find, and the preponderance of the articles I read showed that – that Seroquel, number 1, increases glucose, but number 2, can tip somebody over into diabetes, and number 3 is even worse for somebody who already has diabetes because their blood sugars even increase further.").

[59] *Id.* at 149.

syndrome was the only other potential cause of Ms. Hopkins' diabetes that Dr. Greene attempted definitively to rule out through any remotely scientific process.[60] To address and rule out Ms. Hopkins' chronic morbid obesity, Dr. Greene relied solely upon the notion that Ms. Hopkins had been chronically obese for many years without developing diabetes, and then developed diabetes after being exposed to Seroquel®.[61] Dr. Greene employed this "temporality" analysis beyond her broader specific causation opinion in order to explain even the more nuanced aspects of her opinions. For example, when asked how she determined that Ms. Hopkins' loss of weight while on Seroquel® resulted from decreases in the dosages of the medication, Dr. Greene explained that she reached the conclusion "[b]y comparing the time and the dosing to

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[60] *Id.* at 709.

[61] *See, e.g., id.* at 596-97 ("[S]he had morbid obesity for 20 years before she had the Seroquel, and she did not develop it during 20 years of having it. It was not until she had the Seroquel that she got the diabetes. So she needed a triggering factor to trigger her diabetes, because she obviously [sic] fat, very fat without having diabetes before."), 598-600 ("[S]he had [obesity] for many, many, many years without diabetes . . . . I will give you drugs such as steroids are a good example of the challenges she has survived without developing diabetes, and she goes on and on with her morbid obesity, possibly over the years increasing her risk of getting diabetes because of her longstanding morbid obesity, but she doesn't get diabetes until she gets Seroquel."), 635 ("I feel that many, many years of morbid obesity, despite various risk factors, increasing over the time, the various challenges to her did not cause her to have diabetes and she did not have diabetes until she took the Seroquel, and she probably would not have gotten diabetes during this interval of time had she not taken this Seroquel."), 639 ("[A]t that given time, when she took the Seroquel was when she got the diabetes; and, therefore, with her many, many years of morbid obesity, I don't think that was the major cause, because I think she would have continued bubbling along, but again, this is my conjecture just as she was before without developing diabetes."), 643 ("I said the temporal relationship indicates that the thing that pushed her over was the Seroquel . . . . I went over her longstanding history of morbid obesity without developing diabetes, and she didn't get diabetes, despite her longstanding morbid obesity until she took the Seroquel.").

her weight."[62] In other words, according to Dr. Greene, she was able to determine that decreasing the dose of Seroquel® caused a decrease in Ms. Hopkins' weight simply by virtue of the fact that Ms. Hopkins lost weight after her Seroquel® dose was decreased.

Finally, after Dr. Greene acknowledged the well-settled and significant link between chronic morbid obesity and the onset of diabetes, she was asked directly (once again) how she was able to rule out obesity as the cause of Ms. Hopkins' diabetes.[63] In response to that question, Dr. Greene gave a detailed answer about all of the other events that might have triggered Ms. Hopkins' diabetes, including pancreatitis, several short courses of steroids, and an episode of renal insufficiency.[64] She ruled out these medical conditions as the cause of Ms. Hopkins' diabetes because, notwithstanding the known link between these conditions and diabetes, "[Ms. Hopkins] doesn't get diabetes until she gets Seroquel."[65] Dr. Greene then explained that she employed the same "methodology" to rule out chronic morbid obesity,

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[62] *Id.* at 493.

[63] *Id.* at 598.

[64] *Id.* at 598-600.

[65] *Id.* at 599-600.

sedentary lifestyle, ethnicity, depression, chronic sleep loss, stress, and Zyprexa as the causes of Ms. Hopkins' diabetes.[66]

III.

AZ contends that Dr. Greene's opinion does not pass muster under *Daubert* for several reasons, all of which formed the bases for exclusion of the specific causation opinion in *Scaife*. First, Dr. Greene failed to articulate her methodology in a manner that would allow the Court to assess its reliability as mandated by *Daubert*. In this regard, AZ points to Dr. Greene's repeated general explanations of her approach to considering the issues in this case without any reference to an actual method. To the extent any methodology can be gleaned from Dr. Greene's report or deposition, AZ contends that the "methodology" consists of a singular and improper reliance upon the temporal relationship between Ms. Hopkins' exposure to Seroquel® and her development of diabetes. Next, AZ points to Dr. Greene's failure to account for Ms. Hopkins' chronic morbid obesity, a known and substantial risk factor for Type II

[66] *See, e.g., id.* at 605 ("Because she had many, many years of fibromyalgia with sedentary lifestyle and still did not develop her diabetes, so I don't think it was a major factor. It might have been a contributing factor . . . . I know with a reasonable degree of medical certainty that [Ms. Hopkins' sedentary lifestyle] was not a major factor, because she's had it for so many years and nothing has triggered her diabetes until then."), 607-08 ("I think I answered it the same way I'm going to answer every other question you are going to ask me the same thing, which is: She's had [depression and anxiety] for many years. It's not a new event in her life and yet she doesn't have diabetes until she takes Seroquel . . . . Q: You have ruled out in your mind preexisting obesity, sedentary lifestyle, ethnicity, depression, chronic sleep loss, stress and any other risk factors that Ms. Hopkins may have had for diabetes, you ruled out those sole causes because she did not develop diabetes until she started Seroquel? A: Sole causes, yes, I ruled them all out.").

diabetes, as the sole cause of Ms. Hopkins' diabetes. Finally, AZ contends that Dr. Greene's supposed reliance upon medical literature and other data in reaching her opinion does not transform an otherwise unreliable opinion into a reliable opinion because Dr. Greene has failed to explain how she incorporated this data into her analysis and how specifically it supports her conclusions.

For her part, Ms. Hopkins counters AZ's arguments first by noting that she does not agree that *Scaife* was correctly decided. Thus, to the extent that AZ would have the Court simply follow *Scaife*, Ms. Hopkins urges the Court to revisit *Scaife* and to conclude that it was too restrictive in its view of *Daubert*'s reliability component. Even if the Court concludes that it correctly decided *Scaife*, Ms. Hopkins argues that Dr. Greene's work in this case is readily distinguishable from the expert testimony at issue in *Scaife*. First, Ms. Hopkins points to the fact that Dr. Greene's opinions are not the "moving target" that the Court confronted in *Scaife*; Dr. Greene's opinions have remained consistent and have not evolved in response to the arguments raised by AZ. Moreover, according to Ms. Hopkins, Dr. Greene has gone to greater lengths to explain her methodology and, specifically, the means by which she excluded other potential causes for Ms. Hopkins' diabetes. To the extent there are gaps in the methodology, Ms. Hopkins contends that these can be exposed by vigorous cross examination of Dr. Greene at trial.

IV.

In *Minner v. Amer. Mort. & Guar. Co.*,[67] the Court engaged in 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. The Court noted 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."[68] 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."[69]

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.[70] In recognition of this phenomenon, the Federal Rules of Evidence, and now 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

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[67] 791 A.2d 826, 833 (Del. Super. 2000).

[68] *Id.* at 841.

[69] *Id.* at 843.

[70] Steven J. Breyer, *Introduction to* Fed. Judicial Ctr., *Reference Manual on Scientific Evidence* 2 (2d ed. 2000) [hereinafter *Reference Manual*].

> witness qualified as an expert by knowledge, skill, experience, 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.[71]

In 1999, the Supreme Court of Delaware explicitly adopted *Daubert* as the law of this state in recognizing that our rules of evidence mirrored the federal counterparts upon which *Daubert* was decided.[72] Thus, "[u]nder *Daubert*, *Kumho*, and *M.G. Bancorporation*, the Trial Judge acts as the gatekeeper to ensure that the scientific testimony is not only relevant but reliable."[73] Although *Daubert* frequently is associated with the several non-exclusive factors it recommends as a litmus test for admissibility, at its core, *Daubert* dictates that courts look to Rule 702 as the governing standard for the admissibility of expert evidence by specifying that "'[*i*]*f scientific*, technical, or other specialized *knowledge will assist the trier of fact* to understand the

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[71] *See* D.R.E. 702.

[72] *M.G. Bancorp. v. Le Beau*, 737 A.2d 513, 521 (Del. 1999).

[73] *Minner*, 791 A.2d at 843 (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999); *Daubert*, 509 U.S. 579; and *M.G. Bancorp.*, 737 A.2d 513). *See also Cunningham v. McDonald*, 689 A.2d 1190, 1193 (Del. 1997) (adopting a five-step test to determine the admissibility of scientific or technical expert testimony - (1) the witness is qualified; (2) the evidence is relevant and reliable; (3) the opinion is based upon information "reasonably relied upon by others in the expert's field;" (4) the expert's testimony will "assist the trier of fact to understand the evidence or determine a fact in issue;" and (5) the testimony will not create unfair prejudice or confuse the jury (quoting *Nelson v. State*, 628 A.2d 69, 74 (Del. 1993))).

evidence or to determine a fact in issue' an expert "'may testify thereto'"[74] 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."[75] And "knowledge" is more than unsupported beliefs; it must be derived from supportable facts and methodologies.[76]

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.'"[77] If proffered testimony is not related to the case, then it will not aid in clarifying a contested fact and is, therefore, not relevant.[78] Accordingly, the "helpfulness" standard requires that evidence have "a valid scientific connection to the pertinent inquiry as a

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[74] *Daubert*, 509 U.S. at 589 (quoting Fed. R. Evid. 702).

[75] *Id.* at 590.

[76] *Id.* (quoting *Webster's Third New International Dictionary* 1252 (1986), and noting that the term "knowledge" "applies to any body of ideas inferred from such facts or accepted as truths on good grounds").

[77] *Id.* at 591 (quoting Fed. R. Evid. 702).

[78] *Id.*

precondition to admissibility."[79] *Daubert* characterized this requirement as one of "fit."[80]

As the trial judge performs his role as gatekeeper, and attempts in that process to test the expert testimony against the standards of reliability and relevance as directed by *Daubert*, it cannot be forgotten at the end of the day that "[the] judge is not a scientist, and a courtroom is not a scientific laboratory."[81] Thus, although judges are expected vigorously to perform the role of gatekeeper as directed by *Daubert*, there is no expectation that they will do so with scientific precision.[82] And to assist the Court in the performance of its gatekeeping function, it is now well settled that the party proffering the expert has the burden of presenting evidence sufficient to allow the Court to conclude by a preponderance of that evidence that the expert's opinions are both relevant and reliable.[83] The failure to meet this burden precludes the Court from

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[79] *Id.* at 592.

[80] *Id.* at 591.

[81] *Reference Manual* at 4.

[82] *Id. See also Bowen v. E.I. du Pont de Nemours & Co.*, 2005 WL 1952859, at *8-9 (Del. Super. June 23, 2005) ("[I]t is not necessary that the judge decide the admissibility of scientific evidence with the degree of certainty required in scientific circles."); David L. Faigman et al., *Preface to Science In The Law: Standards, Statistics and Research Issues* v (2002) ("Judges and lawyers, in general, are not known for expertise in science and mathematics . . . . Indeed, law students, as a group, seem peculiarly averse to math and science.").

[83] *See Bowen v. E.I. du Pont de Nemours & Co.*, 906 A.2d 787, 795 (Del. 2006).

fulfilling its mandated function under *Daubert* and results in the inevitable conclusion that the expert cannot pass through the courtroom gate.[84]

V.

After carefully considering the motion *sub judice*, the Court has concluded that its prior opinion in *Scaife* is controlling here. As discussed below, Dr. Greene's specific causation opinion is inadmissible under *Daubert* and its progeny because (1) she has failed adequately to explain her methodology to allow the Court to perform its mandated gatekeeping responsibility; (2) to the extent she has described her methodology, she has failed to describe a reliable methodology in that her approach placed too much emphasis upon the temporal relationship between Ms. Hopkins' exposure to Seroquel® and the onset of her diabetes; (3) she has failed to rule out Ms. Hopkins' chronic morbid obesity as the sole cause of Ms. Hopkins' diabetes; and (4) she has failed adequately to explain the manner by which she incorporated data from the epidemiological studies and clinical trials into her analysis and ultimate conclusions. The Court will address these issues *seriatim*.

A. Dr. Greene's Failure Adequately To Explain Her Methodology

[84] *Id.*

More than a decade has passed since the United States Supreme Court redirected the focus with respect to the admissibility of expert testimony from "general acceptance" to "relevance and reliability." Since then, it has become clear that trial judges are expected to pay particular attention to the reliability of the expert's methodology.[85] And given that the party proffering the expert bears the burden of establishing admissibility of the expert's testimony, it is axiomatic that the party must supply sufficient evidence of the expert's methodology to enable the Court to determine if the methodology is reliable.[86] Vague, generalized descriptions of methodology are not sufficient to allow the trial judge to do his job. Thus, when experts repeat over and again that they have reviewed all available information and have applied their training and experience to reach conclusions, without providing more detail, in effect, they have said nothing that can assist the court in the performance of its gatekeeping responsibilities.[87] Yet this is precisely what Dr. Greene

[85] *See, e.g.*, *Gen. Motors Corp. v. Grenier*, 981 A.2d 531, 538 (Del. 2009) (focusing on trial court's analysis regarding the reliability of experts' methodologies); *Bowen*, 906 A.2d at 796-97 (same); *Eskin v. Carden*, 842 A.2d 1222, 1231 (Del. 2004) (same).

[86] *See Eskin*, 842 A.2d at 1231 ("The proponent of the expert scientific or technical testimony must establish its admissibility consistent with the *Cunningham* five-step test [which includes the "reliability" of the expert's methodology].").

[87] *See United States v. Fredette*, 315 F.3d 1235, 1239-40 (10th Cir. 2003) ("[A] witness 'relying solely or primarily on experience' must 'explain how that experience leads to the conclusion reached; why that experience is a sufficient basis for the opinion; and how that experience is reliably applied to the facts.'"); *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough."); *Claar v. Burlington N. R.R.*, 29 F.3d 499, 502 (continued...)

has done in this case.[88] In *Scaife*, the expert witness at least offered some insight into her albeit changing opinion on the mechanism by which Seroquel® could ultimately cause diabetes.[89] In this case, Dr. Greene has not even done that much. Rather, Dr. Greene admits that she does not understand either the mechanism by which Seroquel® causes weight gain which then causes diabetes (her original theory of causation), or the mechanism by which Seroquel® causes diabetes directly.[90] By failing to present a meaningful description of her expert's methodology, Ms. Hopkins

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[87](...continued)
(9th Cir. 1994) ("Fundamentally, the district court was concerned that the experts . . . failed to explain the basis for their conclusions. Before admitting the affidavits, the . . . court was affirmatively required to find that the experts' conclusions were based on scientific knowledge. This requirement means that the court had to determine that [the experts] arrived at their conclusions using scientific methods and procedures, and that those conclusions were not mere subjective beliefs or unsupported speculation. In an effort to make this determination, the . . . court repeatedly ordered the experts to explain the reasoning and methods underlying their conclusions. Despite those orders, the affidavits are devoid of any such explanation. Consequently, the . . . court could not make the findings required by Rule 702, and therefore properly refused to admit the affidavits into evidence."); *Alderman v. Clean Earth*, 2007 WL 1334565, at *7 (Del. Super. Apr. 30, 2007) (noting that expert improperly articulated his opinions in a "because-I-say-so fashion," the court found that the expert's failure to articulate a methodology created the risk that the jury would "agree with [the expert] simply because he is an 'expert'); *Bowen*, 2005 WL 1952859, at *11 (holding that expert's *ipse dixit* was inadmissible because the opinion was "not sufficiently tied to the facts of the case" and was "not the product of reliable scientific principles and methods").

[88] *See, e.g.*, Greene Dep. 184-85, 187, 600-01.

[89] *See Scaife*, 2009 WL 1610575, at *8-10.

[90] Greene Dep. 20-22 ("I don't know the mechanism by which it causes weight gain. I'm intrigued by the fact that it causes weight gain, but I don't understand it . . . . I think people are actively investigating all of the atypical antipsychotics and what causes diabetes with these drugs . . . . So I'm not saying that it's unknown, I'm saying we still don't know which of the theories is correct or if there's another theory by which it causes diabetes, which is more correct. I don't know which of the theories is correct, but there are many theories.").

has failed to meet her burden to demonstrate the reliability of Dr. Greene's opinion by a preponderance of the evidence.

B. Dr. Greene Relied Too Heavily If Not Exclusively On Temporality

To the extent any methodology can be drawn from Dr. Greene's report and deposition beyond her refrain that she "considered everything," it is that Ms. Hopkins was obese before taking Seroquel® and did not develop diabetes, she was obese at the time she was taking Seroquel® and did develop diabetes and, therefore, the Seroquel® must have caused Ms. Hopkins to develop diabetes.[91] As this Court explained in *Scaife*, "[t]he case law is legion that an expert may not rely upon temporal proximity alone as a basis to reach a specific causation opinion."[92] But this is precisely what Dr. Greene has done here. Under these circumstances, the Court cannot conclude that Dr. Greene's "methodology," such as it was, adequately followed accepted scientific methods such that it can be deemed reliable under *Daubert*.[93]

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[91] *See, e.g., id.* at 596-97, 598-600, 635, 639, 643.

[92] *Scaife*, 2009 WL 1610575, at *16 & n.240.

[93] *See Minner*, 791 A.2d at 855 (holding that temporal association as a means to determine specific causation fails to "follow a logical, scientific, and deductive process to exclude other possible causative factors").

C. Dr. Greene Failed To Rule Out Ms. Hopkins' Chronic Morbid Obesity As The Sole Cause of Her Diabetes

Dr. Greene has acknowledged that morbid obesity is a very significant risk factor for Type II diabetes.[94] Indeed, when asked about the relative strength of risk factors for diabetes, Dr. Greene stated "family history is probably number 1 and obesity is probably number 2."[95] Yet, notwithstanding her recognition that Ms. Hopkins was morbidly obese (chronically so), and that morbid obesity is among the greatest risk factors for Type II diabetes, Dr. Greene did nothing reliably to rule out morbid obesity as the cause of Ms. Hopkins' Type II diabetes.

In *Scaife*, the Court held that given the high background rate for Type II diabetes, and the significant association between morbid obesity and the onset of Type II diabetes, the plaintiff's specific causation expert must reliably rule out a plaintiff's morbid obesity as *the* sole cause before the expert will be permitted to testify that Seroquel® was *a* proximate cause of the plaintiff's diabetes.[96] Dr. Greene's failure to engage in this scientific process renders her methodology unreliable and her resulting opinion inadmissible.[97]

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[94] Greene Dep. 311, 320 (noting that after family history, chronic obesity is "by far the largest risk factor for diabetes").

[95] *Id.* at 319.

[96] *See Scaife*, 2009 WL 1610575, at *15-19.

[97] *Id. See also In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 763 (3d Cir. 1994) (excluding testimony of specific causation expert who "provided no reason to explain" why he ruled out other

D. Dr. Greene's Purported Reliance Upon Data From Epidemiological Studies and Clinical Trials Does Not "Shore Up" Her Otherwise Unreliable Methodology

As did her counterpart in *Scaife*, Dr. Greene attempted at deposition to bolster her methodology by making general references to her review of relevant data in the scientific and medical literature and in AZ's own clinical trials. Like the expert in *Scaife*, however, Dr. Greene failed meaningfully to incorporate her review of the literature and scientific data into her analysis. And, just as in *Scaife*, the Court must conclude that such vague references to supporting data are unavailing in the *Daubert* context. As the Court explained in *Scaife:*

> It is not enough for [an expert] simply to say she referred to medical literature and then to state generally that it supports her conclusion. *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. And it demands that she adequately explain that process. This has not occurred here.[98]

Nor has it occurred here. Consequently, Dr. Greene's reference to scientific and medical literature, and data from clinical trials, does not constitute a reliable methodology in itself, and does not transform her otherwise unreliable methodology into a reliable one.

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known risk factors).

[98] *Scaife*, 2009 WL 1610575, at *19 (footnotes omitted).

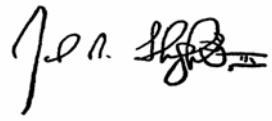
E. In The Absence of Competent Expert Testimony On Specific Causation, Ms. Hopkins Is Unable To Meet Her *Prima Facie* Burden To Establish Proximate Causation

Under Ohio law, Ms. Hopkins must establish proximate causation as a *prima facie* element of each of her claims against AZ.[99] Having determined that Dr. Greene's specific causation testimony must be stricken under *Daubert*, the record is devoid of any competent evidence that Ms. Hopkins' exposure to Seroquel® proximately caused any injury to her. Consequently, in the absence of proof that would create a genuine issue of fact with regard to a *prima facie* element of plaintiff's claims, the Court must grant AZ's motion for summary judgment.[100]

VI.

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

IT IS SO ORDERED.



Joseph R. Slights, III

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[99] *See Hickey v. Otis Elev. Co.*, 840 N.E.2d 637, 642 (Ohio Ct. App. 2005) ("Proof of causation is an essential element of any products liability action.").

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