SUPERIOR COURT OF NEW JERSEY

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

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NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS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 Plaintiff's Specific Causation Expert Testimony

Skala v. Johnson & Johnson, et al., Docket No. MID-L-6820-06
(In re: Risperdal®/Seroquel®/Zyprexa® Litigation, Case No. 274)

Defendants: Jodi Sydell Rosenzweig, Esq., Drinker Biddle & Reath LLP

Plaintiff: Fletch V. Trammell, Esq., Bailey Perrin Bailey
Robert W. Cowan, Esq., Bailey Perrin Bailey

Dated: November 18, 2011

Defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (collectively "Defendants") filed a motion to exclude the report and specific causation testimony of Dr. Joel Zonszein. Plaintiff Gary Skala ("Plaintiff" or "Mr. Skala") offers the expert report of Dr. Zonszein to support his claim that treatment with Risperdal® was the cause-in-fact of Plaintiff's onset of diabetes. After considering the parties moving papers, Dr. Zonszein's deposition testimony and Dr. Zonszein's expert report,[1] the court determines that Defendants' motion to exclude the report and specific causation testimony of Dr. Zonszein is **DENIED**.

[1] This court previously assessed Dr. Zonszein's testimony at an N.J.R.E. 104 evidentiary hearing in the case of Tate v. AstraZeneca Pharmaceuticals, LP, et al. and concluded that Dr. Zonszein was qualified in the field of endocrinology to offer expert testimony on the causes of diabetes. Memorandum of Decision on Defendants'

BACKGROUND

Plaintiff offers the opinion of his specific causation expert, Dr. Joel Zonszein M.D., C.D.E., F.A.C.E., F.A.C.D., to show that "Mr. Skala's ingestion of Risperdal® was a substantial contributing factor to his development of diabetes." Plaintiff's Opposition to Defendants' Motion to Exclude the Report and Specific Causation Testimony of Dr. Zonszein ("Pl. Opp. Br.") at 2-3. Defendants move to exclude all specific causation testimony of Dr. Zonszein on the grounds that he failed to employ a proper differential diagnosis. Defendants' Brief in Support of Motion to Exclude the Report and Specific Causation Testimony of Dr. Zonszein ("Defs. Br.") at 3. The doctor acknowledges that there are various risk factors associated with diabetes and that Mr. Skala had some of these risks factors before taking Risperdal®. Id. at 2. Defendants argue that Dr. Zonszein attributes Plaintiff's injuries to Risperdal® without properly ruling out Mr. Skala's other risk factors. Id. at 3. Further, Janssen contends that Dr. Zonszein relies on Plaintiff's "self-serving assertions which contradict unequivocal facts." Id. at 14. According to Defendants, Dr. Zonszein relies on the temporal association between introduction of Risperdal® and the development of diabetes in concluding that Mr. Skala's injury is attributable to the drug. Id. at 15. Thus, Defendants argue that Dr. Zonszein's unsubstantiated conclusions are unreliable and inadmissible at trial. Id. at 16.

Plaintiff refutes the argument that his expert's testimony is scientifically unreliable. Pl. Opp. Br. at 1. In his opposition papers, Mr. Skala argues that Dr. Zonszein's differential diagnosis considers all possible causes of Plaintiff's diabetes. Id. at 4. After evaluating Plaintiff's medical records, Dr. Zonszein concludes that, in his opinion, known risk factors associated with the onset of diabetes were not the cause of Mr. Skala's diabetes in this case. Id.

Motion to Exclude the Testimony of Dr. Joel Zonszein, Tate v. AstraZeneca Pharmaceuticals, LP, et al., Docket No. MID-L-1608-07 (L. Div. Feb. 5, 2010) at 10–11.

at 5. Plaintiff argues that Dr. Zonszein does not have to rule out unequivocally all other causes of diabetes. Id. at 9. Instead, Plaintiff contends that his expert need only articulate well-founded reasons why other factors did not cause Mr. Skala to develop diabetes. Id. at 7. Plaintiff argues that Dr. Zonszein has presented a sufficient differential diagnosis and thus Defendants' motion to exclude his expert report and specific causation testimony should be denied. Id. at 19-20.

RELEVANT LAW

To establish liability, Plaintiff must show that treatment with Risperdal® caused him to develop, or was a substantial contributing factor in the development of his diabetes. Kemp ex rel. Wright v. State, 174 N.J. 412, 417 (2002). In order to satisfy this burden, Plaintiff offers the expert testimony of Joel Zonszein, M.D., an endocrinologist, who opines that Risperdal® may directly lead to diabetes through its metabolic effects on the body. The admissibility of expert testimony in New Jersey is governed by New Jersey Rules of Evidence ("N.J.R.E.") 702. The rule 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 an opinion or otherwise.

[N.J.R.E. 702.] To be deemed admissible, an expert's testimony must satisfy three requirements:

> (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 do not dispute that Dr. Zonszein is rendering an opinion regarding "scientific, technical, or other specialized knowledge" that is "beyond the ken of the average juror," and that "will assist the trier of fact to understand the evidence or to determine a fact in issue." Defs. Br. at 11; Landrigan, supra, 127 N.J. at 413; N.J.R.E. 702. Nor do Defendants contest Dr. Zonszein's qualifications as an endocrinologist with "sufficient specialized knowledge" to explain why he believes that Risperdal® is a significant contributing factor in the development of diabetes. Ibid. Defendants contend that the specific causation testimony of Dr. Zonszein is not "sufficiently reliable" under N.J.R.E. 702. Defs. Br. at 13; N.J.R.E. 702.

Plaintiff bears the burden of demonstrating the reliability of his expert's testimony under N.J.R.E. 702. Suanez v. Egeland, 353 N.J. Super. 191, 196 (App. Div. 2002) (citing State v. Harvey, 151 N.J. 117, 167 (1997)). Typically, the proponent of the testimony must demonstrate that the expert's opinion or theory is accepted generally within the scientific community. "A theory of medical 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. The Supreme Court of New Jersey has recognized that the differential diagnosis process 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. Creanga, supra, 185 N.J. at 355.

In order for an expert's differential diagnosis to be proper, the expert must first '"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.'" Creanga, supra, 185 N.J. 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 symptoms." Ibid. (quoting Clausen, supra, 339 F.3d at 1057-58) (internal quotations omitted). If an expert includes potential causes that are not capable of causing the patient's symptoms, then the expert's differential diagnosis is improper. Ibid. (quoting Clausen, supra, 339 F.3d at 1058) (internal quotations and emphasis omitted). Likewise, if an expert fails to consider potential causes that are capable of causing the patient's symptoms, the expert's flawed methodology would be scientifically unreliable, and thus,

inadmissible. Ibid.

"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. (internal citations and quotations omitted). When "ruling out" factors, the expert is not required to establish that the alleged cause of a plaintiff's injuries is the only single contributing factor to those injuries. Ibid. (quoting Heller v. Shaw Indus., Inc., 167 F.3d 146,156 (3d Cir. 1999). "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)). However, an expert "need not conduct every possible test to rule out 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, supra, 167 F.3d at 156) (internal quotations omitted). 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).

LEGAL ANALYSIS

Dr. Zonszein is board-certified in internal medicine, endocrinology, and nuclear medicine. Expert Report of Joel Zonszein, M.D. ("Zonszein Report") at 1. He currently serves as the Director of the Clinical Diabetes Center at the University Hospital of the Albert Einstein College of Medicine. Ibid. Dr. Zonszein has specialized in the study and treatment of diabetes since 1993, and his past appointments include more than a decade as the Chief of the Division of Endocrinology and Metabolism at the Bronx-Lebanon Hospital Center in New York City. Ibid. Dr. Zonszein's ongoing research projects include the prevention and care of diabetes especially as it relates to underserved minority populations. Ibid. He has written and researched extensively on the causes and treatment of diabetes, and has served as an investigator in numerous clinical trials studying diabetes' prevention and treatment. Ibid.

Dr. Zonszein opined that Plaintiff's use of Risperdal® was a substantial contributing factor to Mr. Skala's development of diabetes. Id. at 44. In support of this conclusion, Dr. Zonszein employed a differential diagnosis, ruling in all plausible causes of the Plaintiff's condition, and ruling out causes that were non-contributory. Id. at 34-44. The doctor reviewed an extensive body of medical literature concerning atypical antipsychotics and their possible diabetogenic effects. Id. at 13-14. He also reviewed Plaintiff's complete medical records, including prescribing history, weight measurements, and metabolic parameters. Id. at 44.

As part of the proper diagnostic procedures, Dr. Zonszein first ruled in all plausible causes for Plaintiff's condition, looking to the factors that are generally associated with the development of diabetes. August 8, 2011 Transcript of Deposition of Joel Zonszein, M.D. ("Zonszein Dep.") at 75:22-80:8. Dr. Zonszein explained in his report and confirmed in his deposition that Mr. Skala had several risk factors prior to taking Risperdal®. Zonszein Report at

34. Mr. Skala was overweight, did not lead a particularly active lifestyle and consumed alcohol regularly. Id. at 30-31, 34. Additionally, Mr. Skala was diagnosed with hypothyroidism in 1989 at which time he began treatment with hormone replacement therapy. Id. at 32. According to Dr. Zonszein, Plaintiff had several elevated lipid values but none were taken while fasting. Id. at 37. Further, the doctor could not find any abnormal blood sugar results prior to Mr. Skala's use of Risperdal®. Id. at 35. Finally, while Plaintiff did not present with cardiovascular risk factors prior to being prescribed Risperdal®, records did indicate "a slightly elevated blood pressure reading when in the Emergency Room with a Xanax drug overdose" in January of 1996. Id. at 38.

Defendants contend that Dr. Zonszein did not conduct a proper differential diagnosis because "notwithstanding his admission that the referenced conditions are risk factors for diabetes, Dr. Zonszein relies on his own 'subjective beliefs,' 'unsupported speculation' and highly suspect diagnostic tools to rule out Plaintiff's risk factors." Defs. Br. at 13 (quoting Creanga, supra, 185 N.J. at 358). However, Dr. Zonszein explained how he arrived at his conclusion and cited scientific literature in support of this conclusion. Zonszein Report at 38-44.

Plaintiff's expert adequately "eliminat[ed] 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." Creanga, supra, 185 N.J. at 356. While Mr. Skala was overweight prior to treatment with Risperdal®, he experienced "approximately a 30% weight gain in the years he was treated" with the medication. Zonszein Report at 39. The doctor indicated that the correlation between Risperdal® and weight gain is confirmed by Mr. Skala's weight loss after terminating treatment with the drug. Id. at 35. In ruling out Mr. Skala's alcohol consumption, Dr. Zonszein explained that while Plaintiff drank every day, "he was never

diagnosed as having dependency to alcohol." Id. at 42; Zonszein Dep. at 32:1-32:6. The doctor noted that alcohol itself is not a cause of diabetes but explained that the high caloric content of alcohol can lead to weight gain, which in turn is a risk factor for diabetes. Zonszein Report at 42; Zonszein Dep. at 76:17-22.

Dr. Zonszein also ruled out Mr. Skala's hypothyroidism as the cause of his diabetes. Zonszein Report at 42. To combat hypothyroidism, Plaintiff is prescribed thyroid hormone replacement but still has elevated thyroid readings due to poor adherence. Ibid. The doctor admitted that hypothyroidism can cause dyslipidemia and, in severe cases, hypoglycemia. Ibid. However, Dr. Zonszein opined that hypothyroidism cannot cause hyperglycemia. Ibid.

In assessing the role of Plaintiff's hypertension in the development of his diabetes, Dr. Zonszein explained that hypertension "is not a cause, but rather a cardiovascular risk associated to diabetes and insulin resistance." Id. at 41. Dr. Zonszein further argued that while some anti-hypertensive medications can precipitate the onset of diabetes, Mr. Skala was treated with anti-hypertensive medications shown to "have a protective effect." Ibid.

In Dr. Zonszein's opinion, multiple observational studies, case reports, clinical trial data and adverse event reports, "in totality prove the causal relationship between atypical antipsychotic agents [("AAAs")] and diabetes" and in particular between Risperdal® and diabetes. Id. at 16. Dr. Zonszein explains that he relied on published and unpublished documents, including published, peer-reviewed medical studies on the causes of diabetes and its risk factors; articles pertaining to the treatment of mental disorders with AAAs; clinical and epidemiological studies involving Risperdal® as well as other second generation antipsychotic agents; and published case reports. Id. at 13-20. His expert report describes his review of a wide variety of data, weighing some pieces of evidence more heavily than others. Id. at 14-16. He

further explained his analysis and sorting of the data, discounting certain data points and highlighting others, giving specific examples of this analysis. Id. at 38-45. Although he believes that randomized, placebo-controlled clinical trials "are the optimal design" for testing causation in cases such as this, Dr. Zonszein stressed that a large majority of Risperdal® clinical trials were primarily designed to assess the efficacy, rather than the safety, of the drug. Id. at 3, 14-15. The doctor further explained that some clinical trials are less reliable indicators of Risperdal®'s metabolic effects because participants may not be representative of the population as a whole. Id. at 14-15. Dr. Zonszein further criticized studies evaluating Risperdal®'s metabolic effects as being too short in duration, lacking "baseline data characteristics" and improperly testing for glucose abnormalities. Id. at 15.

Dr. Zonszein relied principally upon studies that, in his view, properly controlled for psychiatric and medical co-morbidities, such as bipolar disorder, schizophrenia, hypertension, obesity, and dyslipidemia, and studies that adjusted for confounding factors such sex, age, race, ethnicity, and income. Id. at 16-17; Zonszein Dep. 25:11-28:2. He considered the hazard ratio calculated by researchers and the statistical significance of their findings. Zonszein Report at 17. Dr. Zonszein concludes that "these studies have shown that diabetes resulted from Risperdal® treatment." Ibid.

According to Dr. Zonszein, there are "specific limitations" to observational studies failing to demonstrate a significant increased risk of diabetes with Risperdal® compared to typical treatment. Id. at 18. Further, he does not consider the findings of studies that compared the metabolic effects of Risperdal® against other atypical antipsychotics to be persuasive, explaining that "a proper comparison is to the general population and not to another potentially diabetogenic drug such as AAAs is necessary." Ibid.

Defendants argue that Dr. Zonszein relies solely on temporal associations in concluding that Risperdal® caused Plaintiff's diabetes. Defs. Br. at 16. While exclusive reliance on temporality may not be enough to support an expert's causation opinion, an expert may properly consider temporality in rendering his opinion. Creanga, supra, 185 N.J. at 359. As articulated previously, Dr. Zonszein's methodology is explained clearly and adequately in his expert report and his causation opinions are not based upon temporal association alone.

Finally, Defendants contend that Dr. Zonszein's report misstates much of Mr. Skala's medical history contrary to the actual medical records and Plaintiff's own deposition testimony. Defs. Br. at 13-15. Janssen claims that Dr. Zonszein's conclusion is based on "unsubstantiated personal beliefs based upon his omissions and misstatements of the factual evidence and the fanciful self-serving assertions of Plaintiff." Id. at 15. However, any inconsistencies in Mr. Skala's medical history are properly challenged at trial through cross-examination and by the testimony of Defendants' own experts. Factual disputes affect the weight to be accorded to the evidence but do not compel exclusion of Dr. Zonszein's opinion.

CONCLUSION

Based upon the foregoing, the court finds that the testimony of Plaintiff's specific causation expert, Dr. Zonszein, is sufficiently reliable to be admissible at trial. Therefore, Defendants' motion to exclude Plaintiff's specific causation expert testimony is **DENIED** and the court shall sign an order accordingly.

11/18/14

JESSICA R. MAYER, J.S.C.

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FILED
NOV 18 2011
JUDGE JESSICA R. MAYER

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY
	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	CIVIL ACTION
	ORDER
Docket No. MID-L-6820-06	

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having heard and considered the moving papers, any opposition papers, any reply papers, and the arguments of counsel, and good cause having been shown;

IT IS on this 18th day of November, 2011,

ORDERED that defendants' Motion to Exclude the Report and Specific Causation Testimony of Joel Zonszein, M.D. is hereby granted; DENIED for the reasons set forth in the Court's memorandum dated November 15, 2011;

IT IS FURTHER ORDERED that a copy of this Order shall be served upon plaintiffs' counsel within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C. 4/18/4

This motion was:

✓ Opposed

_____ Unopposed

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