IN RE: ACCUTANE LITIGATION	SUPREME COURT OF NEW JERSEY Docket No.: 079958 On Petition for Certification from Superior Court of New Jersey Appellate Division Docket No.: A-4698-14T1 A-0910-16T1 Sat Below: Hon. Susan L. Reisner, P.J.A.D. Hon. Ellen L. Koblitz, J.A.D. Hon. Thomas W. Sumners, Jr., J.A.D. On Appeal from: Superior Court of New Jersey Law Division, Atlantic County Case No. 271 (MCL) Sat Below: Hon. Nelson C. Johnson, J.S.C. Civil Action **ORAL ARGUMENT REQUESTED**

Brief & Appendix of Amici Curiae HealthCare Institute of New Jersey, New Jersey Business & Industry Association, Commerce and Industry Association of New Jersey, and New Jersey Chamber of Commerce

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PRELIMINARY STATEMENT

Proposed amici curiae HealthCare Institute of New Jersey (HINJ), New Jersey Business and Industry Association (NJBIA), Commerce and Industry Association of New Jersey (CIANJ), and New Jersey Chamber of Commerce respectfully submit this brief in support of defendants-petitioners Hoffmann-La Roche Inc. and Roche Laboratories, Inc.'s ("Roche") Petition for Certification.

This case raises an issue of substantial public importance that this Court has considered, but has yet to resolve, for nearly two decades: whether New Jersey's standard for the admissibility of expert opinion should be clarified in order to ensure that unreliable and unfounded expert testimony is kept from New Jersey juries. That issue is particularly important to these proposed amici, which together represent a significant cross-section of New Jersey's vital life sciences industry, largest employers, and business leaders.

The absence of an effective standard to preclude "junk science" from reaching a jury gives rise to a paradox that flies in the face of sound public policy. In particular, under the standard articulated by the Appellate Division in this case, the state's research-based life sciences industry - an industry dedicated to developing lifesaving treatments derived from hard science - is forced to defend against specious product liability claims as long as a plaintiff's expert can assert that his or

her "novel" conclusions arise out of a methodology that "some expert consensus" accepts, irrespective of whether the methodology actually is scientifically reliable or actually yields testimony relevant to the facts of the case.

Adoption of the Daubert standard for admissibility of expert testimony in civil cases - a standard established in the federal courts nearly a quarter-century ago and adopted by 39 states and the District of Columbia in the ensuing years - would remedy that inequity. The differences between Daubert and the standard that lower courts in New Jersey have often applied in cases involving "novel" causation theories are real and deleterious to New Jersey's economy and its judiciary. Indeed, experts routinely precluded from testifying in Daubert jurisdictions are permitted to offer their questionable testimony in New Jersey, forcing New Jersey companies to defend against unreliable challenges to their important innovations and forcing New Jersey's already over-burdened court system to shoulder an inordinate volume of mass tort suits brought by out-of-state plaintiffs.

Accordingly, these proposed amici curiae respectfully submit that this Court should grant Roche's Petition for Certification and take this opportunity to determine, once and for all, whether New Jersey will join the federal courts and nearly all other state courts in adopting Daubert to ensure that

only reliable and reliably applied expert testimony enters New Jersey's courts.

STATEMENT OF INTEREST

Proposed amici curiae HINJ, NJBIA, CIANJ, and the New Jersey Chamber will, if granted leave to appear as amici curiae, provide this Court with unique perspectives on the broad implications of this case. As set forth in detail in the Certification submitted with this brief, their memberships consist of business leaders and the largest employers in the state, many of which are at the cutting edge of the research-based life sciences industry that contributes so vitally to New Jersey's economy and welfare. This Court should grant their motion to appear as amici curiae and consider the arguments and important public policy issues set forth in this brief.

HINJ is a 20-year-old organization comprised of 27 of New Jersey's leading pharmaceutical and medical technology manufacturers. HINJ's purpose is to speak for New Jersey's life sciences industry and to raise awareness of the significant impact that industry has on New Jersey's citizens' economic well-being and quality of life. HINJ also strives to increase public support for New Jersey's research-based pharmaceutical and medical technology industry by increasing awareness and understanding of the industry's importance among New Jersey's elected and appointed officials, media, citizens, and opinion

leaders. HINJ seeks to advance the development and implementation of sound public health and business policies that further the interests of New Jersey, its people, and its research-based life sciences industry. A list of HINJ's 27 member organizations is available at http://hinj.org/about-hinj/hinj-member-companies/.

NJBIA, which has been granted leave to appear as amicus curiae in numerous cases before this Court, is the country's largest single state-wide organization of employers, with a membership consisting of more than 19,000 companies reflecting all industries and representing every region of New Jersey. Founded in 1910, NJBIA strives to provide information, services, and advocacy for its member companies in an effort to build a more prosperous New Jersey. Its membership ranges from most of the 100 largest employers in New Jersey to thousands of small and medium-sized employers from every sector of the economy. A primary goal of NJBIA is to reduce the costs of doing business in New Jersey, including by limiting unwarranted litigation burdens, in order to promote economic growth for all New Jerseyans. See New Jersey Business & Industry Association, About Us, http://www.njbia.org/JoinNJBIA/About.aspx.

Since its founding in 1927, CIANJ has been dedicated to leading free enterprise advocacy to provide an economic climate that fosters business potential through education, legislative

vigilance, and membership interaction. CIANJ's primary objective is to make New Jersey a better place to live, work, and do business. CIANJ's nearly 1,000 members consist of Fortune 100 companies and sole proprietors representing a variety of enterprises and industries. See Commerce and Industry Association of New Jersey, About Us, http://www.cianj.org/about-us/. CIANJ also has been granted leave to appear as amicus curiae in several cases before this Court.

Created in 1911, the New Jersey Chamber actively supports legislation, regulation, and policy initiatives designed to lead to economic growth, job creation, and prosperity throughout the state. Members of the New Jersey Chamber represent every industry doing business in the state and include New Jersey's most prestigious and innovative companies. The New Jersey Chamber consistently works to improve New Jersey's business climate and provide its members with opportunities to promote and grow their businesses. See New Jersey Chamber of Commerce, About Us, http://njchamber.com/index.php/about-the-nj-chamber-of-commerce.

These proposed amici curiae intend to address the significant public policy issues implicated by an important question raised by this appeal: whether New Jersey should join the federal courts, 39 other state courts, and the District of

Columbia by adopting the Daubert standard to ensure that juries are presented with only reliable and reliably applied expert testimony. As explained in greater detail in this brief, the differences between the Daubert standard and the more relaxed, plaintiff-friendly approach for evaluating the admissibility of expert testimony that lower courts in New Jersey have applied are real and consequential. As a result, defendants in New Jersey product liability cases - particularly the research-based life sciences entities that contribute so heavily to New Jersey's economy[1] - typically must proceed to trial and defend against unreliable expert testimony that would not be admitted in courts that apply the Daubert standard due to serious methodological flaws and/or a failure to demonstrate that the testimony actually fits the facts of the case in a manner that is helpful to the jury.

Proposed amici curiae HINJ, NJBIA, CIANJ, and the New Jersey Chamber's expertise as chief representatives of New Jersey's business community, including its crucial life sciences industry, will provide this Court with a valuable perspective

[1] See Industry Cluster - Focus, State of N.J. Dep't of Labor & Workforce Development, http://lwd.dol.state.nj.us/labor/lpa/pub/empecon/empeconomy_index.html (reporting that, pursuant to the "Bio Pharma Life Science Study: Summer 2017," "[t]he vitality of the biopharmaceutical and life-sciences cluster in New Jersey is fundamental to the state's economic health with its well-paying jobs").

from those responsible for and dedicated to employment, economic prosperity, and innovation in New Jersey. Indeed, the issue in this case is one that this Court and its Committee on the Rules of Evidence have considered for nearly two decades, and these proposed amici curiae have frequently submitted comments for this Court's consideration in the rule-making process. This case finally presents this Court with the long-awaited adversarial controversy in which to resolve the issue once and for all. HINJ, NJBIA, CIANJ, and the New Jersey Chamber therefore respectfully request that this Court avail itself of their expertise and unique perspective, and grant this motion or leave to appear as amici curiae.

LEGAL ARGUMENT

I. THE DIFFERENCES BETWEEN DAUBERT AND THE APPROACH TO EXPERT TESTIMONY APPLIED BY MANY NEW JERSEY COURTS ARE DETRIMENTAL TO NEW JERSEY'S INNOVATORS, EMPLOYERS, AND JUDICIAL SYSTEM.

Sound public policy compels granting certification to decide whether to clarify New Jersey's varying expert-admissibility standards to a single, uniform rule that ensures the admission of only reliable and reliably applied scientific opinion testimony. New Jersey's life sciences industry - which includes many of the state's largest employers - is a community of research-based companies that are in the business of thorough, well-developed, science. Yet, paradoxically, New Jersey's rules governing the admissibility of expert opinion are applied in a

way that unfairly exposes those innovators to civil liability simply because the claims brought against them are novel challenges to their exhaustive, often FDA-approved, scientific developments.

Although this Court has emphasized that the gatekeeping analysis focuses on the reliability of an expert's methodology, see Landrigan v. Celotex Corp., 127 N.J. 404, 417 (1992) (requiring experts "to identify the factual bases for their conclusions, explain their methodology, and demonstrate that both the factual bases and the methodology are scientifically reliable"); accord Kemp ex rel. Wright v. State, 174 N.J. 412, 427 (2002), New Jersey courts have not formally adopted the Daubert factors, see Kemp, 174 N.J. 424, n.3, which give concrete guidelines to consider in determining whether the expert has demonstrated that the methodology actually is reliable and that it was applied reliably and in a manner that actually "fits" the facts of the case and helps the jury evaluate the specific case before it. See Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 591 (1993) (holding that in addition to satisfying federal reliability criteria, expert testimony must "fit" the facts and issues in the case, i.e., it must be "'sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute'" (quoting U.S. v. Downing, 753 F.2d 1224, 1242 (3d Cir. 1985))).

As a practical matter, the differences between Daubert and the standard applied in many New Jersey cases can be consequential, and demonstrate the very real risk of unfair imposition of tort liability on New Jersey's vital life sciences industry. Even though this Court's Kemp/Rubanick jurisprudence requires a type of gatekeeping akin to that required by Daubert, the practical reality is that it has not been applied that way.[2]

In fact, New Jersey courts have permitted the very same litigation-driven expert opinion testimony that courts applying Daubert routinely exclude, essentially holding that under New Jersey's standard it is for the jury to decide whether the plaintiffs' expert opinion really is "junk science." Compare In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig. ("Zoloft I"), 26 F. Supp. 3d 449, 465 (E.D. Pa. 2014) (excluding plaintiffs' epidemiology expert's testimony under Daubert in

[2] These proposed amici recognize that when considering this issue in the rule-making process, this Court has questioned whether there is something in Daubert that is not in Kemp. See Webcast of Supreme Court of New Jersey, Hearing on Proposed Amendments to N.J.R.E. 702, May 19, 2015, at 14:40-15:57 (Justice Patterson inquiring "What would you say is in Daubert that is not in Kemp?," and considering the significance of the much more extensive body of federal case law under Daubert compared to the paucity of reported New Jersey decisions applying Kemp), available at https://www.youtube.com/watch?v=CJfJiYbd6SI&feature=youtu.be). As discussed herein, these proposed amici respectfully submit that there are real-world consequences that arise out of the differences between the two standards, not the least of which is the admission of specious expert testimony in New Jersey courts that is precluded in cases pending in Daubert jurisdictions involving the same products and the same experts.

light of serious methodological flaws in case alleging SSRI medicine caused birth defects); In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig. ("Zoloft II"), 26 F. Supp. 3d 466, 480-81 (E.D. Pa. 2014) (excluding plaintiffs' embryology and pediatric cardiology experts for similar reasons), with Transcript of Motion Rulings at 21:17-22 (Aa21[3]), Capicotti v. Forest Research Institute, Inc., No. HUD-L-3895-14 (Law Div., May 27, 2016) (denying Kemp motions to bar very same experts in New Jersey SSRI birth defect litigation, and observing that "[u]nlike the Daubert factor-based approach, in New Jersey, the Trial Court need not consider factors as to whether the experts' hypotheses can be tested[,] whether the methodology is subject to peer review in publication, and whether the methodology has actually been accepted")[4]; and compare Jones v. AstraZeneca LP,

[3] "Aa" refers to Amici's Appendix accompanying this brief.

[4] In addition to denying Kemp motions to bar the same expert testimony that already had been barred in Daubert jurisdictions, the trial court in Capicotti also concluded with a rhetorical inquiry that underscores the ripeness of this matter for certification in order to clarify New Jersey trial courts' understanding and application of the crucial role they play in screening experts' novel causation testimony: "Despite the poetry [written about the court's gatekeeping function], the [c]ourt is left to ask the question as to what we, as trial [j]udges, are gatekeeping." Transcript of Motion Rulings at 39:22-24 (Aa39), Capicotti, supra, No. HUD-L-3895-14. "Rhetorical as this question might be," the court ruled that the filing of Kemp motions by both sides "essentially" asked the court "to thwart the ability of each side to present their individual cases to an impartial jury, and have the community decide the elements in dispute." Id. at 39:24 to 40:4 (Aa39-40).

No. 07C-01-420-SER, 2010 Del. Super. LEXIS 128, *3-4 (Aa59) (Del. Sup. Ct., Mar. 31, 2010) (excluding endocrinologist's specific-causation testimony under Delaware's Daubert standard because she "refused to expand the explanation of her methodology beyond her mantra that she had read 'everything' relating to the case and had applied her extensive training and experience to consider these materials and reach the conclusion that [the drug at issue] had caused [the plaintiff's] diabetes"), with Baker v. AstraZeneca Pharms. LP, No. MID-L-1099-07-MT (Law Div. Feb. 5, 2010) (slip op. at 1-25) (Aa70-94) (denying Kemp motion to exclude testimony of same endocrinologist in New Jersey mass tort involving same claims and same drug).[5]

Adoption of Daubert therefore would be sound public policy to ensure that real, reliable science - not junk science presented to lay juries - dictates whether to impose civil liability on New Jersey's research-based biopharmaceutical innovators. Like the examples discussed above, the Appellate Division's decision in this case is a stark reminder that New

[5] Although denying the motion to bar the endocrinologist's testimony, the trial court in Baker nevertheless suggested that its ruling could have been different if New Jersey applied the Daubert standard, because that rule "permits an expert to testify only '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 methods reliably to the facts of the case.'"). Baker, supra, No. MID-L-1099-07-MT (slip op. at 3 n.5 (quoting Fed. R. Evid. 702)) (Aa72).

Jersey finally should join the federal courts and almost all other state courts and the District of Columbia in adopting a standard that faithfully reflects a trial court's essential gatekeeping role.

Providing a clear definition of the contours of that gatekeeping role has never been more crucial to New Jersey's research-based life sciences industry -- and to the judiciary itself, for that matter. The approximately 20,000 pharmaceutical product liability cases already pending in New Jersey are likely to be joined by a substantial influx of additional cases brought by out-of-state plaintiffs, given the United States Supreme Court's recent decision holding that state courts lack specific jurisdiction over non-resident pharmaceutical companies for injuries allegedly sustained by plaintiffs in other states. See Bristol-Myers Squibb Co. v. Sup. Ct. of Cal., 137 S. Ct. 1773 (2017).

That influx is even more likely, and would be even more overwhelming to New Jersey's court system, if plaintiffs' lawyers continue to believe that New Jersey is a more hospitable environment for novel (even scientifically unsound) causation theories because, in their view, trial courts are not required to conduct a robust evaluation of the reliability and helpfulness of expert testimony. See, e.g., Letter from Arthur Luxenberg, Weitz & Luxenberg, P.C., to Plaintiffs' Counsel, at 2

(Aa96) (Dec. 29, 2004) (encouraging out-of-state plaintiffs' lawyers to file Vioxx lawsuits in New Jersey Superior Court because, unlike the Daubert or Frye standards, New Jersey's Rubanick standard does not permit the trial court to "determine the soundness even of the methodology, much less of the study itself").

II. THIS COURT SHOULD GRANT CERTIFICATION TO RESOLVE THE SIGNIFICANT, AND LONG-PENDING, ISSUE OF WHETHER NEW JERSEY SHOULD ADOPT DAUBERT AS THE STANDARD FOR ADMISSIBILITY OF EXPERT OPINION TESTIMONY IN NEW JERSEY CIVIL CASES.

This case presents this Court with the long-awaited opportunity to answer an important question that has remained unanswered for nearly two decades: whether New Jersey should join the federal courts, the District of Columbia, and nearly all other state courts [6] in adopting the more thorough and effective Daubert standard and factors for ensuring that only reliable expert evidence is admitted at trial.

The history of that pressing issue underscores the propriety of granting certification in this matter. This Court and its Committee on the Rules of Evidence have studied the question presented by this case several times dating back to its

[6] Thirty-nine of the fifty states and the District of Columbia have adopted Daubert as their standard for admissibility of expert opinion testimony. See Motorola Inc. v. Murray, 147 A.3d 751, 757 (D.C. Ct. App. 2016); Michael Morgenstern, Daubert v. Frye - A State-by-State Comparison, Expert Institute (Apr. 3, 2017), available at, https://www.theexpertinstitute.com/daubert-v-frye-a-state-by-state-comparison/.

2000-2002 term, but this Court has yet to provide a conclusive answer. Despite substantial commentary from all sides, recommendations from the Committee, and a hearing before this Court - and despite decades of well-developed case law explaining and applying the Daubert reliability criteria - New Jersey's Rule 702 has remained unchanged and its courts remain bound by a standard that eschews a true "gatekeeping" assessment of actual reliability and helpfulness to the factfinder.

The Committee's first examination of the issue in its 2000-2002 term yielded the Committee's decision not to recommend any changes to N.J.R.E. 702 at that time, given the relative nascence of Federal Rule of Evidence 702's codification of Daubert. Returning to the issue in its 2007-2009 term, the Committee issued a nineteen-page report and recommended that this Court update N.J.R.E. 702 to require that "the basis for the testimony [be] generally accepted or otherwise shown to be reliable" before it would be admissible. These proposed amici and other stakeholders submitted comments opposing that recommendation due to its vagueness and lack of explicit criteria for ascertaining whether the proffered opinion is "otherwise shown to be reliable." This Court declined to adopt the Committee's 2009 recommendation, thereby leaving in place the New Jersey rule that mirrored the pre-2000 version of the federal rule.

The Committee again considered the issue in its 2011-2013 term upon receipt of amendment proposals by various members of New Jersey's medical, biopharmaceutical, and business communities. In response to the Committee's request for direction concerning this Court's amenability to further study of the issue, this Court instructed the Committee to prepare a report on whether N.J.R.E. 702 and related case law have led to application of inconsistent standards by trial courts and/or turned New Jersey into a magnet for a disproportionate number of negligence and mass tort cases that more appropriately belong in other jurisdictions. In its 2015 report, the Committee stated that its "fact-finding" did not indicate that trial courts were applying inconsistent standards and that there was "no definite or conclusive evidence" that current New Jersey law attracted a disproportionate number of personal injury and mass tort cases from other states.[7] Given the limited scope of its charge,

[7] The Committee made that statement despite the known reality that plaintiff-side personal injury law firms advertise New Jersey as a plaintiff-friendly jurisdiction due to an expert-admissibility standard that would permit specious causation opinion testimony that would be barred in other jurisdictions under the Daubert standard. See, e.g., Letter from Arthur Luxenberg, Weitz & Luxenberg, P.C., to Plaintiffs' Counsel, supra, at 2 (Aa96). Moreover, although referring to an absence of "definite or conclusive evidence," the Committee acknowledged that approximately 93% of the plaintiffs in cases filed against New Jersey-based pharmaceutical manufacturers and pending in New Jersey's Multi-County Litigation system reside outside of New Jersey. See 2013-2015 Report of the Sup. Ct. Comm. on the Rules of Evid., Part II, at 15, 108 (Jan. 15, 2015), available at

however, the Committee did not evaluate the crucial question of whether current New Jersey law has allowed the admission of unreliable expert testimony.

In May 2015, this Court held a hearing on the issues and arguments raised in the Committee's report and in the comments submitted in response by these proposed amici and other stakeholders. During that hearing, this Court expressed concern that its rule-making procedure was not a suitable vehicle for modification or amendment of New Jersey's expert-admissibility standard, and instead suggested that any potential change should await the appropriate case so that it may be decided in an adversarial context and with amici curiae presenting arguments on both sides of the issue.[8] This is that case.

Certification is warranted because this "appeal presents a question of general public importance which has not been but should be settled by the Supreme Court," "calls for an exercise of the Supreme Court's supervision," and because "the interest of justice requires" a ruling from this Court. R. 2:12-4. This

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https://www/njcourts.gov/courts/assets/supreme/reports/2015/evidence22015.pdf.

[8] See, e.g., Webcast of Supreme Court of New Jersey, Hearing on Proposed Amendments to N.J.R.E. 702, May 19, 2015, at 22:30-22:45 (Chief Justice Rabner inquiring whether the more suitable approach would be to await an appeal that raises the issue and "consider it in an adversarial context" with amici curiae appearing in support of each side) (available at https://www.youtube.com/watch?v=CJfJiYbd6SI&feature=youtu.be).

Court now has the opportunity to address in a zealously litigated appeal an issue of significant public importance that has been considered by this Court and its Rules Committee without resolution for nearly two decades. In a state whose citizens rely so heavily on its substantial community of innovators, the importance of ensuring a fair and reliable expert-admissibility standard in cases that rise and fall on scientific opinion testimony cannot be understated.

Accordingly, this Court should grant Roche's Petition for Certification and decide whether New Jersey will join the federal courts and the majority of its sister state courts in adopting a standard that ensures admissibility of only reliable and reliably applied expert opinion testimony that "fits" the facts and issues involved in the case.

CONCLUSION

For the foregoing reasons, proposed amici curiae HealthCare Institute of New Jersey, New Jersey Business and Industry Association, Commerce and Industry Association of New Jersey, and New Jersey Chamber of Commerce respectfully request that this Court grant them leave to appear as amici curiae, grant Roche's Petition for Certification, reverse the Appellate Division's decision, and adopt the federal Daubert standard as New Jersey's test for the admissibility of expert opinion testimony in civil cases. Proposed amici curiae also respectfully request leave to file a brief on the merits of this appeal in the event their motion for leave to appear is granted and Certification is granted.

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By: 
Edward J. Fanning, Jr.
A Member of the Firm

Dated: September 21, 2017

APPENDIX

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: CIVIL PART
HUDSON COUNTY
DOCKET NO: HUD-L-3895-14
A.D. # _____

JAMIE CAPICOTTI,

Plaintiff,

vs.

FOREST RESEARCH INSTITUTE, INC.

Defendant.

TRANSCRIPT
OF
MOTION RULINGS AND
CASE MANAGEMENT CONFERENCE

Place: Hudson County
Administration Building
595 Newark Avenue
Jersey City, NJ 07306

Date: MAY 27, 2016

BEFORE:

HONORABLE JEFFREY R. JABLONSKI, J.S.C.

TRANSCRIPT ORDERED BY:

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I N D E X

I N D E X T O W I T N E S S E S

NAME	DIRECT	CROSS	REDIRECT	RECROSS

No witnesses were called during this proceeding.

I N D E X T O E X H I B I T S

NUMBER	DESCRIPTION	ID	EVD

No exhibits were cited during this proceeding.

UNIDENTIFIED RESPONDER: Yes, Your Honor. This is Scott Nabers and Matt Greenberg with the plaintiff.

THE COURT: Good. Good morning. Good after -- well, I guess, is it morning by you? No. It's two hours back; right?

UNIDENTIFIED RESPONDER: Just one hour, Your Honor. 12:30 in Texas.

THE COURT: Okay. Well, good afternoon. Okay. Hi, Mr. Jeffer, how are you doing? Okay. There were three applications -- well, there were three matters that we need to discuss today. One has to do with the case management conference on Grayson versus Forest Research, that we'll hold until the end. And there are two motion decisions to be made. The first application that I'm going to address is the plaintiff's application seeking to strike the testimony of Dr. Oscar Benavidez.

Dr. Benavidez is a pediatric cardiologist who specializes in cardiac birth defects. At the request of the defendants, he authored the report as to causation. And the plaintiff contends that the report was not served within the general causation stage of the discovery process.

According to the plaintiff, Dr. Benavidez is

a general causation expert. And the defendants disagree and believe that he is a case-specific expert concerning the Capicotti and Enoch plaintiffs.

The plaintiffs made procedural issues regarding the need to bar the report because it is untimely. And, further, they make a substantive argument that his report should be barred since it does not meet the Kemp standards.

The defendants contend that the reports are case-specific and timely as they are also -- and they are also reliable and admissible under Kemp. In reply, the plaintiffs argued that Dr. Benavidez is a general causation expert whose report was untimely filed and is, further, unreliable under Kemp. Essentially, reasserting the arguments that they make in their initial moving papers.

The deadline to produce case-specific reports was amended by an email amongst counsel as of December 31st, 2015. Dr. Benavidez' report was issued on that date. Dr. Benavidez was retained by the defendants in this case to provide an expert opinion based on a reasonable degree of scientific and medical certainty regarding the structure and general development of the heart as it relates to defects suffered by the plaintiffs Capicotti, the diagnostic -- pardon me,

diagnosis, treatment, and management of congenital heart disease, generally. And, in particular, heard defects plaintiffs Capicotti -- plaintiff Capicotti. Whether Lexapro caused the birth defects of plaintiff Capicotti, and the long-term prognosis and treatment for the plaintiff Capicotti.

In addition, I've been, according to Dr. Benavidez, "I have been retained to review and respond to the expert reports submitted by the plaintiff's case-specific experts, and, in particular, Dr. Ra-id Abdulla and Dr. Thomas Sadler."

Although he could have, Dr. Benavidez did not elect to examine the plaintiff because the medical records were sufficient, in the doctor's opinion, to render his opinion. The doctor, then, proceeds with a discussion of the heart and its development in utero.

Throughout the opinion, frequent references are made specifically to the plaintiff Capicotti. Although there are some notations as to general fields of study, including cardiology and epidemiology, periodically, throughout the report, they are noted, generally, to provide a framework as to the specific analysis that is contemplated, and for which the doctor was retained.

On pages 28 through 35, in particular, the

doctor provides relevant factual background, the history of the plaintiff's pregnancy, the diagnosis, the treatment contemplated, and the impressions of past treatment.

Further, a long-term prognosis and treatment was discussed, and conclusions were given. At the end, the doctor provides his opinion that is specific to the plaintiff's atrial septal defect, and this is a case-specific conclusion.

I find, following a review, that Dr. Benavidez is not a general causation expert. But, was retained to provide a specific determination about a singular defect suffered by an individual plaintiff. Further, for the reasons set forth in my decision, and that I will make as to the Kemp applications, the request to bar Dr. Benavidez is denied, since he engaged in the proper scientific methodology to permit him to come to these conclusions. The plaintiff's application, therefore, is denied. And an order will be generated as a result.

The second application concerns the decision on a number of applications brought by the parties to this litigation. They are, the defendant's applications to bar the testimony of plaintiff's experts, specifically, Dr. Amick Berard; Dr. Robert

Cabrera; Dr. Thomas Sadler; Dr. Ra-id Abdulla; and the plaintiff's application to bar the testimony of the defendant's experts, specifically, Jeffrey -- Dr. Jeffrey Brent; Dr. Michael Bracken; and, Dr. Henry Sucov.

The challenges to Dr. Berard's and Dr. Bracken's testimony were heard. And expert testimony together with the oral arguments were received by the Court at a plenary hearing conducted pursuant to State -- Kemp v The State of New Jersey, 174 N.J. 412 (2002). And it is required under rule 104(a).

The arguments made as to the request for the exclusion of the other experts are identical. And oral argument as to the subject methodology would be duplicative to that already heard, tested, and considered. Hearings for the remaining applications are not necessary in this Court's view.

The purpose of these experts is proffered and the arguments regarding these applications are summarized as follows, Dr. Amick Berard is the plaintiff's epidemiology expert -- excuse me.

The defendants argue that her opinions are unreliable and inadmissible. Specifically, the defendants argue that her opinions are not based on neither sound nor scientifically accepted methodology,

since she relies on findings that are not statistically significant. She does not properly account for chance, bias, and confounding, and is engaged in what the defendant characterizes as situational science.

Her opinions and summary are driven by litigation purposes and her reliance of fact gathered from a lack of consideration of the totality of the evidence and other SSRI data is unreliable, in the defendant's view.

Noting that both the FDA and the scientific community, as the defendants characterize her opinions, that there is -- that there is a causal link between Lexapro and birth defects as a class effect has been rejected. In its moving brief, the defendants make a number of arguments as to the lack of causation, as well, followed the assumed rejection of Dr. Berard's opinions.

In response, the plaintiffs argue that the question that is presented here is not causation but methodology. Beginning with the premise that the FDA has recognized that SSRI should be treated as a class, and that other SSRI's have been treated as such by other Courts, there is a risk that ingestion of an SSRI has a causal connection to birth defects.

That question, however, is framed by the

plaintiffs and to these applications is not the recognition of the causal relationship between the defects and the chemical; but that Dr. Berard's methodology in testing her hypothesis and arriving at her conclusions certainly meets the unique approach that New Jersey takes when considering the admissibility of expert testimony on medical causation under Kemp.

Characterizing the standards as minimal, the plaintiffs note that Dr. Berard easily meets the Kemp standards. Dr. Berard's opinion, according to the plaintiff, is methodologically sound. In reply, the defendants reassert their position regarding the perceived unreliability of Dr. Berard's opinions.

As to the defendant's application to bar the testimony of Dr. Ra-id Abdulla. Dr. Abdulla is a pediatric cardiologist who has been named by the plaintiffs as a general causation expert.

He notes, in essence, that the epidemiological data demonstrate that the use of Lexapro by pregnant women who are in their first trimester increased the risk of congenital cardiac defects in infants.

In his report, he notes that there is a biological, plausible mechanism and establishes a

causal link between Lexapro and cardiac defects.

The defendants argue that Dr. Abdulla's human causation opinions are unreliable and inadmissible. In accusing Dr. Abdulla as engaging, also, in situational science, the defendants argue that his conclusions are not based on statistically significant findings, and that his failing to recognize the methodological limitations are unreliable, rendering his report infirm, and, therefore, evidentially inadmissible.

In response, the plaintiffs make similar arguments as they did to support their position that Dr. Berard's opinions are admissible.

For almost identical reasons, the plaintiffs argue that Dr. Abdulla's report and testimony meet the characterized minimal Kemp standard.

In reply, the defendants reassert their positions and testimony, and their -- that the reports are unreliable, particularly in the area of the biological mechanism opinion.

As to the request to bar the -- bar the testimony of Drs. Cabrera and Sadler, Drs. Cabrera and Sadler are proffered by the plaintiffs as biological mechanism experts.

The defendants argue that Drs. Cabrera and Sadler's human causation opinions are unreliable and

inadmissible. Making similar arguments as to the lack of qualifications as the purposeful selection of pertinent data. To support its opinions, the defendants reassert their cherry picking and situational science positions.

As to the specific methodological criticism, the defendants argue that biological plausibility in animals is not human causation. Therefore, to the defendants the positions that the doctors have taken are infirm.

In response, the plaintiffs make a substantial -- substantially similar arguments as they have submitted in opposition to the defendants in other applications. More specifically, as to Drs. Cabrera and Sadler, their reliance on animal studies to demonstrate causation is completely appropriate, according to the plaintiff, because the FDA similarly relies on these methods.

The doctors, according to the plaintiff, also account for dose response issues, and other dosage issues. Although, to the plaintiff, these are not necessary.

In reply, the defendants reassert their arguments and noted that -- and note that the experimental data do not support the doctor's

hypotheses.

The plaintiffs brought similar application seeking to bar the testimony of the defendants experts. Dr. Bracken is proffered as an expert in perinatal epidemiology, and has authored reports presenting what the defendants characterize as a comprehensive analysis of the epidemiolo -- epidemiolo -- goodness -- epidemiological studies relevant to the question of whether Lexapro causes birth defects.

The plaintiffs argue that Dr. Bracken's report is, "Scientifically suspect and bias to the point of cynicism." He, according to the plaintiffs, cherry picks the Bradford Hill criteria and omits a number of them, and, "stacks the deck" from the outset against the causation analysis and determination.

To the plaintiff, Dr. Bracken's analysis, both of the underlying issues, and the criticism of other expert reports, requires, "Robust statistical significance as a mandatory precondition to consideration of other causation criteria." This, to the plaintiffs, is a fatal flaw.

In response, the defendants argue that Dr. Bracken's opinions are admissible, since they are consistent with the scientific consensus. Dr. Bracken appropriately recognizes the importance of statistical

significance when assessing the generalized question of the issue that had presented, a teratogenicity, as well as the totality of the scientific evidence in rendering his decisions.

In reply, the plaintiffs reiterate its consistent opposition that the defendants seek to divert attention away from the Kemp analysis presented in these applications to the ultimate causation questions.

Dr. Bracken's report analyses are incorrect and fundamentally flawed, according to the plaintiffs. Furthermore, and interestingly, the plaintiffs note that despite the valid arguments under rule 702, Dr. Bracken's opinions must be barred, since it will -- since that opinion will, "Confuse the jury on a matter already difficult for laypeople to comprehend."

Considerable prejudice and confusion will undoubtedly flow to the jury if Dr. Bracken were permitted to testify, employing his, what is characterized as, "Idiosyncratic and improper standards of proof."

The plaintiffs also seek to bar the testimony of Dr. Henry Sucov. Dr. Sucov is a developmental biologist who has been preferred in opposition to the plaintiffs experts, Drs. Cabrera and Sadler.

Dr. Sucov, in his report, identifies certain methodological flaws in both Drs. Cabrera and Sadler's reasoning, as to the biological mechanism of action of both Lexapro and Celexa.

According to the plaintiffs, Dr. Sucov cannot render an epidemiological opinion regarding human epidemiological studies. Further, according to the plaintiffs, Dr. Sucov's methodology is flawed and unreliable, since it does not reference nor include that which the plaintiff characterizes as critical FDA documents and animal studies that demonstrate, according to the plaintiffs the drug's carotogenicity.

In response, the defendants agree that Dr. Sucov cannot render an opinion on epidemiology; but, he has not. Furthermore, Dr. Sucov, according to the defendant, properly considered the totality of the evidence concerning *in vivo* animal toxicology studies, and these opinions are consistent with the FDA's evaluation of that particular data.

In reply, the plaintiff's reassert their argument suggesting that the opinions rendered by Dr. Sucov regarding the animal studies is fundamentally flawed.

The plaintiffs also seek to bar the testimony of Dr. Jeffrey Brent. Dr. Brent is a medical

toxicologist. He is proffered by the defendants and is proffered by the defendants to serve as a general causation expert.

In seeking to bar his testimony, the plaintiffs make identical arguments accusing Dr. Brent of engaging in the same flawed scientific methodology as all of the defendant's experts.

In response, the defendant reiterates its arguments made in support of the strength of its experts testimony. In reply the plaintiff reasserts its previous arguments that Dr. Brent does not perform a full epidem -- epidemiological analysis of what the plaintiff determines to be statistically significant studies. His opinions, therefore, are evidentially infirm.

Lexapro is the brand name for Escitalopram, and is one drug in a class of drugs characterized as SSRI's, selective serotonin reuptake inhibitors. It is alleged in this litigation that Lexapro is a teratogen, or a condition that is capable of causing birth defects.

Teratology is the scientific field that deals with both the cause and the prevention of birth defects. This Court understands that when an allegation is made that a medication is a teratogen, it

is common to prove both general and specific causation through expert testimony. The opinions of which are based on epidemiological evidence.

The most precise and, perhaps, most conclusive scientific methodology is a double blind, randomized control study. Which such studies, however, are not ethically conducted on pregnant women. Therefore, epidemiologist must rely on observational evidence. Epidemiology, of course, is the study of the incidents, distribution, and ideology of the disease, of disease in human populations.

Based on the Federal Judicial Center Reference Manual on Scientific Evidence, 551, 3rd Edition, as cited in Conrick v Exxon Mobil Corporation, 216 Westlaw 439, 361, (February 4, 2016). A slip opinion on page 4.

At bottom, and at issue in this case, it is alleged that the respective individual's examining the data, and in light of the litigation hypotheses taken by the parties in this case, differ substantially with the probable -- the possible cause in claimed birth defects caused by the ingestion of Lexapro by women who are pregnant.

Each application to be considered here was extraordinarily and comprehensively and -- pardon --

extraordinarily and comprehensively and expertly briefed and presented, both preliminarily, during the science day presentations, and during the Kemp hearings that were held in this matter under Kemp v State, 174 N.J. 412 (2002).

This provided the Court with opportunities to assess both the factual bases and underlying methodology as -- and whether both were scientifically liable as is required under a Kemp analysis. That's Kemp at page 427.

As with many things legal in New Jersey, the state of the law is to the admissibility of expert testimony is, in a word, fascinating. Its hybrid approach takes -- that is taken, bears a historical review to demonstrate its evolution into the current state of the law.

Beginning in 1923, the D.C. circuit announced its landmark decision about expert testimony based on novel scientific procedures in Frye v the United States, 293 Fed. 1013 (D.C. cir. 1923).

The Frye standard becomes -- became the deferral standard for Judges to apply in attempting to evaluate scientific evidence.

New Jersey adopted that standard in State v Arnwine, 171 Atlantic 2nd 124 (Sup. Ct. 1961). Since

then, New Jersey has been known as a Frye jurisdiction. That standard might be considered colloquially -- colloquially as a general acceptance standard, permitting expert testimony if the theory espoused was generally accepted by experts in the field.

In 1993, the United States Supreme Court decided Daubert v Merrell Dow Pharmaceuticals, Incorporated, 113 Sup. Ct. 2786 (1993). This was a birth defect case allegedly linking Bendectin to birth defects.

In that decision, the Court adopted a new standard for the admission of scientific evidence, and required a two-step process to be considered by a Trail Court.

Number one, a preliminary assessment as to whether the reasoning or methodology underlying the testimony is scientifically valid, and of whether the reasoning or methodologically -- or methodology properly can be applied to the case facts.

The Court also provided a number of five non-exhaustive factors to assist the Trial Court in admitting evidence. As noted by Judge Bernstein in Porter v SmithKline Beecham Corporation, on February 10th, 2016, pursuant to the Daubert standard scientific consensus, does not per se permit opinion testimony.

A scientific consensus that proper methodology was employed is only one of several non-exclusive criteria for determining whether the expert testimony will assist the jury.

The Daubert standard required the Court to make an independent, judicial, scientific judgment whether the methodology is sound, even if a scientific consensus of propriety exists. That's a slip opinion at page 4.

New Jersey, however, remained a Frye jurisdiction. In the early 1990's the New Jersey Courts, perhaps recognizing that certain types of cases would need to relax the quite conservative general acceptance rule, our Supreme Court decided Rubanick v Witco Chemical Corporation, 125 N.J. 421 (1991). And Landrigan v Celotex, 127 N.J. 404 (1992).

These cases fashioned a standard that some might characterize as a more liberal standard to meet the chara -- the specific challenged faced by the admission of novel scientific evidence. Specifically, in Rubanick, the Court found that, "A scientific theory of causation that has not yet reached general acceptance, may be found to be scientifically reliable, if it is based on a sound, adequately founded scientific methodology, involving data and information

of the type reasonably relied upon by experts in the scientific field." Rubanick, 125 N.J. 449.

The appropriate inquiry under this precedent becomes whether comparable experts in the field would actually rely on that information, and not whether the Court finds an expert's reliance on the underlying data to be reasonable. The focus, therefore, centers on the methodology that the expert employs in making his or her decision.

The Rubanick Court instructed Trial Courts to consider whether or not other individuals in the field used similar methodologies and should also consider factors that are typically relied upon by other medical professionals, such as medical tests, patient examinations, and scientific literature. That's Rubanick, 125, 449-450.

Unlike the Daubert factor-based approach, in New Jersey, the Trial Court need not consider factors as to whether the experts hypotheses can be tested. Whether the methodology is subject to peer review in publication, and whether the methodology has actually been accepted. That's Timothy Corriston and Angela Iuso, in an article entitled, New Jersey Supreme Court Expands Application of the Flexible Standard for Admission of Scientific Evidence on Causation.

Rubanick did, however, note the existence of the hired gun phenomenon. And that, "Experts can be found to testify to the truth of almost any factual theory, or to disagree with almost any theory, and to discount the research of others." That's the In re Accutane decision, under docket number 271 authored by Judge Johnson in February -- on February 20th, 2015, at page 7.

In 1997 the Supreme Court addressed the Daubert standards in State v Harley, 151 N.J. 117, specifically, 168 and 170, and affirmed the Ladriqan and Rubanick standards; and, despite the opportunity to address the more stringent standards, reaffirmed the general accepted, or Frye standard in criminal cases.

In 2002, the New Jersey Supreme Court again reaffirmed the Rubanick admissibility standards in Kemp v State, 174 N.J. 412.

The burden possessed by the parties seeking the admission of the testimony under Kemp, therefore, is to demonstrate that the methodology used by the expert is consistent with sound scientific principles and methodologies accepted in the medical and scientific communities. That's Kemp at 431.

Finally, in 2015, the Court decided Townsend v Pierre, 221 N.J. 36 (2015). The Supreme Court noted

that the expert testimony may be suspect when an inquiry is made as to whether the opinion is based on scientifically sound reasoning or unsubstantiated personal beliefs couched in scientific terminology. Kemp, 174 N.J. 427, citing Landrigan v Celotex, 127 N.J. 404 (1992).

A search and review in philosophical contemplation of these precedents by this Court reveals that the state of the law, as it applies to New Jersey, as to the admissibility of expert testimony as to causation theories, in the toxic Court realm, is one characterized by flexibility rather than by a -- a factor based or objective approached.

A Kemp inquiry must be flexible and as noted in the Accutane litigation, based on principles and methodology, and not necessarily on the conclusions or opinions that such scientific methodology may generate.

In the course of the Kemp hearing, an expert must be able to identify the factual basis for his or her conclusion, explained his or her methodology, and must demonstrate that both the factual basis and underlying methodology are scientifically reliable. Even if such opinion is not generally accepted by his or her peers. That's the Accutane decision at page 9.

A Trial Court's review, therefore, is as

broad as the breadth of the proffer, and the challenges thereto that the parties present.

Reflective of the Court's role as a legal scholar, rather than as a scientist, and the problems relating to the blurring of those rules, this Court notes Justice Handler's wise words. In determining the soundness of the methodology, the Trial Court should directly and independently determine that, as a matter of law, that is the controversial and complex scientific methodology is sound.

The critical determination is whether comparable experts accept the soundness of the methodology, including the reasonableness of relying on this type of underlying data and information.

Great difficulties can arise when judges, assuming the role of the scientist attempt to assess the validity of a complex scientific methodology. Rubanick at page 451. This is the state of the law as it applies to expert testimony now.

As noted, this Court has had the benefit of a specific presentation, provided by both sides, as to the nature of the science underlying this litigation. And has also had the benefit of reviewing thousands of pages of supporting documentation, as well as two live presentations.

From a rule perspective, evidentiary decisions, including those that -- expert testimony reviewed under the Abuse of Discretion standard, because, from it's genesis, the decision to admit or exclude evidence is one firmly entrusted to the Trial Court's discretion. Estate of Hanges v Metro Property and Casualty Insurance Company, 202 N.J. 369, 383-384 (2010).

Under this standard, an Appellate Court should not substitute its own judgment for that of the Trail Court, unless the Trial Court's ruling was so wide of the mark that a manifest denial of justice resulted. Hanisko v Billy Casper Golf Management, Incorporated, 437 N.J. Super. 349, 362 (App. Div. 2014), quoting State v Brown, 170 N.J. 138, 147 (2001).

A determination of the admissibility of expert testimony is committed to the sound discretion of the Trail Court. A Trial Court's grant or denial of the motion to preclude expert testimony is entitled to deference on Appellate review. The Court has instructed that the Appellate Division to -- to apply a deferential standard to the Trial Court's decision to admit expert testimony, reviewing it against an abuse of discretion standard. That's Townsend, 221 N.J. 53, quoting Pomerantz Paper Company New Community -- v New

Community Corporation, 207 N.J. 334, 371-372 (2011).

Despite the interpretive state of the law, it is still fundamental that two rules of evidence frame the analysis for determining the admissibility of expert testimony under rule 702. Specifically, rules 702, 703, and read in comparison with one another. And, specifically, 702, identifies when expert testimony is permissible, and requires that experts be qualified in their respective fields.

New Jersey rule of evidence 703 addresses the foundation for expert testimony. It mandates that expert opinion be grounded in facts or data derived from the expert's personal observations, or evidence admitted at trial, or data relied upon by the expert, which is not necessarily admissible in evidence; but which is of the type of data normally relied upon by experts. Townsend, 221 N.J. 53.

Related to that rule is a -- a -- another issue in this case, which is the net opinion rule. Which is a corollary of rule 703, which forbids the admission into evidence of an expert's conclusions that are not supported by factual evidence or other data.

Under the net opinion rule, an expert is required to give the whys and the wherefores that supports their opinion, rather than a mere conclusion.

The net opinion rule, however, mandates that experts be able identify the factual bases for their conclusions, explain their methodology, and demonstrate that both the factual bases and methodology are reliable.

In short, the net opinion rule is a prohibition against speculation, or speculative testimony. Harte v Hand, 433 N.J. Super. 457, 465 (App. Div. 2013), quoting Grzanka v Pfeifer, 301 N.J. Super. 563, 580 (App. Div. 1997).

In essence, a Trial Court must ensure that expert opinion is -- and -- and an expert providing it, is not permitted to express speculative opinions or personal views that unfounded in the record. Townsend, 221 N.J. 63.

As the proponent of the evidence on general causation, the proponent bears the burden of establishing admissibility. Kemp, 174 N.J. 429.

The admissibility of the expert reports depends on the Trial Court's assessment, both of their qualifications and those expert's methodology. Landrigan, 127 N.J. 422.

The key to the admission of the opinion is the validity of the expert's reasoning and methodology. Despite the qualifications of the experts, their reasoning and methodology is slanted away from

objective science, and in the direction of advocacy, it should be barred.

It appears that the opinions that are expressed by the opinions are motivated by preconceived conclusions, and that they have failed to demonstrate that the data or information that were used, were soundly and reliably generated are the -- and are of the type reasonably relied upon by comparable experts. Rubanick, 477.

A Trail Court must make an evaluation of the validity of the studies on which the experts rely, and determine admissibility, and must examine each step in the expert's reasoning. Landrigan, 421.

Courts, as noted by Judge Johnson in the Accutane litigation, are experts in the law not science. In re Accutane litigation docket number 271, the MCL Atlantic County, February 20th, 2015. He notes that this Court's review is as broad as the proffer in the challenges thereto that the parties present. That's at the slip opinion at page 2, citing Hisenaj -- H-N -- pardon me. H-I-S-E-N-A-J -- v Kuehner, 174 N.J. 6, 19 (2008).

Judge Johnson reiterates the oft-cited principle that is quote -- quoted frequently, I feel, without the benefit of reflection, that Trial Courts

are gatekeepers, based upon the proofs presented by the parties, and are charged with whether or not the hypothesis of causation advanced by the experts and the plaintiff is sufficiently reliable to present -- to be presented to a jury.

It is in light of these principles that these facts and these applications are considered.

Now, initially, this Court notes that at least one other Trial Court has already rejected some of the plaintiff's experts proffered to testify in this matter under the more restrictive Daubert standards in Pennsylvania.

Alternatively, a Trial Court in Missouri has permitted the testimony, as has a Trial Court -- another Trial Court in Pennsylvania in similar litigation.

These decisions, of course, are not binding on this Court. No Court in New Jersey, nor one interpreting New Jersey law, that is binding on this Court concerning expert testimony has specifically barred these identical witnesses. In further distinction, Judge Coogler specifically noted that in these same defendants, in these applications, do not allege that plaintiffs here are involved in the Zoloft -- the Zoloft litigation, and acknowledge, in their own

filing, that Zoloft may have had different properties than Lexapro. Soderberg v The Forest Research Institute -- Institute, 1014 U.S. Dist. Lexus 155, 296 (November 3rd, 2014), slip opinion at page 13.

These applications, brought essentially on procedural grounds, have a dispositive substantive effect, no doubt. The question, at bottom, then becomes whether the experts are permitted to testify under the Kemp framework as those opinions are methodologically accurate.

As affirmed by Kemp and as established in Landrigan, there are three components to permit an expert to testify as to medical causation. The intended -- number one, the intended testimony must assist the trier of fact. Number two, the field about which the expert will testify must be a state of the art. And, three, the expert must have sufficient expertise to offer the testimony.

As to prong one, there is no question that the complexity of the matters that are involved in this causation analysis require the need for expert testimony.

As to prong three, there can be no credible dispute as to the professional qualifications of the experts proffer to testify. Each expert's individual

credentials are impeccable. And, certainly, no party can be critical as to the education, training, or experience of these individuals. The only valid challenge that is made to the opinions rendered by non-epidemiologist, as to an opinion outside of their field of study.

This is only an argument, and the proffered witnesses are not rendering their opinion as to an epidemiological determination; but, only basing their opinions within their individual realm of expertise.

Bringing the discussion, this issue, to the ultimate question under prong two, whether the opinions expressed are reliable. The test for this determination is found in Kemp, though through the procedural mechanism of a 104 hearing.

Specifically, an expert's opinions testimony is admissible if he or she is able to identify the factual basis for a conclusion, explain the methodology, and demonstrate that both the factual basis and underlying methodology are scientifically reliable. Kemp, 427.

It is the function of an epidemiologist to examine the general population, compare the incidents of the disease among these people exposed to the factor in question, and -- and to those not exposed.

The epidemiologist then uses statistical methods and reasoning to allow that researcher to draw a biological inference between the fact being studied and the diseases ideology. Bratt v Merrell Dow Pharmaceutical, Incorporated, 174 Fed. 2nd 307, 311 (5th Cir. (1989), cited by Conrick, Super. slip opinion at 4.

As noted by Judge Vance in her Conrick decision, a quote -- "A Court cannot exclude testimony -- expert testimony, because it disagrees with the expert's conclusions. But, an expert's conclusions must be connected to existing data by a -- by more than a mere say so of the expert." Conrick, slip opinion at 5, citing General Electric Co. v Joiner, 522 U.S. 136 at 140 -- pardon me. Page 136 and page 146 of a 1997 decision.

Conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. A Court may conclude that there is simply too great an analytical gap between the data and the opinion offered. Such is not the case here.

Each and every expert engaged in practically identical assessments of the problem presented to him or her. With, I might suggest, the appropriate

scientific precision.

The reports were not simply and ippsidixet (phonetic) of the witness' merely including a list of studies, a summary of the findings, and the statements of a conclusion.

On the contrary, each expert considered the researched question. Each exhaustively considered the studies contained on other data considerations in the field. Each expert considered reviews and reviewed drug utilization studies, drug duration studies, and commentaries.

Meta analyses were considered as part and parcel of this body of knowledge. Each considered extensive medical and scientific literature involving SSRI's, peer literature was considered, initial hypotheses were formed and later tested, associations were identified. The cause/effect relationship was contemplated, bias and confounding factors were assessed and considered, the Bradford Hill criteria were employed where appropriate.

Each expert, without exaggeration, presented a meaningful analysis in which each reconciled the various studies and explained the relevance of the facts of the case.

Inasmuch as each expert appeared to engage in

identical analytical methods, albeit with different conclusions reached, there is nothing methodologically infirm about their commonly accepted approaches to the assessment of the problem.

Each exercised his or her own professional judgment based on the body of knowledge that was created and ultimately considered. These methods of scrutiny are unquestionably embraced as generally accepted in the scientific community; and, therefore, satisfy Kemp.

All expert's testimony will be helpful here to the jury. The reports are based on sufficient facts and details. The conclusions are the product of reliable principles and methods -- and methods. The experts have adopted this sound methodology and incorporated it into their reports, and have addressed the specific research question appropriately. Yates v Ford Motor Company, 113 Fed. Sup. 3rd, 841, 862 (Dist. N.C. 2015).

Focusing on the many hundreds of trees that were sacrificed to divert attention away from the forest formerly comprising them, in very broad strokes, this is the inquiry that Kemp requires. The consideration of the expert's methodology, rather than the procedures used to formulate those opinions.

Quite candidly, the expert's opinions might be wrong. New Jersey Trial Courts recognize this, and include and incorporate these assessments into the trial procedures. As noted by Judge Bernstein in Porter, real scientific knowledge is not, and never has been, static. Even using proper methodology, scientists routinely disagree, and even reach different conclusions while accepting the same underlying data as accurate.

Through the interaction of differing, but scientifically appropriate conclusions derived from commonly accepted data, knowledge progresses. Likewise, different scientific disciplines may properly opine on the same questions using different but proper methodologies. Bauer, slip opinion at 5.

It is axiomatic in our trial system that expert testimony is important; but, is only a component of the fact finder's responsibility. Expert testimony is designed to assist the trier of fact in it's fact finding responsibilities.

As noted in the model civil jury charge 113, jurors may hear testimony from a witness who is called as an expert. Generally, witnesses can testify only about the facts and are not permitted to give opinions. However, an except to this rule exists in the case of

an expert witness. An expert may give an opinion on a matter in which -- or on which the witness has some specialized knowledge, education, skill, experience, or training. That's New Jersey evidence rule 702.

An expert witness may be able to assist the jury in understanding the evidence in this case, or in performing duties as a fact finder. That's New Jersey rule of evidence 702, 703, and 704. Also cited by Landrigan v Celotex, 127 N.J. 404 (1992).

However, it's noted in the instructions, Courts emphasis that the determination of the facts in this case rests solely with the jury. We, as Trial Court Judges, specifically instruct jurors that in examining each expert's opinion, jurors may consider the person's reasons for testifying, if any.

Jurors may also consider the qualifications of the individuals, and the ultimate believability of the expert, including all of the considerations that generally apply when jurors decide whether or not to believe any witness' testimony. State v Perez, 218 N.J. Super. 478, 486 (App. Div. 1997).

The weight of the expert's opinion depends upon the facts on which the expert bases his or her opinion. Polyard v Terry, 160 N.J. Super. 497, 511 (App. Div. 1978).

Jurors are also charged with a determination as to whether the facts on which the expert relies actually exist.

Finally, jurors are not bound by the testimony of an expert. Jurors may give an expert's opinion whatever weight each juror deems to be appropriate. Jurors may accept or reject all of an expert's opinion. State v Spann, 236 N.J. Super. 13, 21 (App. Div. 1989).

At bottom, I truly have faith in the jury system. And my experience has been that jurors, despite humble backgrounds, have a unique ability to consider properly the evidence that is set and tested before them. The opinions here will only assist these individuals in meeting their Constitutional obligations.

With competing expert testimony of both sides impermissible speculation will be at a minimum. Michael Green and Joseph Sanders wrote, Admissibility Versus Sufficiency Controlling the Quality of Expert Witness Testimony, 50 Wake Forest Law Review, 1057, page 1093 (2015).

This general precept is adopted in many other jurisdictions, as well, and is most succinctly stated by Judge Neal in Missouri, a jurisdiction in which

doctors Berard, Cabrera, and Sadler were permitted to testify. "Vigorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof of the traditional and appropriate means of attacking shaky but admissible evidence. These conventional devices are appropriate safeguards where the basis of scientific testimony meets the standards of admissibility. Foster v Pfizer, slip opinion at 4, citing Daubert v Merrell Dow Pharmaceuticals, Incorporated, 509 N.J. -- oh, pardon me. U.S. 579, 596 (1993).

As noted by Judge Neil in Missouri, "So long as the expert is qualified, any weakness in the expert's knowledge is for the jury to consider in determining what weight to give the expert." Foster v Pfizer, slip opinion at page 3, citing Kivland v Columbia Orthopaedic Group, LLP, 331 S.W.3d 299, 311 (Mo. banc 2011).

So long as the expert is qualified, any expert in the weakness -- any weakness in the expert knowledge is for the jury to consider in determining what weight to give to the expert. That's Kivland 331 S.W. at 311.

The jury will decide whether to accept the expert's analysis as to the facts and data. Kivland

331 S.W. at 311.

Any weakness in the factual underpinnings of the expert's opinion goes to the weight that that testimony should be given, and not to its admissibility. That's Foster slip opinion at 4, citing Elliott v State, 215 S.W. 3rd, 88 (Mo. bank 2007).

Finally, and may I attempt to wax eloquent about this final point. It appears in much of the written opinion as to this topic much is said about the gatekeeping requirement possessed by Trial Court Judges. Judge Johnson highlighted this principle in Accutane, noting that the hypothesis of causation advanced by plaintiff's experts is sufficiently reliable to be presented to a jury.

Similarly, Judge Ruth noted in Zoloft, that the Court is mindful of its function as a gatekeeper. It is not for the Courts to be pioneers forging new trails in scientific thinking, especially that that means departing from well-established research principles, such as the principle of statistical significance.

Despite the poetry, the Court is left to ask the question as to what we, as trial Judges, are gatekeeping. Rhetorical as this question might be, adopting the position taken by both of the parties here

are asking me, essentially, to thwart the ability of each side to present their individual cases to an impartial jury, and have the community decide the elements in dispute.

This, ironically, offends the very notion of both substantive and procedural due process. The very notion that gatekeeping is designed to protect. As noted in United States v Stanley, 533 Fed. Ap. 325, 327 (4th Cir. 2013), the Trial Court's role as gatekeepers is not intended to serve as a replacement for the adversary system.

For these reasons, therefore, the applications from all parties to bar their experts' opinion are denied. Thank you very much.

ATTORNEYS PRESENT IN COURT: Thank you, Your Honor.

THE COURT: Let's take just five minutes. And, then, we'll proceed with the case management conference. Mr. Greenberg and Mr. Nabers, may I call you back?

MR. NABERS: That's fine, Your Honor.

THE COURT: Are you the only ones on the line?

UNIDENTIFIED RESPONDER: No, Your Honor. There's others.

THE COURT: Okay. Let me do this. Let me just put you on hold, and we'll take five minutes. And, then, I'll be right out to discuss case management. Okay?

UNIDENTIFIED RESPONDER: Thank you, Your Honor.

(Off the record. Back on the record.)

UNIDENTIFIED RESPONDER: Your Honor, we're back.

THE COURT: Okay. Very good.

UNIDENTIFIED RESPONDER: Yes, Your Honor.

THE COURT: Okay. The Grayson matter has a discovery end date, currently, of March 28th, 2017. It is a track three matter, and I have the discretion of extending the discovery end date for a period of 120 days. I'm going to do that, at this point. The new discovery end date will be 7-26-17. So, July 26, 2017.

I figure that best just to extend it now and develop discovery dates within that framework. Hopefully, we can keep within that period, because it's a year from now.

What I might propose is this. That expert depositions be completed by the 26th of July, 2017. That all defense expert reports be submitted by May 26th, 2017. Plaintiff's expert reports by March 27th,

2017. And all fact and party depositions to be completed by January 26th, 2017. What is the status, Mr. Rodriguez, of the paper discovery, at this point?

MR. RODRIGUEZ: You know what? I -- we have to ask Mr. Nabers.

THE COURT: Okay. Mr. Nabers, may I ask you sir?

MR. NABERS: Yes, Your Honor.

THE COURT: What -- on paper discovery.

MR. NABERS: Okay. You know, Judge, this case really has not had much discovery done. Although I think that both parties would agree that we've done a tremendous amount of discovery in connection with the three cases that we -- we discussed earlier. And, so, a lot of that discovery, you now, will overlap and will be applicable in these cases.

There will be some obvious case discovery that needs to be done with regard to this particular case. But, I -- I think it's, you know, it's not outside the normal. I think we can get it done, you know, within the timing you're talking about.

THE COURT: If I suggested that all paper discovery, of whatever nature, be completed by October 3rd, would that be sufficient? Ms. Stevens looks like she's nodding. Yeah.

MS. STEVENS: I believe so, Your Honor.

THE COURT: Mr. Cheffo, you would agree?

MR. CHEFFO: Yeah, I think it's within -- within -- within reason --

MR. NABERS: I -- I think it would, Your Honor. I would agree with that.

THE COURT: Okay. I -- I don't want to micro manage whatever paper discovery is there. So, let me just broad stroke it by saying all paper discovery shall be completed. So, that would, of course, require any service of notices and -- and whatever might be, within the appropriate timeframes. To have everything completed by the 3rd. Is that -- is -- I think that's a reasonable approach among -- among -- the way that you all have been working with one another.

MR. CHEFFO: Mmm-hmm.

THE COURT: I think you can do that; right?

MR. CHEFFO: Mmm-hmm.

MR. IPSARO: Your Honor, this is Mr. Ipsaro.

THE COURT: Yes, sir. Oh, hi, Mr. Ipsaro.

MR. IPSARO: Good afternoon. I -- the -- the only caveat to that would probably be records collection. I don't know if you're considering that part of the written discovery. But, records collection will go on beyond that date. And, as you're likely

familiar with by virtue of the other cases, that if this continues as an ongoing process throughout the pendency of the case.

So, I -- I just wanted to make that point, real quick.

THE COURT: Okay. I think we would all be in agreement with -- with that statement; right? I -- I don't -- I don't think I have to set any sort of deadlines with that, with the understanding that the parties know that records will -- will be an ongoing -- as all discovery is ongoing, of course. And I know that there are going to be exceptions.

But, I think we've probably defined the parameters in this matter. Because this also involves a ventricular septal defect; right? So, we're talking about the heart. And, so, we're not -- we don't have a new birth defect that we have to -- we have to address.

So, I -- I mean I -- I understand the discovery, and it will proceed as -- as liberally as I can. But, at least we're not dealing with a brand new area of the -- of the body, which I think is helpful.

Okay. So, let me establish it that way. Now, I also understand, in reading the -- the Benavidez supporting brief, that you will probably wish to do case specific Kemp hearings on -- oh, I'm sorry -- on

the case specific experts, on -- on both sides, I assume? Okay. Let us talk about that. Can we talk -- anything more on the Grayson case management?

MR. NABERS: I think we've covered it, Your Honor.

THE COURT: Yeah.

MR. NABERS: I think we're good on Grayson.

THE COURT: I -- I think so, too. Do we have to make a distinction between case and general on experts with Grayson, as well? I mean, there's general -- will there be general causation as to ventricular septal defects? There will be. Okay.

MR. NABERS: There will be; correct.

THE COURT: Okay. So, we have to -- we have to make a distinction between general causation experts. And can we -- can I keep the -- all expert reports, to be submitted by these dates? Or do I have partial --

MR. NABERS: That's fine with, Your Honor.

THE COURT: Yeah. Can we -- can we do that? I mean, I know that we'll probably have similar case Kemp issues on Grayson, which is fine. We'll deal with that, when we have to deal with that.

MR. CHEFFO: Yeah, I think that's fine, Your Honor.

THE COURT: Okay. Let's just leave it, again, broad strokes. All right. Okay. So, let's talk about the case specific Kemp. The 22nd of August, and I don't have my calendar in front of me, so I'm going by memory. The 22nd of August is the third week in August for which we do not have any jury trials scheduled. I'm going to schedule the Kemp hearings for that week, as well.

MR. NABERS: Your -- Your Honor?

THE COURT: Yeah?

MR. NABERS: Can I just say something about that, just -- just before we schedule that?

THE COURT: Sure.

MR. NABERS: And -- and -- I'm -- if you don't mind, just kind of hear me out.

THE COURT: Yep.

MR. NABERS: You know, and obviously, I know the defendants may have something to say about it. But, you know, we -- we've done this, now, spent significant time, and -- and I need to say significant money, because it becomes, you know, somewhat more problematic for me than for them.

But, the reason that I point this out is is that there is another way for us to do this. You know, we can still have a deadline by which to do our Kemp

motions. And -- and, then, also have a deadline by which either party responds to those Kemp motions.

But, you know, as opposed to having a whole nothing (sic) Kemp week where I -- I have -- incur the cost of bringing experts, and they do the same, why couldn't we just file all of our papers; and, then, at the time of trial, before the witness comes, have a voir dire process where they can either challenge them on qualifications or challenge them with regard to methodology?

Because, that way, we have the expert there. The Court will already be informed about what the -- either the defendant's or plaintiff's arguments are about the methodology. And -- and -- and they'll already have the ability to have seen, you know, any responses and replies. And all of that paperwork will already have been done at the time that we're at trial.

But, then, it can be a very focused questioning, either by the Court or by the parties, before that witness goes on the stand. And it just seems to me that if -- if we wait until the trail, if that would be an appropriate time to do this, as well.

THE COURT: Mr. Nabers --

MR. NABERS: And the other thing I might point out, too, is is there are many, many experts that

the defendants have listed as -- as do the plaintiffs. But, all of those experts aren't going to come to this trial. There have been other cases, not in other trials, not in a Lex -- in the -- in a Lexapro case; but, in the Zoloft trials, you know, for example, the defendants designated many experts. But, it -- in both trials, they only called two or three experts. And the plaintiff, likewise, had designated a lot of experts and ended up not bringing all of their experts.

And, so, it -- it -- I'd hate for us to spend a whole bunch of time, effort, and money on experts, before the trial, who are likely not even going to come to trail. And, because, if we hold this over, and do it in a voir dire situation, then -- then, you're only going to be doing it as to the experts that you know will actually be at trial.

THE COURT: I -- I appreciate that, Mr. Nabers. The -- the issue, and I'll -- I'll certainly heard -- hear from the defense with regard to this. The issue really is to what Kemp requires. Kemp was quite clear with regard to the need and the requirement to have a 104 hearing, to the extent that the -- the Appellate Division and the Supreme Court made a determination that it was plain error not to have one.

So, I am all for deciding these matters on

the papers. And not to incur the -- the -- the consumption of judicial resources, because I will tell you that trying to fit in significant hearings, long hearings, is -- is very, very difficult. Particularly since I have other cases that I have to address during the same time period.

But, the -- the -- the Courts have spoken with regard to it, and I have to be guided by what the -- the Courts are telling me. Unless, however, you want to make a determination the defense and to speaking with the defense that you can wave the request for a -- a 104 hearing, with regard to it.

But, you bring up the issue with regard to the assessment of -- well, the -- the issue with regard to the voir dire. I mean, Mr. Cheffo, I -- I know --

MR. CHEFFO: Yes.

THE COURT: -- that you are --

MR. CHEFFO: I -- I mean -- a few things --

THE COURT: -- you -- you want to be heard. So, go ahead.

MR. CHEFFO: I -- I do. I mean, you know, I mean, to some extent, I -- you know, I don't disagree; right? I'm sure that Mr. Nabers and his colleagues would prefer not to have to spend money that they don't need to spend. And, certainly, our client would rather

spend it on researching new medicines; right? Than -- than wasting money. So, we all share that. No one is trying to --

And I also think that, you know, maybe this is an opportunity that we can, you know, we should and can talk to one another. Because I -- I -- I do agree that there's probably more experts than you can shake a stick at, that are listed. And I would find it hard to believe, frankly, from a trial strategy perspective, that both sides would all those experts.

So, having said that, though, I also would kind of strenuously disagree, like kind of just wait until -- because frankly, I -- I know that this is kind of a -- you know, an offer by Mr. Nabers, in good faith, to try and save time. Which, frankly, as you know, could you imagine how much time we have to spend to prepare for a trial. Or I -- you know --

THE COURT: I could imagine.

MR. CHEFFO: -- you know, and -- and --

THE COURT: Yeah.

MR. CHEFFO: -- and pretrial exhibits and deposition designations. And, then, to basically have all of that done and, then, not know exactly what's coming in or what the parameters are until, literally, the day before the expert gets on the stand, or two

days before. That, you know, this is not a kind of car accident case; right?

THE COURT: Mmm-hmm.

MR. CHEFFO: So, I -- so, I don't think that that would be workable. But, what I -- what I do think may be workable is to see I f we can have a good faith conversation and find out, really, if we could narrow the expert list. That might address some of his concerns. It certainly would help us. And probably help Your Honor.

THE COURT: Mmm-hmm.

MR. CHEFFO: And it would give you back a few days.

THE COURT: Absolutely.

MR. CHEFFO: And, then -- and, then, maybe, talk about some timing issues, as well, and see if there's any, you know, flexibility with the Court on -- on that. Whether we need to do it in August, or not. But, again, I don't want to speak for the parties or the clients. But, maybe if you'd indulge us and give us, you know, a week to talk to Mr. Nabers, we might be able to have another, you know, proposal.

THE COURT: Let -- let us do that. Let us do that. I think that's a fine suggestion. What I do need to do, however, is lock everybody in to a

particular period of time.

MR. CHEFFO: Sure.

THE COURT: I can always cancel it, which will free up me to do other things. But, unless I lock everybody into those two weeks --

MR. CHEFFO: Okay.

THE COURT: -- I -- I have to do that. So, I'm going to schedule the 20 -- the week of the 22nd, and the week of the 29th for Kemp applications. It's the only time that we're not having the added pressure of juries.

MR. CHEFFO: Yes, Judge.

THE COURT: With that, however, we still have assigned what we characterize as DC and SC cases, which are small claims and Special Civil Part cases that we -- we, as Lexapro, will have to accommodate.

Now, I can do that by bringing you in later in the morning and -- and potentially working through lunch. Because I -- I have other staff members that can work, and we can continue, and make up time that way. But, the reason why they have those two weeks without jury trials is because they -- there's a transition with law clerks.

And, also, all the administrative stuff occurs during those two weeks. Which, thankfully, I

won't have to deal if -- because I'll be doing this. But, we -- we do need to accommodate those, because it's a kind of a catch-all week. But, that is not for you to contend with, that's my problem. Okay?

So, let us lock in the 22nd and the 29th, for those two weeks. And all of the Kemp applications must be resolved by then. And these are case specific, non-Grayson cases. Okay?

I've also spoken, because I know that everyone is thinking about it, about what trial dates we're talking about. I've spoken with Tracey Pignatelli, who is our Trail Court coordinator in conversa -- and she has also spoken with Judge Costello. And, until we resolve these issues with regard to Kemp and who is going to be testifying, and whether they're going to be able to testify, we are just kind of in a holding pattern with regard to scheduling trial dates.

MR. CHEFFO: Thank you.

THE COURT: Mr. Rodriguez, you brought the matter, a couple of case management conferences ago, as to being focused or the -- the ends in the end of January we're going to get trial dates, and then we're going to have to make -- I've addressed that --

MR. RODRIGUEZ: Okay.

THE COURT: -- in house.

MR. RODRIGUEZ: Thank you.

THE COURT: Okay? So --

MR. RODRIGUEZ: Well, I think we all appreciate that.

THE COURT: Of course. Just so you don't have to worry about that. Because I know that you're flying in people, and people are going to be coming in, and we've got to get everyone's schedules --

MR. RODRIGUEZ: Sure.

THE COURT: -- so, we don't have --

MR. RODRIGUEZ: They still are of the position that we can't be preassigned to you, however; right?

THE COURT: Actually, that -- that -- there is some thinking about that, anyway.

MR. RODRIGUEZ: Ah.

THE COURT: Yeah. Under the theory that I'm familiar with the issues, why ask somebody else to bring themselves up to speed, after months of work.

MR. RODRIGUEZ: Oh, yeah. Or torture themselves, at this point.

THE COURT: No, I would never say that.

MR. RODRIGUEZ: No, no. I said it.

THE COURT: Okay.

MR. RODRIGUEZ: You didn't say it.

THE COURT: Okay.

MR. RODRIGUEZ: Me.

THE COURT: Okay. So, we'll -- let us do this. Let us -- a week is the third of June -- god bless you.

MR. RODRIGUEZ: Bless you.

THE COURT: -- the 3rd of June, I believe.

MR. RODRIGUEZ: I'm sorry, what is?

MR. CHEFFO: It is.

COURT CLERK: June 3rd.

THE COURT: June 3rd is next Friday?

COURT CLERK: Yes.

MR. CHEFFO: Yeah.

THE COURT: Okay. We don't need to have a conference call with regard to this. So, may I just ask, Mr. Cheffo and Ms. Stevens, if you don't mind, someone, let me know what the results of the -- of the conference are by email. And we can address it that way.

MR. RODRIGUEZ: Okay.

MR. CHEFFO: That works.

THE COURT: Okay? I will email you a copy of the case management order on Grayson, as well as email you all of the orders on the other matters. You

will see that some of those orders are duplicates. And when I asked you, and I appreciate you doing this, in withdrawing your applications, they still remain on our motion docket. So, you will see Dr. Bracken times two. Because I do need to generate an order in order to close out the motion. That's the only reason for the duplicate -- the duplication.

MR. RODRIGUEZ: Judge, are you attaching, like, a typed version of your oral opinion to the orders?

THE COURT: No.

MR. RODRIGUEZ: Or not?

THE COURT: I'm not.

MR. RODRIGUEZ: We'll just order the transcript?

THE COURT: You'll have to order the transcript, as a result.

MR. RODRIGUEZ: Not a problem.

THE COURT: Okay.

MR. RODRIGUEZ: Just asking.

THE COURT: I appreciate that. Okay. Thank you all very much.

MR. CHEFFO: Thank you, Judge.

THE COURT: And have a nice weekend.

MR. RODRIGUEZ: Thank you.

MS. STEVENS: Have a good holiday.

THE COURT: Okay. Gentlemen, ladies, on the phone, thank you all very much, and enjoy your weekend, as well.

MR. NABERS: Thank you, Your Honor. You, too.,

THE COURT: All right. Bye-bye, now.

MR. RODRIGUEZ: Thank you.

(Proceeding concluded.)

Certification

I, Jenny Power, the assigned transcriber, do hereby certify the foregoing transcript of proceedings on CourtSmart, from index number 1:33:11 to 2:16:24, and from index number 2:19:28 to 2:34:28, is prepared in full compliance with the current Transcript Format for Judicial Proceedings and is a true and accurate non-compressed transcript of the proceedings as recorded.

/S/ Jenny Power 06-03-16

Jenny Power AOC #640 (Date)

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Jones v. Astrazeneca LP

Superior Court of Delaware, New Castle

January 7, 2010, Submitted; March 31, 2010, Decided

C.A. No. 07C-01-420-SER

Reporter
2010 Del. Super. LEXIS 128 *; 2010 WL 1267114

CAROLINE JONES, Plaintiff, v. ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, KBI SUB INC., ASTRAZENECA AB, ASTRA USA, INC. and ASTRAZENECA PLC, Defendants.

Notice: THIS OPINION HAS NOT BEEN RELEASED FOR PUBLICATION. UNTIL RELEASED, IT IS SUBJECT TO REVISION OR WITHDRAWAL.

Disposition: [*1]

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Judges: Joseph R. Slights, III, J.

Opinion by: Joseph R. Slights, III

Opinion

MEMORANDUM OPINION.

SLIGHTS, J.

I.

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

The Court's decision in *Scaife* naturally served as the backdrop of the motion *subjudice.* Given the outcome of that case, it is not surprising that the plaintiff in this case, Caroline Jones, went [*3] to great lengths to distinguish her case from *Scaife.* AZ, of course, argued that this case was distinguishable from *Scaife* only to the extent that it presented an even stronger case for *Daubert* exclusion of the specific causation expert.

After carefully reviewing the record and the parties' extensive briefing, the Court agrees with Ms. Jones that she (and her expert) have presented a case factually distinguishable from *Scaife* in several significant

[1] 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993).

[2] *See generally Scaife v. Astrazeneca Pharm., LP*, 2009 Del. Super. LEXIS 216, 2009 WL 1610575 (Del. Super. June 9, 2009) (holding that plaintiff's specific causation expert had not offered a sufficiently reliable opinion to pass muster under *Daubert*).

respects. Nevertheless, notwithstanding these distinguishing characteristics, the specific causation opinions offered by her expert have much in common with those offered in *Scaife,* particularly with regard to the methodology, or lack thereof, employed by both experts to reach their respective conclusions. Like the specific causation expert in *Scaife,* Ms. Jones' expert failed to articulate the methodology she employed to reach her specific causation opinion in a manner that would allow the Court meaningfully to exercise its *Daubert* gatekeeping function. Although repeatedly pressed to do so at deposition, the expert simply refused to expand the explanation of her methodology beyond her mantra that she had read "everything" relating to the **[*4]** case and had applied her extensive training and experience to consider these materials and reach the conclusion that Seroquel(R) had caused Ms. Jones to develop Type II diabetes. Without more, this evidence does not satisfy Ms. Jones' burden under *Daubert* to prove the reliability of her expert's opinions. Consequently, AZ's Motion *In Limine* To Exclude Medical Causation Testimony of Dr. Susan Zweig must be **GRANTED.** And because Ms. Jones lacks sufficient competent evidence to create a genuine issue of fact regarding a *prima facie* element of her claims (proximate cause), AZ's Motion for Summary Judgment must also be **GRANTED.**

II.

A. Caroline Jones

Ms. Jones is a 22-year old woman from Boston, Massachusetts who has been diagnosed at various times in her medical history with mental health issues. In November, 2003, when Ms. Jones was sixteen years old, a nurse practitioner prescribed Seroquel(R), a so-called atypical anti-psychotic medication developed and manufactured by AZ, to treat Ms. Jones' anxiety, depression and insomnia. [3] Ms. Jones remained on Seroquel(R) until approximately April, 2004. She alleges that, as a result of her exposure to Seroquel(R), she developed Type II diabetes, first **[*5]** detected by an elevated blood glucose reading in July, 2005.

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

Ms. Jones was at some increased risk for developing Type II diabetes prior to her exposure to Seroquel(R). [6] For instance, the record suggests that there was a family history of diabetes which, according to the American Diabetes Association's consensus statement, "is strongly associated with Type 2 diabetes in children." [7] She smoked, exercised little, at times ate poorly and was (at least medically speaking) overweight. [8] Her last recorded weight prior to starting on Seroquel(R) was 143 lbs. [9] There are no recorded weights during the time she took Seroquel(R). Ms. Jones, however, reports gaining as much as 20 lbs while on the drug. [10] The next recorded weight, 140 lbs, was taken on November 10, 2004, approximately five months after Ms. Jones stopped taking Seroquel(R). [11] By June, 2005, more

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

[4] *See* Appendix to **[*6]** AZ's Opening Brief in Support of its Motion *In Limine* To Exclude Medical Causation Testimony of Dr. Susan Zweig (Tr. ID. 27885601) Ex. C at 99 [hereinafter DX]; Ex. F at 60, 129, 174-75; Ex. G at 114-18.

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

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

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

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

[9] DXM.

[10] PX 7 at 63-64.

[11] DX D.

than a year post-Seroquel(R), she weighed 172 lbs. [12]

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

B. Susan Zweig, M.D.

Ms. Jones has designated Susan Zweig, M.D., as her specific **[*8]** causation expert. Dr. Zweig is an endocrinologist with a busy private practice in New York City. She received her medical degree from the Sackler School of Medicine of Tel Aviv University in 1997, and completed her internship and residency at the Columbia University hospital system in New York in 2000. She completed a fellowship in Endocrinology at the Beth Israel Medical Center, Albert Einstein College of Medicine, and is Board Certified in Internal Medicine and Endocrinology, Metabolism and Diabetes. In addition to her private practice, Dr. Zweig is on the faculty of the New York University School of Medicine. She has authored a chapter in a medical text book on PCOS, and has engaged in and published results from diabetes-related research. [15] AZ has acknowledged that Dr. Zweig is highly qualified to render expert opinions regarding diabetes, and the Court agrees. The outcome of this motion will not turn on the expert's qualifications.

1. Dr. Zweig's Report

On September 19, 2008, Dr. Zweig issued an eleven page expert report in which she summarized her experience, her review of Ms. Jones' medical records and history, and her "assessment" of the case. [16] In her "assessment," **[*9]** she identified common risk factors for diabetes, a disease which she acknowledged affects approximately 8% of Americans (around 24 million people) and is a "major cause of morbidity and mortality in the United States." [17] She described the criteria for diagnosing diabetes. She then referred generally to the "many studies showing that a cause of [Type II diabetes] is the use of atypical antipsychotics, such as Seroquel." [18] In this regard, Dr. Zweig referred specifically to unidentified epidemiological studies that, according to her review, support an association between atypical antipsychotics and weight gain and diabetes. [19] Later, she referred specifically to studies that discuss weight gain as a "well-documented metabolic side effect with atypical antipsychotics." [20]

Turning specifically to Ms. Jones, Dr. Zweig concluded unequivocally that Ms. Jones does not have PCOS. [21] Her opinion with respect to whether Ms. Jones suffered from Type II diabetes, however, was less certain. She stated that "[i]nitially it was difficult to make a strict diagnosis of diabetes mellitus." She then went on to refer to an undocumented glucose tolerance **[*10]** test disclosed to her by Ms. Jones that "indicated type 2 diabetes," and she confirmed that the reported reading from that test "is in diabetic range." [22]

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

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[12] DX N.

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

[14] *See* PX 3 at 74.

[15] DX Q at 1-2.

[16] *See generally id.*

[17] *Id.* at 4.

[18] *Id.* at 5.

[19] *Id.*

[20] *Id.* at 7.

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

[22] DX Q at 6.

[23] *Id.*

her report. [24] In particular, she made no effort to rule out other causes for the weight gain she believed occurred in Ms. Jones while on Seroquel(R).

After discussing generally the health risks posed by diabetes, Dr. Zweig offered her conclusion that "Ms. Jones's Seroquel use significantly **[*11]** contributed to her development of diabetes." [25] She acknowledged that "the time between ingestion of a drug and commencement of a disease is not absolute definitive evidence of causation," but then went on to conclude that, in this case, "the time sequence is certainly persuasive proof that Seroquel was a substantial contributing factor." [26] She determined that the mechanism by which Ms. Jones developed diabetes was her weight gain, presumably while taking Seroquel(R). According to Dr. Zweig, the diagnosis of diabetes was made more difficult in Ms. Jones because she was taking medication (Metroformin) for an incorrectly diagnosed condition (PCOS) that masked her symptoms and made her blood glucose levels lower than they otherwise would have been without the medication. [27]

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

> The preceding report was based on my review of Caroline Jones's records including but not limited to her doctor's and psychiatrist's progress notes, lab reports, pharmacy notes, phone interview with the patient, and a review of depositions [unspecified]. My opinions were made based on my many years of medical **[*12]** training including, my fellowship studies in endocrinology at Beth Israel Medical Center, Albert Einstein College of Medicine, my work on many research projects, publications, and essays [unspecified] that were directly related to metabolism and diabetes, the numerous journals, lectures, conferences and seminars with which I'm involved on a regular basis [unspecified], and literature that I read for this case [again, unspecified]. [28]

[24] *Id.* at 7.

[25] *Id.* at 8.

[26] *Id.*

[27] *Id.*

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

2. Dr. Zweig's Deposition

Dr. Zweig's deposition comprises 446 pages and was clearly taken with an eye toward *Daubert* motion practice. After briefly reviewing her experience, and how she became involved in this litigation, Dr. Zweig discussed in great detail the criteria she employs to diagnose diabetes. She then turned to the diagnosis of diabetes in Ms. Jones and confirmed that the medical records do not reveal a clear diagnosis of diabetes but do confirm that she was being treated for the disease. [29] She attributed the ambiguity in the medical records to the fact that "not everybody practices the way we do here." [30] Dr. Zweig relied upon her conversation with Ms. Jones, including Ms. Jones' description of the glucose tolerance test that appears **[*13]** nowhere in the medical records, to clarify the medical picture and ultimately to conclude that Ms. Jones, in fact, has diabetes. [31]

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

The substance of Dr. Zweig's opinion, for the most part, remained unchanged from her report to her deposition.

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

[30] *Id.* at 100.

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

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

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

[34] PX **[*14]** 19 at 10-11.

[35] Zweig Dep. 114, 117.

She continued in her belief that Ms. Jones' medical presentation justified a diagnosis of diabetes. [36] She also continued in her belief that Ms. Jones presented virtually no risk factors for diabetes prior to her exposure to Seroquel(R). She reiterated her view that the medical literature "overwhelming[ly]" supported an association between exposure to Seroquel(R) and the development of diabetes. [37] With regard to the mechanism by which Seroquel(R) caused diabetes, however, Dr. Zweig's opinion changed dramatically from her report to her deposition. [38] In her report, Dr. Zweig subscribed to the theory the Seroquel(R) caused patients, including Ms. Jones, to gain weight which, in turn, put the patient at higher risk of developing Type II diabetes. This is what she believed occurred to Ms. Jones, at least as of the time she disclosed her specific causation opinion in her report. [39] In her deposition, however, when confronted with medical records she had not seen before which revealed that Ms. Jones weighed the same in November, 2004 (months after **[*15]** stopping Seroquel(R)) as she did when she began taking Seroquel(R) in November, 2003, she conceded that she could not conclude that weight gain from Seroquel(R) had caused Ms. Jones to develop Type II diabetes. [40] Having abandoned the weight gain theory, [41] Dr. Zweig at deposition moved on to a theory that Seroquel(R) had a "direct effect" on the body's metabolism making the body more susceptible to diabetes. [42] When pressed to explain the basis of her "direct effect" theory, Dr. Zweig was unable to point to any supporting literature and ultimately retreated for support to the temporal proximity of Ms. Jones' alleged diabetes diagnosis to her exposure to Seroquel(R). [43]

As might be expected in a *Daubert*-driven deposition, much of the discussion focused on Dr. Zweig's methodology in formulating her opinions. The deposition discussion of methodology was particularly important in this case since Dr. Zweig provided no indication whatsoever in her report regarding the process(es) she followed to review the materials that had been supplied to her, including the medical records, medical literature, and scientific studies, or the means by which she **[*17]** assimilated this information in order to reach her specific causation opinions. At deposition, she repeatedly explained that she believed her methodology was "inherent in the report" or "inherent in how I practice medicine and interpret medical data." [44] When asked to explain the methodology that was inherent in her report, she testified that she had not followed a "differential diagnosis" or "differential etiology" approach and that her "methodology doesn't have one specific name." [45] When pressed to offer specifics regarding her methodological approach, time and again Dr. Zweig repeated simply that she had "put everything [or "it all"] together" to construct the foundation of her opinion, and then applied her training and experience to formulate the opinions themselves. [46]

In apparent hopes of piercing through the repeatedly vague explanations of her methodology, the questions at deposition frequently directed Dr. Zweig to offer specifics in the medical records, medical literature, scientific studies, or clinical **[*18]** trials that either she relied upon in formulating her specific causation opinion or that would otherwise support her opinions. All to no avail - - Dr. Zweig consistently explained(often

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

[37] *Id.* at 154.

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

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

[40] Zweig Dep. 204 (when shown the medical record documenting the November 2004 weight, Dr. Zweig acknowledged "[t]his actually **[*16]** does not look familiar to me"), 210 ("Q: So, if she weighed 140 pounds in November of 2004, you couldn't draw the conclusion that Seroquel caused diabetes from weight gain alone; is that fair? A: I'd say that's likely fair.").

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

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

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

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

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

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

apologizing) that she was not prepared at deposition to discuss specifics and that she would have to "get back to [counsel]" after reviewing additional information or re-reviewing what had already been supplied to her. [47] Her lack of memory made exploring her methodology practically impossible. [48]

III.

AZ contends that Dr. Zweig's opinion is inadmissible under *Daubert* for several reasons: (1) she failed to articulate any reliable methodology by which she reached her opinions; (2) she failed to identify a verifiable mechanism by which Seroquel(R) caused Ms. Jones to develop Type II diabetes; (3) she improperly relied upon the temporal connection between Ms. Jones' exposure to Seroquel(R) and her **[*19]** development of Type II diabetes; (4) she failed reliably to rule out other causes of Ms. Jones' diabetes; and (5) she failed to make a reliable diagnosis of diabetes.

Ms. Jones responds that Dr. Zweig's methodology was more than adequate to pass muster under *Daubert*. First, she argues at some length that her case is factually distinguishable from *Scaife* in significant respects that make the outcome there unjustified here. Specifically, Ms. Jones argues that, unlike the plaintiff in *Scaife*, when she began taking Seroquel(R) she was not otherwise predisposed to develop Type II diabetes. Thus, when Dr. Zweig considered the specific causation question in this case, her analysis was not confounded by other risk factors that may alone have caused Ms. Jones to develop diabetes. And, according to Ms. Jones, Dr. Zweig systematically considered all known risks for Type II diabetes in the context of Ms. Jones' medical presentation at the time she began taking Seroquel(R) and specifically ruled out those risks as contributing factors in Ms. Jones' development of Type II diabetes. Notwithstanding her expert's deposition testimony in which Dr. Zweig apparently retreated from her initial views regarding **[*20]** the mechanism of injury, Ms. Jones contends that Dr. Zweig has consistently maintained that Seroquel(R) caused Ms. Jones' weight to spike which, in turn, caused her to develop diabetes. This opinion, according to Ms. Jones, is well supported in the medical literature. Finally, Ms. Jones argues that Dr. Zweig diagnosed her diabetes in the same manner, and using the same criteria, as she would employ in her own medical practice.

IV.

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

> [O]ur scepticism of such compensated advocacy is high and we no longer rest on the mere proper credentials of the expert witnesses or even on being satisfied as to the general relevancy of the expert's opinion. The basis of the opinion must have "good grounds" when judged by experts in the same general field as the witness. The Trial Judge must determine whether the reasoning and methodology is valid by the professional standards of the scientific, professional, or business field of the expert. And the Trial Judge must determine whether the expert's reasoning or methodology can be applied **[*21]** to the facts at issue. The burden is a heavy one and one that will tax even the best Trial Judges, a hearty breed who pride themselves as decision-making pragmatists in the field of battle. But there can be no question that the burden has been imposed. [50]

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

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

[48] *See, e.g., id.* at 106-09, 125, 127, 131, 134, 136, 142-43, 145, 149, 156-57, 169-71, 174, 179-80, 184, 186, 194, 201-02, 215-16, 224-25, 227-33, 239, 257-58, 274-76, 316-17, 331-32, 337, 343-47 (counsel's frustration over the expert's lack of recall discussed), 348, 369, 379-80, 397, 401, 403.

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

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

[51] *See Daubert,* 509 U.S. at 579, 589 n.7 (the United States **[*22]** Supreme Court's seminal decision announcing the trial court's responsibilities under the Federal Rules of Evidence to scrutinize the qualifications, methodology, and ultimate conclusions of the expert and characterizing this exercise as the court's "gatekeeping" function). *See also* D.R.E. 104(a) (identical to its Federal counterpart, this rule requires the Court to determine preliminarily such matters as the "qualification of a person to be a witness" and "the admissibility of evidence").

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

Boiled to its essence, *Daubert* requires the Court to answer two fundamental questions before admitting expert testimony: (1) is **[*23]** the testimony relevant?; and (2) is the testimony reliable? [53] The party offering the testimony bears the burden of establishing both prongs of the *Daubert* analysis, i.e., relevancy and reliability, by a preponderance of the evidence. [54]

The parties here have focused on the "reliability" component of *Daubert's* mandated inquiry. The reliability of the expert's opinion obviously depends, in part, upon her competency within her field of expertise, i.e., the expert must be qualified to render the opinions she intends to offer at trial. [55] In addition, by referring specifically to "scientific, technical or other specialized knowledge," Delaware Rule of Evidence 702 implicitly requires "a grounding [of the opinion] in the methodology and procedures" of the proffered expert's specialized discipline. [56] And the reference to "knowledge" in Rule 702 "connotes more than subjective belief or unsupported speculation." [57]

Certain factors may guide the Court's analysis of the "reliability" of the expert's testimony, including "'testing, peer review, error rates, and 'acceptability' in the **[*24]** relevant scientific community.'" [58] These factors, however, are neither exclusive nor exhaustive. The Rule 702 review is a "'flexible one,'" [59] and the "gatekeeping inquiry must be tied to the particular facts" [60] Regardless of its ingredients, the key to the "reliability" inquiry is to ensure that "an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." [61]

Before turning to the analysis, the Court must address one additional preliminary matter - the adequacy of the *Daubert* hearing conducted in this case. *Daubert* instructs: "[when f]aced with a proffer of expert [] testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to: (1) scientific knowledge that **[*25]** (2) will assist the trier of fact to understand or determine a fact at issue." [62] "And, with that statement, the so-called *Daubert* hearing was born." [63] *Daubert* did not, however, set the parameters for the evidentiary process it had created. Confusion among the circuits followed. It was not until *Kuhmo Tire* that the Court definitively addressed whether a full evidentiary hearing is required before the Court can adequately perform its gatekeeping function. It is not. [64] A full evidentiary hearing must be conducted only if "special circumstances" warrant. [65] Otherwise, it is sufficient if the Court considers the expert's report, the expert's

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

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

[54] *Id.*

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

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

[57] *Id.*

[58] *M.G. Bancorporation*, 737 A.2d at 521 (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999)).

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

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

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

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

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

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

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

deposition testimony, and any supporting affidavits. [66]

Here, the Court offered to conduct a *Daubert* hearing but the parties declined the invitation. Instead, the parties agreed that Dr. Zweig's report and deposition **[*26]** were sufficient to allow the Court to perform its gatekeeping function with regard to Dr. Zweig's opinions. [67] Although the Court ultimately has found Dr. Zweig's report and deposition testimony to be lacking in the detail necessary to allow Ms. Jones to sustain her *Daubert* burden, the Court is satisfied that the process by which the parties submitted the *Daubert* issue to the Court was more than adequate to facilitate the Court's gatekeeping responsibility. [68]

V.

A. This Case Is Factually Distinguishable From *Scaife*

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

At the **[*27]** outset, the Court agrees with Ms. Jones that her case does present several significant factual differences from *Scaife*. First, the record suggests that Ms. Jones apparently was at a lower relative risk of developing Type II diabetes than Ms. Scaife prior to their respective exposure to Seroquel(R). In this regard, Ms. Jones is substantially younger than Ms. Scaife; she was just a teenager when she began taking Seroquel(R). [69] The risk of developing Type II diabetes increases with age. [70] In addition, while Ms. Jones was overweight and, therefore, at increased risk for developing diabetes, unlike Ms. Scaife, she was not morbidly obese. [71] Morbid obesity is a prime risk factor for Type II diabetes. [72] Next, when read in a light most favorable to Ms. Jones, the record reveals that, unlike Ms. Scaife, Ms. Jones had a less significant family history of diabetes - another prime risk factor for developing the disease. [73] Both were smokers, a known risk factor, although Ms. Jones smoked less and for a shorter duration. [74]

Ms. Jones also asserts that Dr. **[*28]** Zweig, as compared to the expert in *Scaife*, was generally more familiar with Ms. Jones and her medical history at the time she rendered her specific causation opinion in this case. Again, the Court concurs, although the Court must note that the expert in *Scaife* set the bar quite low. [75] As noted above, Dr. Zweig's level of familiarity with the specifics of Ms. Jones' medical records (and the specifics of medical and scientific literature/data upon which she relied) during her deposition was less than impressive. [76] Ms. Jones also points to the fact that Dr. Zweig's opinions have not been subjected to the extensive revisions and alterations that plagued her counterpart's opinions in *Scaife*. Again, the Court agrees. In *Scaife*, plaintiff's expert appeared to alter or amend her opinion with every new *Daubert* ruling in the Federal multi-district Seroquel(R) litigation, or with every new attack mounted against her opinion by AZ. [77] Aside from the arguable revision of her mechanism of injury opinion, which appears to have morphed from a "weight gain" to "direct metabolic effect" theory, Dr. Zweig's

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[66] *Id.*

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

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

[69] PX 19 at 2.

[70] DX KK at S15.

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

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

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

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

[75] *See Scaife,* 2009 Del. Super. LEXIS 216, 2009 WL 1610575, at *4-6 (noting certain deficiencies in Dr. Peck's ability to recall plaintiff's medical history).

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

[77] *See Scaife,* 2009 Del. Super. LEXIS 216, 2009 WL 1610575, at *17 n.250.

opinions have otherwise remained consistent from initial report through deposition. This too **[*29]** distinguishes Ms. Jones' case from *Scaife*.

Having reviewed the factual distinctions presented by this case and *Scaife,* the Court must acknowledge that Ms. Jones has presented a stronger case for the admission of her expert's specific causation opinion than was presented in *Scaife*. Her medical profile presents fewer of the known risk factors for Type II diabetes. And her specific causation expert has not presented the "moving target" that epitomized the specific causation opinions in *Scaife*. Nevertheless, as discussed below, while **[*30]** these factual distinctions cannot be ignored, they do not overcome the lack of evidence of Dr. Zweig's methodology and the ultimate revelation of her opinion as mere *ipse dixit.*

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

Before turning to Dr. Zweig's specific causation opinion, the Court first addresses AZ's contention that Dr. Zweig's diagnosis of diabetes for Ms. Jones is not supported by the medical evidence and is the product of flawed methodology. Specifically, AZ questions Dr. Zweig's considerable reliance upon Ms. Jones' report of an oral glucose tolerance test, not noted in her medical records, and her report of results which were suggestive of Type II diabetes. [78] But for the elevated blood glucose level, Dr. Zweig admitted that she would be unable to reach a diagnosis of diabetes. [79] AZ also points to significant evidence in the record suggesting that Ms. Jones has never been diagnosed with diabetes by any of her treating physicians. [80] For her part, Dr. Zweig testified that she made her diagnosis of Type II diabetes based on criteria and information she regularly relies upon in her own medical practice. She routinely relies upon history provided to her by her patients **[*31]** and had no reason to discount Ms. Jones' report of the oral glucose tolerance test. [81] Moreover, she notes that while Ms. Jones' medical records may not reveal a formal diagnosis of diabetes, they do reveal that Ms. Jones' doctors were treating her for diabetes. [82]

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

> Because the objectives, functions, subject matter and methodology of hard science vary significantly from those of the discipline of clinical medicine, as distinguished from research or laboratory medicine, the hard science techniques or methods that became the '*Daubert* factors' [sic] generally are not appropriate for assessing the evidentiary reliability of a proffer of expert clinical medical testimony . . . . Simply stated, a diagnosis in the practice of clinical medicine "is not an exact science **[*32]** . . . . [P]hysicians make probabilistic judgments on a day-to-day basis, even when they can supplement a patient's history and physical [examination] with the results of extensive laboratory tests." *Daubert* is not an easy fit under these circumstances. And courts must be mindful of this dynamic when subjecting clinical medical testimony . . . to a *Daubert* analysis. [83]

Dr. Zweig testified persuasively that she employed the same criteria, with the same level of scrutiny, to diagnose Ms. Jones as she does for patients she treats in her clinical practice. She found Ms. Jones to be a reliable medical historian and her medical records to be reflective of ongoing treatment for the disease. [84] She squared her diagnosis with criteria from the American Diabetes Association. [85] The Court is satisfied that this record offers sufficient evidence to carry plaintiff's burden under *Daubert* to establish that **[*33]** Dr. Zweig made a reliable diagnosis of Type II diabetes for Ms. Jones.

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

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

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

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

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

[82] *Id.* at 254.

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

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

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

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

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

Specifically with regard to an expert's opinion on specific causation, **[*34]** this Court has held that "[c]ausation of injury must be supported by more than the word of [the expert]." [88] And an expert's impressive qualifications alone will not serve as a license to express *ipse dixit* rather than properly supported expert opinion. [89] Stated differently, "'an expert's failure to explain the basis for an important inference mandates an [sic] exclusion of his or her opinion.'" [90]

At oral argument on the *Daubert* motion, counsel for Ms. Jones explained Dr. Zweig's methodology at great length, including her systematic incorporation of the general causation literature, and her methodical review and exclusion of each of the known risk factors for Type **[*36]** II diabetes, leaving only Seroquel(R) as the sole cause of Ms. Jones' Type II diabetes. [91] According to counsel, Dr. Zweig then addressed the mechanism by which Seroquel(R) caused diabetes in Ms. Jones. Notwithstanding Dr. Zweig's deposition testimony, in which she moved from her "weight gain" to a "direct metabolic effect" mechanism of injury theory, counsel maintained that Dr. Zweig has remained constant in her view that Seroquel(R) caused Ms. Jones to gain weight which, in turn, caused her to develop Type II diabetes. [92]

If the record supported counsel's adaptation of Dr. Zweig's methodology, then the Court might well have grounds to open the gates of the courtroom to Dr. Zweig. It does not. Dr. Zweig was asked over and over again to explain her methodology in sufficient detail to allow AZ to test it, and to allow the Court to exercise its gatekeeping responsibilities. Each time she declined to walk through her methods, and instead repeatedly intoned that she had reviewed all of the information she was supplied, applied her training and experience, and "put it all together." She specifically denied employing a "differential diagnosis" methodology **[*37]** and declined to characterize her approach beyond her abstruse "put it all together" explanation. [93] Apparently frustrated by the

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

[87] *Gen. Elec. Co. v. Joiner,* 522 U.S. 136, 146, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997).

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

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

[90] *Gen. Motors Corp.,* 981 A.2d at 529 n.14 (quoting *Hudgens v. Bell Helicopters,* 328 F.3d 1329, 1344 (11th Cir. 2003)). *See also Scaife,* 2009 Del. Super. LEXIS 216, 2009 WL 1610575, at *19 n.279 ("In the absence of this explanation, the expert's opinion becomes nothing more than inadmissible *ipse dixit,* and the fact finder is left to accept it *ad authoritatum.*") (citing *Alderman v. Clean Earth,* 2007 Del. Super. LEXIS 125, 2007 WL 1334565, at *7 (Del. Super. Apr. 30, 2007) and *Minner,* 791 A.2d at 851); **[*35]** *Quinn v. Woerner,* 2006 Del. Super. LEXIS 424, 2006 WL 3026199, at *3 (Del. Super. Oct. 23, 2006) ("While it is not the function of the Court to make a determination as to whether Dr. McCracken's conclusions are correct by weighing the objective evidence, the Court is charged with the duty to ensure that her opinions are based on some articulable and objective standard. In reaching her opinion, however, Dr. McCracken failed to articulate her use of 'methods and procedures of science' to reach her conclusion. The methodology actually employed by Dr. McCracken consisted of 'looking back' in an effort to determine what could be included and excluded as a cause for Quinn's pre-term delivery . . . . As applied here, however, this 'looking back' method does not impart an objective methodology used to reach a medical conclusion and, as such, does not meet the reliability threshold required by *Daubert.* Dr. McCracken's opinion is, therefore, unreliable.").

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

[92] *Id.* at 98.

[93] Zweig Dep. 403-08. The Court acknowledges that Dr. Zweig's specific causation opinion has recently been admitted in a Seroquel(R) case in New Jersey. The Court notes, however, that in addition to the fact that New Jersey applies

press for more specifics, Dr. Zweig ultimately exclaimed "[l]isten, I'm a double board certified physician. I don't need to, you know, justify how I make a decision." [94] Actually, in order for plaintiff to carry her burden under *Daubert,* this is precisely what Dr. Zweig "needed" to do. [95]

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

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

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

VI.

Based on the foregoing, AZ's Motion *In* ***[*41]*** *Limine* To Exclude The Medical Causation Medical Testimony of Dr. Susan Zweig and Motion for Summary Judgment must be **GRANTED.**

IT IS SO ORDERED.

/s/ Joseph R. Slights, III

Joseph R. Slights, III

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an admissibility standard that is more "relaxed" than the *Daubert* or the *Frye v. United States,* 293 F. 1013 (D.C. Cir. 1923), "general acceptance" standards, the decision in *Baker v. AstraZeneca Pharm., L.P.,* Docket No. L-1099-07, slip. op. (N.J. Super. Feb. 5, 2010), is also distinguishable because the court there specifically found that Dr. Zweig employed a differential diagnosis methodology to reach her opinions in the case. *Baker,* Docket No. L-1099-07, slip. op. at 11. As stated, Dr. Zweig specifically renounced that methodology here. *See* Zweig **[*38]** Dep. 403-08. *See also Scaife,* 2009 Del. Super. LEXIS 216, 2009 WL 1610575, at *15 n.232 (explaining that the "differential diagnosis" (or "differential etiology") methodology involves the expert considering and ruling out potential causes of a medical condition in order to reach a conclusion regarding causation by the process of scientific elimination).

[94] Zweig Dep. 272.

[95] *See Joiner,* 522 U.S. at 146-47 (expert must demonstrate that she employed a methodology to "fit" her conclusions within the data she reviewed); *Gen. Motors Corp.,* 981 A.2d at 529 (holding that "an expert's methodology must be not only reliable intrinsically but also reliably applied to the facts of the specific case"). *See also United States v. Fredette,* 315 F.3d 1235, 1239-40 (10th Cir. 2003) ("[A] witness 'relying solely or primarily on experience' must 'explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.'")(quoting Fed. R. Evid. 702)); *Daubert v. Merrell Dow Pharm., Inc.,* 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. **[*39]** Under *Daubert,* that's not enough.").

[96] *See Daubert,* 509 U.S. at 595-96 ("**Vigorous** cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." (emphasis added)). *See also Bowen v. E.I. du Pont de Nemours & Co., Inc.,* 2005 Del. Super. LEXIS 239, 2005 WL 1952859, at *11 (Del. Super. June 23, 2005) **[*40]** (noting that cross examination cannot adequately test *ipse dixit*).

[97] *See, e.g., Kent v. Massachusetts,* 437 Mass. 312, 771 N.E.2d 770, 777 (Mass. 2002) ("In addition to being the cause in fact of the injury, the plaintiff must show that the negligent conduct was a proximate or legal cause of the injury as well.")(citing *Wallace v. Ludwig,* 292 Mass. 251, 198 N.E. 159, 161 (Mass. 1935)).

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

Hon. Jessica R. Mayer, J.S.C.
Superior Court of New Jersey
Middlesex County Courthouse
56 Paterson Street
New Brunswick, New Jersey 08903
732-519-3642

IN RE:
RISPERDAL/SEROQUEL/ZYPREXA LITIGATION

This Order Applies to:

Ted Baker, et al. v. AstraZeneca Pharmaceuticals LP, et al.
Docket No. MID-L-1099-07-MT

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION:
MIDDLESEX COUNTY

CIVIL ACTION
CASE CODE 274

ORDER

THIS MATTER coming before the Court, by way of motion filed on behalf of defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP, ("AstraZeneca") seeking to exclude the testimony of Susan Zweig, M.D.; and the court having reviewed the written submissions on behalf of the parties; and the court having conducting a hearing pursuant to N.J.R.E. 104 on January 8, 2010; and the court having set forth its reasons in a written memorandum dated February 5, 2010; and good cause having been shown:

IT IS on this 5th day of February, 2010,

ORDERED as follows:

1. Defendants' motion to exclude the testimony of Dr. Zweig is denied for the reasons set forth in the written memorandum dated February 5, 2010.

2. A copy of this Order shall be posted by the court within seven (7) days of the date of this Order.

JESSICA R. MAYER, J.S.C.

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.

MIDDLESEX COUNTY COURT HOUSE
P.O. Box 964
NEW BRUNSWICK, NEW JERSEY 08903-964

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendants' Motion to Exclude the Testimony of Dr. Susan Zweig

Baker v. AstraZeneca Pharmaceuticals, LP, et al., Docket No. L-1099-07
(In re: Risperdal/Seroquel/Zyprexa Litigation, Case No. 274)

For Defendants: Jane Fugate Thorpe, Esq., Alston & Bird LLP

For Plaintiffs: Paul J. Pennock, Esq., Weitz & Luxenberg, P.C.

Dated: February 5, 2010

The court issues this opinion in response to the motion filed by Defendants AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra US Inc., Zeneca Inc., and KBI Sub Inc.'s (collectively "Defendants") to Exclude the Specific Causation Testimony of Susan Zweig, M.D. ("Dr. Zweig"). Upon carefully considering the legal memoranda, exhibits (including the expert's written report), deposition testimony, Rule 104 hearing, and relevant case law, the court determines that Defendants' Motion to Exclude the Specific Causation Testimony of Dr. Zweig is **DENIED.**

Analysis

To establish liability, a plaintiff must, among other things, prove through expert testimony that his or her use of Seroquel® caused him or her to develop diabetes. Kemp ex rel. Wright v. State, 174 N.J. 412, 417 (2002). Hence, the expert testimony of Dr. Zweig is essential

in establishing that the injuries of Mr. Ted Baker ("Plaintiff" or "Mr. Baker") are caused by his use of Seroquel®.

The court, in addressing Defendants' motions to exclude the expert testimony of Plaintiff's case specific expert, Dr. Zweig, reviewed Dr. Zweig's expert report, deposition transcript and related exhibits, her testimony during the evidentiary hearing pursuant to N.J.R.E. 104, along with the briefs of the parties and the arguments of counsel. Having reviewed these materials, the court will not exclude the specific causation testimony of Dr. Zweig.

It should be noted that Dr. Zweig is highly qualified – she is board certified in Endocrinology, Metabolism, and Diabetes; is a diplomat of the American Board of Internal Medicine; graduated from Lehigh University and the Sackler School of Medicine, Tel Aviv University; completed her residency at St. Luke's Roosevelt Hospital Center at Columbia University; has completed subspecialty training in Endocrinology at Albert Einstein College of Medicine/Beth Isreal Medical Center in New York; is a partner at the Concorde Medical Group, specializing in Endocrinology and Internal Medicine; is an attending physician at New York University Medical Center; and received several awards and honors, including being named a Pfizer Scholar of Endocrinology.[1] While, on its own, Dr. Zweig's qualifications are not dispositive as to scientific reliability and methodology, such qualifications add considerable soundness to her opinions.

The court finds that the underlying data relied upon by Dr. Zweig is generally followed by experts in the field of endocrinology and that her opinions are based on proper scientific methodologies. In particular, Dr. Zweig's opinions, predicated on her own research and review of the available medical literature regarding Seroquel® and other atypical antipsychotics and

[1] Expert Report of Susan Zweig, M.D. ("Zweig Report"), p. 2, Appendix A.

their affect on diabetes, constitutes a sufficient basis for her to overcome Defendants' challenges.[2] Furthermore, Dr. Zweig reviewed Plaintiff's entire medical history, which included all of his records, medications, weight measurements, blood pressure readings, metabolic parameters, and laboratory tests.[3] Finally, Dr. Zweig reviewed the depositions of every witness in Plaintiff's case, which includes that of Plaintiff, his wife, their two sons, his prescribing psychiatrist, and his treating and prescribing physician.[4]

N.J.R.E. 702, which governs the admissibility of scientific expert testimony in New Jersey, provides that:

> [i]f 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, experience, training, or education may testify thereto in the form of a opinion or otherwise.
>
> [Ibid.][5]

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[2] Such literature includes consensus statements, reviews, case reports, observational studies, published and unpublished clinical trials, published literature regarding mechanism, published literature comparing the safety and efficacy of atypical versus typical antipsychotics, perspective studies including the CATIE study, Defendants' internal documents, and its communications with the United States Federal Drug Administration ("FDA") regarding Seroquel®. Zweig Report, p. 3.

[3] Deposition of Susan Zweig, M.D. ("Zweig Dep.") at 363:9-16.

[4] Zweig Report, p. 4.

[5] While the New Jersey version of Rule 702 largely tracks the original version of Federal Rule of Evidence 702, it does not incorporate the language added to the Rule in 2000, which permits an expert to testify only "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 methods reliably to the facts of the case." The federal rule was amended for the purpose of codifying the principles of Daubert v. Merrell Dow Pharms., 509 U.S. 579 (1993) (outlining the federal requirements for scientific expert testimony).

In January 2009, the Jersey Supreme Court Committee on the Rules of Evidence explicitly declined to amend N.J.R.E. 702, Testimony by Experts, to follow the 2000 amendment to F.R.E. 702. 2007 – 2009 Report of the Supreme Court Committee on the Rules of Evidence, p. 3. The Committee reasoned that, "if the exact language of F.R.E. 702 was adopted, since the federal rule was intended to incorporate Daubert, it would create the erroneous impression that the Daubert standard governed the admission of expert testimony in New Jersey." Ibid. "Further, the Committee was concerned that was concerned that New Jersey judges would be too inclined to be guided by the federal case law interpreting F.R.E. 702 and Daubert[,]" which they expressed "are sometimes overly restrictive in the admission of expert testimony, tending to exclude evidence that, under current New Jersey law, would be properly admitted as having a reliable basis. Ibid. (citing Edward K. Cheng & Albert H. Yoon, Does Frye or Daubert Matter? A Study of Scientific Admissibility Standards, 91 Va. L. Rev. 471, 473 (2005)).

Under N.J.R.E. 702, for an expert to be admitted:

> (1) the intended testimony must concern a subject matter that is beyond the ken of the average juror; (2) the field testified to must be at a state of the art such that an expert's testimony could be sufficiently reliable; and (3) the witness must have sufficient expertise to offer the intended testimony.
>
> [Creanga v. Jardal, 185 N.J. 345, 355 (2005) (quoting Landrigan v. Celotex Corp., 127 N.J. 404, 413 (1992)).]

Defendants challenge the second requirement in their motions to exclude the testimony of Plaintiff's specific causation expert, Dr. Zweig. Defendants contend that the specific causation testimony of Dr. Zweig is not sufficiently reliable in the field of endocrinology.

Although under the traditional Frye standard an expert's testimony had to be "generally accepted within the relevant scientific community," State v. Chun, 194 N.J. 54, 91 (2008); accord State v. Harvey, 151 N.J. 117, 169-70 (1997) (citing Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923)), New Jersey applies a more relaxed standard. Rather than requiring expert testimony to be generally accepted in the profession, "a scientific theory of causation that has not yet reached general acceptance may be found to be sufficiently reliable if it is based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field." Rubanick v. Witco Chem. Corp., 125 N.J. 421, 449 (1991); accord Kemp, supra, 174 N.J. at 430.[6]

Hence, even if an expert's opinion is not generally accepted in the scientific community, it can still be admitted as evidence, so long as the methodology and reasoning underlying that opinion is sound. See Clark v. Safety-Kleen Corp., 179 N.J. 318, 337 (2004). The Supreme Court of New Jersey has specifically noted that, in the case of pharmaceutical litigation "in

[6] This is particularly applicable to "tort cases involving novel theories of causation offered to connect a plaintiff's injuries to a drug or a toxic substance." Biunno, Current N.J. Rules of Evidence, comment 3 on N.J.R.E. 702 (2008); see Kemp, supra, 174 N.J. at 430-31 (involving defective vaccine); Landrigan, supra, 127 N.J. at 413 (involving exposure to asbestos); Rubanick, supra, 125 N.J. at 449 (involving exposure to a chemical).

which a medical cause-effect relationship has not been confirmed by the scientific community but compelling evidence nevertheless suggests that such a relationship exists," such evidence may be admissible. Kemp, supra, 174 N.J. at 430.

Under this standard, a trial judge must assess "the soundness of the proffered methodology and the qualifications of the expert." Id. at 426 (quoting Rubanick, supra, 125 N.J. at 454) (internal quotations omitted). The role of the trial court is to "determine whether the expert's opinion is derived from a sound and well-founded methodology that is supported by some expert consensus in the appropriate field." Id. at 427 (quoting Landrigan, supra, 127 N.J. at 417) (internal quotations omitted). An expert's methodology can be properly supported by "professional journals, texts, conferences, symposia, or judicial opinions accepting the methodology," and "[c]ourts also may consider testimony from other experts in the field who use similar methodologies." Ibid.

Flaws in an expert's causation testimony are not fatal. Even where an expert draws only a tenuous relationship between "the studies and literature on which [the expert] relied and [his] opinions. . . ," the expert's causation testimony may still be admitted, so long as the expert sufficiently provides the "why and wherefore" underlying his conclusions. Hisenaj v. Kuehner, 194 N.J. 6, 24 (2008) (reinstating the trial judge's admission of defense's biomechanical engineer expert's testimony despite plaintiff's contention that the expert employed flawed methodology; defendant's expert allegedly relied on studies consisting of subjects that were dissimilar from plaintiff in age and physical characteristics, overlooked other factors that would play a causal role in producing plaintiff's alleged chronic injury, and conducted no independent testing of his own); see also State v. Townsend, 186 N.J. 473 (2006) (quoting Rosenberg v. Tavorath, 352 N.J. Super. 385, 401 (App. Div. 2002)). As the Supreme Court of New Jersey

emphasized, flaws in an expert's reasoning may be explored by opposing counsel on cross-examination, but such flaws do not compel exclusion of an expert opinion under N.J.R.E. 702. Hisenaj, supra, 194 N.J. at 24; see also State v. Dreher, 302 N.J. Super. 408, 464 (App. Div.) ("[e]xpert testimony should not be excluded merely because it fails to account for some condition or fact that the opposing party considers relevant[;]" the opposing party "may, on cross-examination, supply the omitted conditions or facts and ask the expert if his or her opinion would be changed by them"), certif. denied, 152 N.J. 10 (1997), cert. denied, 524 U.S. 943 (1998).

Moreover, the Supreme Court of New Jersey has indicated that "[a]lthough trial courts are expected to act as gatekeepers to the proper admission of expert testimony, trial courts [are not expected] to investigate *sua sponte* the extent to which the scientific community holds in esteem the particular analytical writings or research that a proponent of testimony advances as foundational to an expert opinion." Hisenaj, supra, 194 N.J. at 16; see also Landrigan, supra, 127 N.J. at 414 (noting that "the trial court should not substitute its judgment for that of the relevant scientific community"); Rubanick, supra, 125 N.J. at 451 (noting that a court should not "directly and independently determine as a matter of law that a . . . complex scientific methodology is sound"). Instead, "[t]he court's function is to distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs." Landrigan, supra, 127 N.J. at 414.

As to the particular methodology employed by Dr. Zweig in rendering her opinion regarding the specific causal link between Plaintiff's use of Seroquel® and his alleged medical harm, Dr. Zweig employed a differential diagnosis. In Creanga, the Supreme Court of New Jersey determined that, as a general matter under the Kemp standard, differential diagnosis is a

sufficiently reliable methodology for an expert to employ when rendering a specific causation opinion as to a particular patient, and is thus admissible if properly conducted. 185 N.J. at 355. In the context of pharmaceutical products liability litigation, the Creanga Court noted that, while "[d]ifferential diagnosis testimony has been permitted in New Jersey on the causation issue in toxic tort cases," Id. at 356-57 (citing Lapka v. Porter Hayden Co., 162 N.J. 545, 557 (2000); Rubanick, supra, 125 N.J. at 450-51), "such testimony [is not] limited to only toxic torts," Ibid. (citing Lapka, supra, 162 N.J. 545; Rubanick, supra, 125 N.J. 421). Indeed, the Creanga Court noted that the use of differential diagnosis has been broadly accepted at the federal level, as demonstrated by the United States Court of Appeals for the Third Circuit in In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 758 (3d Cir. 1994) cert. denied, 1513 U.S. 1190 (1995) (recognizing that "differential diagnosis generally is a technique that has widespread acceptance in the medical community").[7] Creanga, supra, 185 N.J. at 357 (accepting differential diagnosis as an adequate methodology in light of its "widespread acceptance . . . in the medical community, the recognition of the technique in state and federal courts, and its compatibility with our rules of evidence and prior case law").

In order for an expert's differential diagnosis to be properly employed, the expert must "'rule[] in' all plausible causes for the patient's condition by compiling 'a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration.'" Id. at 356 (quoting Clausen v. M/V New Carissa, 339 F.3d 1049, 1057 (9th Cir. 2003)). In doing so, the expert must look to "which of the competing causes are generally capable of causing the patient's

[7] See also Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) (stating that differential diagnosis "has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results") (citations omitted); Heller v. Shaw Indus., Inc., 167 F.3d 146, 154-55 (3d Cir. 1999)(noting that "differential diagnosis consists of a testable hypothesis, has been peer reviewed, contains standards for controlling its operation, is generally accepted, and is used outside of the judicial context") (internal citations and quotations omitted).

symptoms or mortality." Ibid. (quoting Clausen, supra, 339 F.3d at 1057-58) (internal quotations omitted). Thus, if an expert fails to "rule[] in a potential cause that is not so capable or fails to consider a plausible hypothesis that would explain the condition," that expert's differential diagnoses has not been properly conducted. Ibid. (quoting Clausen, supra, 339 F.3d at 1058) (internal quotations and emphasis omitted). As such, the expert's flawed methodology would be scientifically unreliable, and thus, inadmissible.

In addition, "after the expert 'rules in' plausible causes, the expert then must 'rule out' those causes that did not produce the patient's condition by engaging in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case." Ibid. (quoting Clausen, supra, 339 F.3d at 1058) (internal citations and quotations omitted). However, an expert "need not conduct every possible test to rule out all possible causes of a patient's [injury], so long as he or she employed sufficient diagnostic techniques to have good grounds for his or her conclusion." Ibid. (quoting Heller v. Shaw Indus., Inc., 167 F.3d 146, 156 (3d Cir. 1999) (internal quotations omitted); see also In re Paoli R.R. Yard PCB Litig., supra, 35 F.3d at 761.

Furthermore, when "ruling out" other factors, the expert need not establish that the alleged cause of a plaintiff's injuries is the only single contributing factor to those injuries. There can be other contributing causes that the expert accepts as contributing in some way to a plaintiff's injuries. Where there are concurrent causes of an injury, the Louisiana courts look to whether the conduct in question was a "substantial factor" in bringing about the injury. Perkins v. Entergy Corp., 782 So. 2d 606, 611-12 (La. Ct. App. 2001), rev'd sub nom., Bujol v. Entergy Servs., 922 So. 2d 1113 (La. 2004), aff'd on reh'g, 922 So. 2d 1113 (La. 2006) (citing Jones v. Hawkins, 731 So.2d 216, 220 (La. 1999)). The substantial factor test is the "preferred test for

causation when there are multiple causes." Id. at 612 n.4 (citing Boykin v. La. Transit Co., 707 So.2d 1225, 1232 n.10 (La. 1998)). In establishing causation under Louisiana's substantial factor test, the court looks to "whether each of the multiple causes played so important a role in producing the result that responsibility should be imposed upon each item of conduct, even if it cannot be said definitely that the harm would not have occurred 'but for' each individual cause." Id. at 612 (citing Graves v. Page, 703 So.2d 566, 570 (La. 1997)); see also Trahan v. State, Dep't of Transp. & Dev., 536 So.2d 1269, 1272 (La. Ct. App. 1988)); Frank L. Maraist & Thomas C. Galligan, Louisiana Tort Law, § 4-3 at 86-88 (1996) (noting that the substantial factor test operates well in cases where there are multiple possible causes-in-fact, but the fact-finder may not be able to conclude that the accident most likely would not have happened but for any one of the causes)). Hence, even where there are other causative factors at hand, a plaintiff's specific causation expert must show only that the plaintiff's use of, or exposure to, a particular product or substance was a significant factor in causing the plaintiff's injuries. Id. at 612. Accordingly, the expert need not absolutely eliminate every possible risk factor as a contributing cause when employing a differential diagnosis, ibid., so long as the expert eliminates alternative hypothesis that the product at issue was not a substantial contributing factor to the plaintiff's injury.

However, an expert's specific causation opinion in not per se admissible "simply by uttering the phrase 'differential diagnosis . . . .'" Creanga, supra, 185 N.J. at 357 (quoting Carlson v. Okerstrom, 675 N.W.2d 89, 105 (Neb. 2004)). To be admitted, "the expert witness must demonstrate what he or she did and that the proper diagnostic procedures were followed when performing the diagnosis." Id. at 357-58 (citing Clausen, supra, 339 F.3d at 1057 (stating that "federal courts, generally speaking, have recognized that a *properly conducted* differential diagnosis is admissible"). "In rejecting the alternative hypotheses, the expert must use 'scientific

methods and procedures' and justify an elimination on more than 'subjective beliefs or unsupported speculation.'" Id. at 358 (quoting Claar v. Burlington N. R.R. Co., 29 F.3d 499, 502 (9th Cir. 1994)). Thus, a court should exclude evidence if an expert "utterly fails . . . to offer an explanation for why the proffered alternative cause" was ruled out. Ibid. (quoting Clausen, supra, 339 F.3d at 1058) (internal quotations omitted); see also Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 202 (4th Cir. 2001)).

Turning to the substance of Defendants' arguments concerning Dr. Zweig's testimony, Defendants do not dispute that Dr. Zweig is rendering an opinion regarding "scientific, technical, or other specialized knowledge [that] will assist the trier of fact to understand the evidence or to determine a fact in issue," or that she is "qualified as an expert by knowledge, skill, experience, training, or education." N.J.R.E. 702. Because Dr. Zweig's intended testimony clearly concerns "a subject matter that is beyond the ken of the average juror," and she has "sufficient expertise to offer the intended testimony," the court will focus on whether Dr. Zweig's testimony is "sufficiently reliable." See Creanga, supra, 185 N.J. at 355 (quoting Landrigan, 127 N.J. at 413).

Defendants raise a number of specific contentions on the issue of whether Dr. Zweig's testimony is sufficiently reliable under New Jersey law. Defendants argue that the testimony of Dr. Zweig should be excluded because Dr. Zweig: (1) failed to articulate her overall methodology and did not employ any scientifically reliable methodology in rendering her opinion; (2) failed to use scientific methods and procedures to justify ruling out or eliminating other possible causes of Plaintiff's diabetes, including his obesity; (3) employed no scientifically reliable methodology with respect to her review of the medical literature; (4) has no scientific or factual basis for her specific causation methodology under either a "weight-gain" or "direct" effect theory of diabetes causation; and (5) unduly relied on temporality in rendering her opinion.

First, Defendants' allege that Dr. Zweig failed to articulate her overall methodology and did not employ any scientifically reliable methodology in rendering her opinion. However, as discussed below, Dr. Zweig, in her expert report and her deposition testimony, articulated, in detail, her overall methodology and employed the accepted method of differential diagnosis in rendering her opinion. See Id. at 355 (determining that differential diagnosis is a sufficiently reliable methodology for an expert to employ when rendering a specific causation opinion as to a particular patient, and is thus admissible if properly conducted).

Although Defendants complain that Dr. Zweig did not explicitly use the term "differential diagnosis" to describe her methodology, an expert is not required to use the term "differential diagnosis" in order to employ such a methodology properly. For example, the Creanga Court made a point of devaluing an expert's mere use of the phrase "differential diagnosis," and instead, stressed the importance of the expert "demonstrate[ing] what he or she did and that the proper diagnostic procedures were followed when performing the diagnosis." Id. at 357-58. Thus, the fact that Dr. Zweig neglected to describe her method with exact and specific terminology is neither dispositive nor relevant in the court's review of her methodology. Instead, it is far more important that Dr. Zweig employed and articulated a methodology that is consistent with a differential diagnosis; i.e., that she properly ruled in and ruled out Plaintiff's potential risk factors through the use of sufficient diagnostic techniques.

Defendants' second main contention – that Dr. Zweig failed to use scientific methods and procedures to justify ruling out or eliminating other possible causes of Plaintiff's diabetes, including his obesity – addresses the more crucial issue of whether Dr. Zweig demonstrated proper diagnostic procedures when performing the diagnosis. On this point, Defendants point to deposition testimony that indicates that Dr. Zweig was unable to quantify specifically the relative

contribution of Plaintiff's various pre-existing diabetes risk factors, such as his chronic obesity,[8] and other factors that Dr. Zweig acknowledges as contributing to Plaintiff's diabetes.[9] However, experts are not necessarily required to specifically quantify the relative contribution of all of a patient's risk factors. Instead, in performing a differential diagnosis, an expert must, through proper diagnostic procedures, rule in all plausible causes for the patient's condition and ruled out the causes that did not produce his or her condition, see id. at 356-8, and consequently reject alternative hypothesis based on the scientific methods and procedures employed. Here, Dr. Zweig properly ruled in all plausible causes for the patient's condition and ruled out the causes that did not produce Plaintiff's condition, concluding that Plaintiff's use of Seroquel® was a substantial contributing factor to his diabetes.

For example, Defendants rely on deposition testimony, where Dr. Zweig stated that Plaintiff's obesity was a "contributing but not the substantial factor in his development of diabetes," but agreed that she "didn't rule it out."[10] The fact that Dr. Zweig found Plaintiff's obesity to be a contributing factor does not render her opinion unreliable. It was not necessary for Dr. Zweig to eliminate every possible risk factor by determining that every other factor did not, in any way, contribute to Plaintiff's diabetes. Perkins, supra, 782 So. 2d at 612. Rather, it was only necessary for Dr. Zweig to employ sufficient diagnostic techniques in support of her conclusion as to the most likely cause of Plaintiff's diabetes. See Creanga, supra, 185 N.J. at 356 (quoting Heller, supra, 167 F.3d at 156; Clausen, supra, 339 F.3d at 1058) (internal citations and quotations omitted). Although Dr. Zweig agreed that she did not "rule it out," it is clear from her deposition testimony that Dr. Zweig was not making a legal conclusion as to her methodology,

[8] Zweig Dep. at 56:18-578, 195:13-20.
[9] Id. at 343:10-346:13, 350:3-10, 358:17-359:15.
[10] Zweig Dep. at 343:9-17.

but instead, was using the term to explain that she did not completely eliminate obesity as a contributing factor. That being the case, Dr. Zweig is not required to explain away all other contributing factors to Plaintiff's diabetes in order to conduct a proper differential diagnosis. The fact that Dr. Zweig confused the colloquial or medical use of that term for the legal use of the phrase "rule out" does not render her testimony unreliable. Dr. Zweig explained that, despite Plaintiff's obesity, she still considered Plaintiff's use of Seroquel® to be a substantial contributing factor in causing Plaintiff's diabetes.

Defendants also raise issue with Dr. Zweig's various admissions that obesity, generally, has a strong link to diabetes.[11] The court finds that this is merely an admission to a fact that is practically worthy of judicial notice. Had Dr. Zweig *denied* that obesity was a potential cause of Plaintiff's diabetes, it would have been a failure to consider a plausible hypothesis that would explain the condition and, therefore, render Dr. Zweig's differential diagnosis insufficient. See Ibid. (quoting Clausen, supra, 339 F.3d at 1058). Dr. Zweig's admission demonstrates, instead, that she properly conducted a differential diagnosis by ruling in obesity as a plausible cause for Plaintiff's diabetes. See Creanga, supra, 185 N.J. at 356 (quoting Clausen, supra, 339 F.3d at 1057). Dr. Zweig was required to look to all competing causes that are generally capable of causing diabetes, which includes obesity. See Ibid. (quoting Clausen, supra, 339 F.3d at 1057-58) (internal quotations omitted). Thus, Dr. Zweig's admission that obesity, in general, has a

[11] Zweig Dep. at 129:19-24 (There is an epidemic of diabetes in this country and an epidemic of obesity); 130:8-11 (The prevalence of diagnosed diabetes is increasing, particularly among obese individuals); id. at 88:11-18 (Most patients with diabetes are obese); id. at 59:24-60:17 (Diabetes "is a progressive condition"); id. at 206:10-207:3 (the risk of diabetes increases with the duration of obesity); id. at 56:18-21 (Mr. Baker was obese "long before" he started taking Seroquel®); id. at 235:17-25 (obese for "about 10 years" before Seroquel® and overweight for 11 years before that); id. at 204:8-17 (Obesity is a "very high risk factor" for diabetes); id. at 58:21-59:11 (There is "high chance" and that "it's probable" that somebody who has obesity will develop diabetes); id. at 205:20-23 ("The epidemic of obesity is the number one reason for an increasing number of patients with type 2 (adult onset) diabetes"); id. at 206:10-207:3 (obesity "accounts for a high percentage or the vast majority" of diabetes cases); id. at 381:18-23 (Scientific studies on attributable risk show that, in people who have a BMI of 35.5 and develop diabetes, 95 percent will have developed the diabetes because of their obesity"); id. at 386:8-14 (same); id. at 368:23-369:1 (Mr. Baker had a BMI of 35.5 before starting Seroquel®).

strong link to diabetes does not render unreliable her ultimate conclusion that Plaintiff's use of Seroquel® substantially contributed to his diabetes.

In ruling in and ruling out other risk factors, Dr. Zweig began by seeking out and reviewing numerous articles related to the "incidence, prevalence . . . pathophysiology, [and] etiology" of diabetes, and relied also on her own clinical experience in examining the risk factors Mr. Baker had for developing diabetes.[12] She ultimately concluded that these risk factors were not substantial contributing factors to Mr. Baker's development of diabetes while taking Seroquel®.[13] Dr. Zweig explained in her report, deposition, and N.J.R.E. 104 hearing that certain risk factors, such as Plaintiff's past history of smoking and drinking, could be ruled out as contributors to his diabetes. She ruled out these factors by confirming, through various medical records and deposition testimony, that Mr. Baker quit drinking and smoking in 1993 and 1990 respectively,[14] and then translated the amount of time and packs Mr. Baker reported smoking into pack years, for which she calculated a relative risk by Rimm 1995's guidelines.[15] Dr. Zweig found both of these risks to be very low,[16] thus ruling out Mr. Baker's history of smoking and alcohol consumption as risk factors that contributed to his development of diabetes.

Dr. Zweig also considered hypertension, in light of Mr. Baker's medical history of hypertension, and concluded that the available data were unclear as to whether or not hypertension was a risk factor for diabetes, and that Plaintiff's hypertension was not severe.[17]

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[12] Zweig Dep. at 52:22-25, 52:15-18.

[13] Ibid.

[14] Id. at 352:9-353:12; see also Zweig Report, p. 12; N.J.R.E. 104 Hearing of Susan Zweig, M.D. ("Zweig Kemp Hearing") at 60:23-61:22.

[15] Rimm EB et al., Prospective study of cigarette smoking, alcohol use, and the risk of diabetes in men, BMJ, 310:555-559 (March 1995).

[16] Zweig Report, p. 12-13; Zweig Dep. at 352:9-19; Zweig Kemp Hearing at 60:23-61:22.

[17] Zweig Report, p. 15-16; Zweig Dep. at 138:7-9; 148:15-20; Zweig Kemp Hearing at 60:13-16 ("I don't think the evidence for hypertension is very clear. I think certainly it may identify a risk, but it's not clear that it

Dr. Zweig testified that because of this conflicting information and data, she did not believe that Mr. Baker's hypertension was the cause of his diabetes.[18] Defendants pointed out during Dr. Zweig's N.J.R.E 104 hearing that the American Heart Association, the American Diabetes Association, and the American Association of Clinical Endocrinologists have all stated that hypertension is a risk factor for diabetes.[19] Dr. Zweig explained that, although she agrees with these organizations in that hypertension is a "risk factor" in the sense that it "identifies patients who are at risk for diabetes[,]" the literature is unclear as to whether it actually causes diabetes.[20] While Plaintiff's history of hypertension is a valid point of contention on Defendants' part, Dr. Zweig's rejection of this risk factor goes to the weight of Dr. Zweig's testimony, but does not render her testimony scientifically unreliable.

Dr. Zweig also testified that she considered Plaintiff's obesity to be a contributing factor but not *the* substantial contributing factor to his development of diabetes.[21] In doing so, Dr. Zweig analyzed whether Plaintiff's Body Mass Index ("BMI") enhanced his risk for diabetes to the degree asserted by Defendants and rejected Defendants' reliance on a 15-year-old study, which employed a small sample size and resulted in a large variance within the confidence interval.[22] Dr. Zweig further renounced the study because the group that most closely corresponded to Plaintiff's pre-Seroquel® BMI of 35.5 incorporated all BMIs above 35, including morbidly obese people with BMIs up to 50, thus, in Dr. Zweig's opinion, skewing the results.[23] Dr. Zweig further found that these study results were not consistent with her clinical

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causes diabetes"); id. at 81:17-19 ("[i]n my opinion, hypertension may identify people who are at risk, but it may or may not be a contributing cause"); Zweig Report, p. 15 (Plaintiff's hypertension was not severe).

[18] Zweig Dep. at 190:11-16; Zweig Kemp Hearing at 60:13-16, 81:17-19.

[19] See Zweig Kemp Hearing at 78:15-82:6.

[20] Id. at 82:10-12.

[21] Zweig Dep. at 343:9-15.

[22] Id. at 563:9-566:17.

[23] Id. at 567:11-568:12.

experience,[24] and also observed that many people suffer from obesity but never develop diabetes.[25]

Dr. Zweig found it significant that Plaintiff had been obese for many years but had maintained non-diabetic glucose readings.[26] She opined that this indicates that Plaintiff's obesity did not completely eclipse the Plaintiff's use of Seroquel® as a substantial factor in causing his diabetes.[27] Although Plaintiff had been obese since 1991, Dr. Zweig explained that his sixteen glucose values prior to initiating Seroquel® treatment showed him to have normal glucose regulation until he began Seroquel® on February 12, 2001. Further supporting Dr. Zweig's conclusion was the fact that Plaintiff gained over 17 pounds in the first three months of Seroquel® therapy and had a triglyceride reading of 701 mg/dL five months after Seroquel® therapy.[28] Dr. Zweig cited articles in her report and during her deposition, including Black 2005[29] and Resnick 2000,[30] which supported her opinion that additional weight gain increases the risk for glucose dysregulation and diabetes in obese patients.[31] In addition, Dr. Zweig used Ford 1997 to support her assertion that there is a 4.5 percent (3.3 – 5.9) change in risk for every kilogram of change in weight.[32] Dr. Zweig's conclusion is based on information that is of the type regularly relied upon by similar experts. As such, any shortcomings in these articles go to the weight of the evidence and can be addressed by defense counsel on cross-examination.

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[24] Id. at 566:18-567:1.

[25] Id. at 27:13-17; 25:4-8.

[26] Id. at 187:10-17.

[27] Ibid.

[28] Id. at 187:10-23, 373:10-17, 231:13-23.

[29] Black E., et. al., Long-term influences of body-weight changes, independent of the attained weight, on risk of impaired glucose tolerance and Type 2 diabetes, 22 Diabetic Medicine 1199–1205 (2005).

[30] Resnick HE, et al., Relation of weight gain and weight loss on subsequent diabetes risk in overweight adults, J. Epidemiol Community Health 54:596-602 (2000).

[31] Zweig Dep. at 399:1-400:14; Zweig Report, p. 16-19.

[32] Zweig Report, p. 18; Ford ES, et al., Weight Change and Diabetes Incidence: Findings from a National Cohort of US Adults, American Journal of Epidemiology, 146(3):214-222 (1997).

Dr. Zweig also ruled in Plaintiff's age, sedentary lifestyle, and psychiatric illness as contributing factors to Mr. Baker's development of diabetes.[33] She then determined that, in light of Plaintiff's other factors and the degree to which Plaintiff's Seroquel® use contributed to his diabetes, even though Plaintiff's age, sedentary lifestyle, and psychiatric illness contributed in part to his diabetes, they were not substantial contributing causes.

In addition, although Plaintiff's triglyceride levels before Seroquel® may have been a contributing factor to his diabetes,[34] Dr. Zweig testified that they were not the cause of diabetes in this patient.[35] For example, Dr. Zweig identified one value taken before Seroquel® – 226mg/dL taken on June 16, 2000 – to be "elevated" but, based on her clinical experience, not particularly high.[36] Additionally, Dr. Zweig testified that Mr. Baker had one pre-Seroquel® HDL cholesterol value that was "slightly low" on June 16, 2000 (38 mg/dL), but concluded that this low pre-Seroquel® HDL did not negate Plaintiff's Seroquel® use as a substantial factor in causing his diabetes.[37] Also, Dr. Zweig noted that Plaintiff's hyperlipidemia worsened while he was taking Seroquel®, citing a 701 mg/dL triglyceride measurement taken on July 12, 2001 and a 306 mg/dL measurement taken on March 25, 2002 that far exceeded any pre-Seroquel® triglyceride reading.[38] Overall, Dr. Zweig testified that the only risk factor she believed to be applicable would be obesity, but concluded that it was not the only cause of his diabetes, given the absence of evidence indicating diabetic readings for so many years.[39] Based on her research

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[33] Zweig Dep. at 344:3-346:13; Zweig Kemp Hearing at 74:22-7623 (discussing age as a risk factor); id. at 76:25-77:12 (discussing sedentary lifestyle as a risk factor); id. at 90:25-91:4 (same); id. at 77:13-20 (discussing psychiatric illness as a risk factor);

[34] Triglyceride levels are a factor in establishing metabolic syndrome, which increases the risk of diabetes. Zweig Report, p. 14.

[35] Zweig Dep. at 347:7-14.

[36] Id. at 349:13-350:2.

[37] Id. at 184:6-185:19.

[38] Id. at 189:12-15; see also Zweig Report, p. 14.

[39] Id. at 183:4-7.

and analysis, Dr. Zweig concluded that Plaintiff's other risk factors did not overwhelm his use of Seroquel® as a substantial factor in causing his diabetes.

While Dr. Zweig may not have conducted every possible test to rule out all possible causes of a plaintiff's diabetes, this is not required under New Jersey law. See Creanga, supra, 185 N.J. at 356 (quoting Heller, supra, 167 F.3d at 156 (internal quotations omitted). The court finds that Dr. Zweig, in rejecting alternative hypotheses, used scientific methods and procedures and justified her eliminations on more than subjective beliefs or unsupported speculation. Id. at 358 (quoting Claar, supra, 29 F.3d at 502). Citing statistical evidence of the links between Seroquel® use and diabetes, and taking into consideration Plaintiff's other risk factors, Dr. Zweig offered an explanation as to why she ruled out other alternative causes. Ibid. (quoting Clausen, supra, 339 F.3d at 1058) (internal quotations omitted). Therefore, the court finds that Dr. Zweig used proper scientific methods and procedures to justify ruling out or eliminating other possible causes of Plaintiff's diabetes, including his obesity. In this regard, Dr. Zweig's testimony is sufficiently reliable to be admitted into evidence.

Next, the court considers Defendants' contention that Dr. Zweig employed no scientifically reliable methodology with respect to her review of the medical literature. Defendants cite numerous examples of how, during her deposition, Dr. Zweig was unable to explain the details of the literature that she reviewed or any inconsistencies as to which literature she relied on.[40] Further, Defendants argue that Dr. Zweig's only identified methodology for

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[40] See, e.g., Zweig Dep. at 51:5-16; id. at 53:24-54:25 ("Again, I read so many articles it is hard for me to remember off the top of my head a specific example of each specific question."); id. at 223:14-23 ("There are studies. I can't tell you something off the top of my head."); id. at 235:10-16 ("I can't tell you off the top of my head."); id. at 326:13-327:7 ("I can't off the top of my head remember specifically each one right now. I did a lot of stuff in the last couple of days."); id. at 536:24-537:18 (unable to recall whether the results of the only placebo-controlled clinical trial she relied on was statistically significant).

Defendants also claim that Dr. Zweig could cite no reliable scientific data showing an increased risk of diabetes from Seroquel® at the low doses ingested by Plaintiff. Id. at 466:7-9 (agreeing "that a 75 to 100-milligram dose of Seroquel is a low dose"). In addition, Defendants point out that, although she claimed in her Report that she

assessing the scientific literature was "look[ing] at the information in totality."[41] Defendants also complain that Dr. Zweig selectively applied standards that were patently inconsistent and contradictory.[42] Moreover, Defendants claim that Dr. Zweig refused to acknowledge Plaintiff's pre-existing hypertension as a diabetes risk factor in this case, even though she acknowledged that the American Association of Clinical Endocrinologists (of which she is a member) recognizes hypertension as a diabetes risk factor.[43] Defendants contrast this with the fact that, although "there are articles that have different conclusions" as to causal links between Seroquel® and diabetes, Dr. Zweig claims that there was "overwhelming" evidence that Seroquel® causes diabetes.[44] Defendants add that Dr. Zweig lacked any methodology for assessing the consistency

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"considered evidence regarding dose-response," Zweig Report, p. 4., Dr. Zweig admitted that the data from the two low-dose studies she exclusively relied upon (Buse and Feldman), Zweig Dep. at 477:21-24 (two low dose epidemiological studies); id. at 490:22-491:3 (no other epidemiological studies), showed that Mr. Baker "was not at an increased risk of diabetes" from his low dose of Seroquel®, id. at 479:9-14 (Buse); id. at 488:16-23; id. at 490:10-21 (Feldman, same). Further, Defendant alleges that Dr. Zweig lacked any scientific methodology for assessing the consistency of the literature she purported to rely on, depicting Dr. Zweig's scientific process as merely asking who wrote it, who is paying for the study, what kind of study is it, and interpreting it. Id. at 167:23-168:18; see also id. at 66:25-167:22.

[41] Zweig Dep. at 164:21-165:16. Defendants add that Dr. Zweig repeatedly attempted to avoid providing specific information by referring generality to the "totality" of her review. See, e.g., id. at 32:24-33-22 ("I am looking at the totality of what is going on with this patient."); id. at 57:15-58:2, 164:21-165:16, 189:3-15, 350:18-22, 360:4-16, 364:11-365:3 ("we have to look at his medical condition in totality"). Dr. Zweig eventually agreed that her "method" was to "put the totality of the picture together." Id. at 436:21-24.

[42] Defendants point out that Dr. Zweig testified that Plaintiff had impaired fasting glucose after taking Seroquel® based on his glucose measurement of 108, which is considered "pre-diabetes" or "impaired fasting glucose" by the American Diabetes Association ("ADA"), id. at 292:14-20, yet refused to consider Plaintiff's pre-Seroquel® fasting glucose measurement of 107 to be "impaired fasting glucose," even though she admitted that it would be "impaired glucose by ADA criteria," id. at 305:24-308:12, 353:13-19; see also id. at 251:13-252:2 (agreeing that "if Mr. Baker had impaired fasting glucose" before taking Seroquel® that "[i]t is likely over a period of time that he may have developed diabetes" even "without taking the Seroquel®").

[43] Id. at 137:22-138:9 (asserting that "the relationship to hypertension is not quite clear. There is conflicting information"); see also 147:22-148:20 ("the literature was not quite clear to me").

[44] Id. at 458:14-459:2; see also 157:21-158:17 (acknowledging that ADA/APA Consensus Statement identifies the Seroquel® studies as "less clear" because "[s]ome studies show an increased risk for diabetes while others do not").

or for evaluating the strengths and weaknesses of the studies.[45] And, again, Defendants attack Dr. Zweig for failing to ascribe a specific term to her method of researching the literature.[46]

Plaintiff, to the contrary, maintains that Dr. Zweig's opinion is derived from a sound and well-founded methodology that is supported by expert consensus in the appropriate field. See Kemp, supra, 174 N.J. at 427. Plaintiff explains that Dr. Zweig's opinion is properly supported by her review of the following materials: epidemiologic evidence, clinical trials, experimental evidence, review articles, and case reports. In addition to doing her own search on Medline, a "commonly used" program by physicians for researching literature on a particular medical quandary, Dr. Zweig also consulted textbooks, lectures or review courses, and previous notes she had on diabetes and the potential hyperglycemic and diabetogenic effects of Seroquel® and other antipsychotic medications.[47] These materials are the type of materials accepted under Kemp. Id. at 427 (experts can rely on "professional journals, texts, conferences, symposia, or judicial opinions accepting the methodology").

As to any inconsistent findings in the literature reviewed by Dr. Zweig, her final conclusion is admissible if a medical cause-effect relationship between Seroquel® use and diabetes has not been fully confirmed by the scientific community, so long as compelling evidence suggests that such a relationship exists. See Id. at 430. Dr. Zweig listed in her report, and discussed during her deposition, numerous articles, studies, and other literature that show such a causal link. Dr. Zweig, with the support of such literature, sufficiently provided the "why and wherefore" underlying her conclusion that Plaintiff's use of Seroquel® substantially

[45] In support of this, Defendants cite deposition testimony where Dr. Zweig was unable to, without having the studies in front of her, directly explain the flaws or limitations in 14 epidemiological studies. Id. at 504:21-505:2.

[46] Defendants note that Dr. Zweig got "the majority of articles" from Plaintiff's lawyers, id. at 591:10-15, and could not specify how she carried out her independent research, ibid.; see also id. at 41:10-44:9, 34:14-35:17.

[47] Id. at 41:14-42:4, 34:23-35:18; Zweig Report, Appendix B.

contributed to his diabetes. See Hisenaj, supra, 194 N.J. at 24. Purported flaws in Dr. Zweig's reasoning may be explored by defense counsel on cross-examination, but such flaws do not compel exclusion of her opinion. Id. at 24.

Further, any complaints that Defendants have with regard to Dr. Zweig's failure to account for a condition or fact that Defendants consider relevant can also be addressed during cross-examination. Dreher, supra, 302 N.J. Super. at 464. Such flaws in Dr. Zweig's opinion do not render Dr. Zweig's testimony inadmissible, but go to the weight of her testimony. See Ibid.; see also Hisenaj, supra, 194 N.J. at 16. It is not the court's role to determine if Dr. Zweig's testimony is irrefutable in its reasoning or supported by uncontestable facts. Rubanick, supra, 125 N.J. at 451. The court, based on the information presented, including Dr. Zweig's deposition testimony, written report, and N.J.R.E. 104 hearing, concludes that Dr. Zweig is not a "self-validating expert" who relies only on scientific terminology to "present unsubstantiated personal beliefs." See Landrigan, supra, 127 N.J. at 414. Therefore, the court finds that Dr. Zweig methodology is scientifically reliable with respect to her review of the medical literature.

Next, Defendants allege that Dr. Zweig has no scientific or factual basis for her specific causation methodology under either a "weight-gain" or "direct" effect theory of diabetes causation. To support her theory that Mr. Baker's weight gain of 17 pounds in the first few months of starting Seroquel® was "Seroquel® induced" weight gain that "substantially contributed to [Mr. Baker's] diabetes,"[48] Defendants' contend that Dr. Zweig did not explain how much of that weight gain was directly caused by Seroquel®, and did not explain how Plaintiff's medical records supported her weight gain theory.[49] In support thereof, Defendants

[48] Zweig Report, p. 8; Zweig Dep. at 436:1-24.

[49] Zweig Dep. at 441:13-442:19.

outline Plaintiff's history of weight fluctuation and obesity absent his use of Seroquel®.[50] Defendants add that Dr. Zweig did not provide any scientific support for the notion that a weight gain of 17 pounds, whether caused by Seroquel® or not, that is lost four months later contributes to the development of diabetes.[51] Additionally, Defendants take issue with Dr. Zweig's failure to point to anything in the medical records supporting her opinion that the "biological mechanisms that are independent of weight gain through which [Seroquel®] can cause diabetes in patients" occurred in Plaintiff's case.[52] And, although Dr. Zweig cited animal and *in vitro* studies showing support for such mechanisms, Defendants object to that fact that she does not perform animal studies in her practice and lacks the expertise to extrapolate from studies in rats or cells to human beings.[53]

In response to Defendants' criticism that Dr. Zweig does not postulate a sole mechanism by which Seroquel® causes diabetes, Plaintiff maintains that it would have been unreasonable for Dr. Zweig to identify with specificity the precise mechanisms by which Seroquel® causes diabetes because each of those mechanisms have yet to be definitively elucidated. According to Defendants' own Seroquel® warning label, "the mechanism of action of quetiapine is unknown,"[54] and Dr. Zweig concurred with that statement during her deposition.[55] Though

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[50] Defendants point out that Dr. Zweig was unable to offer any explanation for the undisputed facts that: Plaintiff gained 71 lbs from 1981 to 2001, prior to ever taking Seroquel®, id. at 371:5-12, Plaintiff gained 20 lbs in the seven months immediately prior to his first Seroquel® prescription, id. at 433:15-434:8, Plaintiff gained a total of only 1.7 lbs in the seven months immediately after first taking Seroquel®, id. at 433:24-434:3, 437:20-438:9, Plaintiff lost 16 of the 17 lbs he gained in his first year of Seroquel® prescription within months, id. at 437:20-438:9, Plaintiff gained 16 lbs after stopping Seroquel®, id. at 448:18-21, Plaintiff gained weight before, during, and after he was on Seroquel®, id. at 448:22-449:2, Plaintiff's weight went up and down before, during, and after he was on Seroquel®, id. at 449:7-15, and Plaintiff remained morbidly obese before, during and after the time that he was Seroquel®, id. at 449:2-6.

[51] Id. at 438:10-439:5.

[52] Zweig Report, p. 19.

[53] Zweig Dep. at 516:2-24 (stating that, in defense of her expertise regarding animal studies was that "certainly, you know, I did go to medical school. I am on faculty at a university and I know how to read studies that have animals in them.").

[54] Plaintiff Exhibit 11 (Seroquel 2009 Label).

unable to postulate the definitive mechanism by which Seroquel® caused Mr. Baker's diabetes, Dr. Zweig detailed five observable ways in which Seroquel® had a significant and serious metabolic effect on Plaintiff, including his rapid weight gain three months after beginning Seroquel® therapy,[56] his rapid weight loss two months after discontinuing Seroquel®,[57] his abnormally high triglyceride readings after ingesting Seroquel®,[58] his development of hyperglycemia and diagnosis of impaired glucose tolerance after beginning Seroquel®,[59] as well as intermittent dizziness while on Seroquel® that subsided when Plaintiff tapered or stopped

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[55] Zweig Dep. at 228:18-25.

[56] Id. at 375:15-16; 246:10-22, 440:2-7. Dr. Zweig explained that this 17 pound weight gain within three months after beginning Seroquel® was not comparable to any weight gain Plaintiff had experienced prior to his Seroquel® treatment, both in amount, time, and its metabolic effects on the body. Id. at 439:6-440:6. Further, Plaintiff explained, Dr. Zweig concluded that Mr. Baker's 17 pound weight gain in the first 90 days of his Seroquel® treatment, despite more activity and consistency in diet, was evidence that "a metabolic derangement ha[d] occurred in a patient who [was] taking a drug known to cause metabolic derangement." Id. at 438:20-439:5. Furthermore, Dr. Zweig relied on the literature previously mentioned, as well as the "general acceptance by the medical community" to conclude that "if you gain that amount of weight in a short amount of time, that is a very big difference than a slow gradual weight gain over a long period of time." Id. at 440:3-6.

[57] In her report, Dr. Zweig wrote that "[o]n November 24, 2006, [Plaintiff] was instructed to taper off of Seroquel®. His weight at the time was 237.8lbs. As of January 23, 2007, [Plaintiff's] weight had dropped to 216lbs." Zweig Report, p. 16; see also Zweig Dep. at 445:5, 445:24-446:18.

[58] Dr. Zweig pointed to two elevated triglyceride readings taken during the first year that Mr. Baker's Seroquel® was started (701 mg/dL on July 12, 2001 and 306 mg/dL on March 25, 2002), id. at 231:19-20; see also id. at 360:12-16; 364:2-8, which represented the highest triglyceride readings in Plaintiff's entire medical history, Zweig Report, p. 14; see also Zweig Dep. at 424:23-425:2.

[59] This supports Dr. Zweig's conclusion that Seroquel® was having a significant effect on his ability to "move the glucose into the cells to use for fuel," Zweig Dep. at 23:13-23, since his "level of glucose in the blood goes up" after beginning Seroquel® therapy, id. at 24:4-5.

Dr. Zweig testified that the numerous blood glucose levels she relied on included the 122mg/dL value taken at 8:17 a.m. on March 25, 2002, the 132 value taken at 8:09 a.m. on June 25, 2002, the 108 mg/dL and 117 mg/dL glucose values, as well as the 6.4% HbA1c, taken on July 22, 2002, the 147 mg/dL value indicated as a fasting lab taken at 9:25 a.m. on February 28, 2003, and the 175 mg/dL value taken at 8:28 a.m. on March 8, 2004 which, along with his elevated HbA1c on that date, was the basis of Plaintiff's diabetes diagnosis. Id. at 320:13-322:18; see Plaintiff Exhibit 1 (Lab Result, Overton Brooks VAMC records, p. 00072, 00070-00071, p. 00069).

In her report and at her deposition, Dr. Zweig also discussed general ways in which Seroquel® can cause hyperglycemic/diabetogenic effects independent of weight gain which are supported by scientific literature. Such mechanisms include "a blockade of glucose transport," Zweig Dep. at 230:4; see also Zweig Report, p. 19, as concluded in Dwyer 2003, "effects on insulin action metabolism," Zweig Dep. at 230:5-6; see also Zweig Report, p. 19, and "direct cellular effects in adipocytes," Zweig Dep. at 230:6-7; see also Zweig Report, p. 19, as demonstrated in Vestri 2007, "stimulation of glucagon secretion," Zweig Dep. at 230:7-8; see also Zweig Report, p. 19, suggested in Smith 2008, as well as epinephrine through "increase[d] sympathetic nervous system activity," Zweig Dep. at 230:8-9; see also Zweig Report, p. 19, as explained by Savoy 2008.

Seroquel®.[60] Plaintiff also points to scientific literature discussed by Dr. Zweig concerning the mechanism behind Seroquel® and its hyperglycemic/diabetogenic effects that can operate independent of weight gain.[61] Thus, in her report and through her deposition testimony, Dr. Zweig provided several possible mechanisms by which Seroquel® could be associated with diabetes and substantiated those mechanisms with factual and scientific support. The fact that Dr. Zweig did not put forth one single mechanism by which Seroquel® causes diabetes does not render her opinion scientifically unreliable.

Defendants' final assertion is that that Dr. Zweig unduly relied on temporality in rendering her opinion. While a reliance on temporality alone may not be enough to support an expert's causation opinion, see Schulman v. Male, 70 N.J. Super. 234, 240 (App. Div. 1961), an expert may properly consider temporality in rendering his or her opinion, especially where a causal link between the product and the alleged harm is supported scientifically and the patient develops symptoms only after encountering that product, see Creanga, supra, 185 N.J. at 359 (quoting Carlson, supra, 675 N.W.2d at 106). Here, Dr. Zweig's analysis was not a mere temporal relationship. Rather, she engaged in an extensive review and application of the relevant medical literature to Plaintiff's medical history.

[60] Id. at 445:5, 445:24-446:18, 231:19-20, 360: 12-16, 364:2-8, 320:13-322:18.

[61] Id. at 230:4-9.

Conclusion

Accordingly, the court finds that Dr. Zweig's testimony is sufficiently reliable because it is based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the field of endocrinology. Therefore, Defendants' Motion to Exclude General Causation Testimony of Dr. Zweig is **DENIED.**

JESSICA R. MAYER, J.S.C.

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December 29, 2004

Re: Vioxx Litigation

Dear Counselor:

While you are probably already familiar with Weitz & Luxenberg's groundbreaking work in asbestos litigation, please be aware that Weitz and Luxenberg is actively pursuing Vioxx cardiac and stroke injury cases, as well as injuries caused by Celebrex and Bextra. We are well situated to do so due to our extensive experience with pharmaceutical liability litigation and the fact that we have two offices in northern and southern New Jersey devoted primarily to pharmaceutical litigation, in addition to our main office in New York. We believe that the New Jersey Superior Court will be the most advantageous forum for the litigation of Vioxx claims. Set forth below is a detailed analysis of why we believe this so strongly. The analysis includes the key citations for your own review. If you would like, we would be happy to provide a packet of the pertinent cases and statutes cited since choice of forum is such a critical issue.

While an MDL is in formation, NJ state court is a far better venue for numerous reasons including speed of resolution, the standards of admissibility of the scientific evidence, a ruling forbidding *ex parte* interviews with treating doctors, the potential avoidance of the learned intermediary defense due to NJ law on direct marketing and a very liberal discovery statute of limitations that even includes wrongful death cases.

Merck is a New Jersey company so plaintiffs throughout the country can file their case in state court New Jersey with no risk of removal to federal court in accordance with 28 U.S.C. 1441(b). There has already been a "mass tort" court assigned to it (NJ Supreme Court appoints certain judges to supervise and try mass torts such as Diet Drugs, PPA, Hormone Replacement, and Vioxx). The Judge, Carole Higbee of Atlantic County has already issued several excellent decisions including a denial of *forum non conveniens* motions involving out of

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state Vioxx plaintiffs holding "NJ has a substantial interest in policing the conduct and protecting the interests of its citizen corporations, such as Merck. While it's unfortunate that Merck and other large corporations generate litigation, that is a burden that any largely industrial state like NJ has to bear in order to receive the benefits that those same industries provide....NJ has a greater interest in allegedly fraudulent action that may have been committed by one of its citizens."

Additionally, Judge Higbee ruled last week that Merck lawyers may not conduct any *ex parte* conversations with any plaintiffs' treating doctors. Judge Higbee relied upon the decision in our case in the PPA litigation *Smith v. American Home Products Corp.*, 372 N.J. Super. 105 (Law Div. 2003). As you know, if the drug company gets access to discuss the case *ex parte* with the doctors, there is great potential for poisoning the causation and learned intermediary testimony. Many federal districts do permit *ex parte* discussions so this is a huge advantage over the MDL.

Given the background incidence of heart attacks and strokes in the older population -- the typical plaintiff who would have been prescribed Vioxx -- we believe federal court is a perilous venue. While the general causation issue -- can Vioxx cause heart attack and stroke -- should be winnable in a *Daubert* hearing, federal courts could dismiss many cases because of the myopic *Daubert* decisions on specific causation where a doctor can not absolutely rule out all alternative causes. However, in New Jersey, neither *Daubert*, nor the general acceptance *Frye* test is applied. Instead, in *Rubanick v. Witco Chemical Corp.*, 125 N.J. 421 (1991), the New Jersey Supreme Court held that the trial court must not "directly and independently" determine the soundness even of the methodology, much less of the study itself. *Id.* at 451. Rather, the "critical determination is whether comparable experts accept the soundness of the methodology..." *Id.* The court explained the policy reasons behind this liberal outlook: because of the extremely high level of proof required before scientists will accept a new theory, and particularly because of the current inability of science to fully comprehend [carcinogenesis], plaintiffs in toxic-tort litigation, despite strong and indeed compelling indicators that they have been tortiously harmed by toxic exposure, may never recover if required to wait general acceptance by the scientific community of a reasonable, but as yet not certain, theory of causation." Id. at 434

Accordingly, the Court rejected the general acceptance test in favor of the more liberal standard of whether comparable experts accept the methodology.

New Jersey law also recognizes that a contributory cause can be a substantial factor even if it is only a small percentage at fault. The New Jersey Supreme Court has held that even a 5% responsibility was a sufficient basis for liability, *Stephenson v. R.A. Jones & Co.* 103 N.J. 194 (1986). Similarly, the New Jersey courts have upheld verdicts that both cigarette smoking and asbestos exposure smoking were concurrent and contributory causes . *Goss v. American Cyanamid*, 278 N.J. Super. 227, 346-348 (App. Div. 1994) Thus, even though a client may have underlying heart problems and be a smoker, Vioxx could still be deemed a substantial contributory factor. In many a federal court, the case would get dismissed at the *Daubert* stage just because the expert could not rule out the other contributory causes

New Jersey also has a very liberal statute of limitations - two years from discovery of injury *and* cause, *and* arguably, wrongdoing. This even applies to wrongful death cases. Indeed, in *Martinez v. Cooper Hospital*, 161 N.J. 45 (2000) the New Jersey Supreme Court held that in a wrongful death case the statute of limitations began to run not from the date of the patient's death, but from the date more than three years later when the mother received an anonymous letter indicating that hospital personnel failed to promptly treat the decedent patient.

New Jersey does *not* have a borrowing statute. In the leading choice of law case the New Jersey Supreme Court refused to apply an out-of state statute of repose which would have barred the claim because "the action is materially connected to New Jersey by the fact that the allegedly defective product was manufactured in and then shipped from this State by the defendant-manufacturer." The court then on to rule that:

> We are satisfied, therefore, that New Jersey in this case has a cognizable and substantial interest in deterrence that would be furthered by the application of its statute of limitations, and that interest is not outweighed by countervailing concerns over creating unnecessary and discriminatory burdens on domestic manufacturers or by fears of forum shopping and increased litigation in the courts of this State.

Gantes v. Kason Corporation, 145 N.J. 478, 492-493 (1995)

The New Jersey Supreme Court also has held that the "learned intermediary doctrine" does not apply to the direct marketing of drugs to consumers and that when the drug manufacturer has advertised its drug directly to consumers, the role of the prescribing doctor does *not* break the chain of causation for a drug company's failure to adequately warn patients of harmful side effects. *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 27 (1999). Given the huge direct to consumer advertising of Vioxx, we believe the learned intermediary defense will be minimized or avoided.

We also believe New Jersey will be the jurisdiction that will have the quickest resolution. The Judge has been handling Vioxx claims for approximately two years already, millions of documents have been exchanged, many Merck depositions have transpired and trials are tentatively set for this Spring. In the federal arena, an MDL court has not even been assigned yet and as you know, no case can be tried by the MDL judge unless the plaintiff happens to reside in that jurisdiction. Thus, your cases probably could not get tried until after the MDL generic discovery is complete and the case remanded, which is years away.

You are probably wondering what are the negative points of filing in New Jersey. The only disadvantage to the client that comes to mind is the limited ability to obtain punitive damages. Under New Jersey law, we must show that important data was withheld from the FDA in order to get punitive damages in cases involving a drug that had been FDA approved. We believe factually that burden can be met. In any event, as a practical matter, due to the United States Supreme Court's *State Farm v. Campbell 123 S. Ct. 1513* (2003) and related cases finding that large punitive verdicts violate the due process clause, large punitive verdicts are

increasingly unlikely or if obtained, are reversed or reduced, especially in a case of a mass tort such as this.

Weitz & Luxenberg would welcome the opportunity to work with you on Vioxx cases and file them on your behalf in Atlantic County, where the court is venued. Fortunately, Atlantic County (home to Atlantic City) is sufficiently far from Merck (125 miles away) and other drug company headquarters so that the jury should not have a pharmaceutical bent. Atlantic County is considered a reasonable county for plaintiffs.

We should note that there may be some situations where we recommend filing a case in the MDL, depending on the details of the case and what we learn about the MDL, but we want you to be aware of the enormous advantages of the New Jersey option which at this juncture we believe is the optimal venue. We will naturally make a decision on a case specific basis after we review the records and when we know more about the MDL option.

If you have Vioxx cases you want us to review or have questions, please contact Glenn Zuckerman, Esq. at (800) 438-9786 extension 583.

Very truly yours,

Arthur Luxenberg