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IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 09-11104

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D. C. Docket Nos. 07-10291-CV-ORL-22-DAB,
06-MD-01769-ACC-DAB

LINDA GUINN,

Plaintiff-Appellant,

versus

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA AB,
ASTRAZENECA LP,
ASTRAZENECA PLC,

Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida

(April 6, 2010)

Before DUBINA, Chief Judge, BIRCH and BLACK, Circuit Judges.

PER CURIAM:

Appellant Linda Guinn brought suit against Appellee AstraZeneca Pharmaceuticals LP (AstraZeneca), claiming her use of the prescription drug Seroquel caused her to develop diabetes. Prior to trial, AstraZeneca filed a *Daubert* motion for the exclusion of the expert testimony of Dr. Jennifer Marks and a motion for summary judgment. After conducting a *Daubert* hearing, the district court entered an order granting both motions. The court found that summary judgment in favor of AstraZeneca was appropriate because Guinn had failed to establish a genuine issue of material fact on the issue of causation. The court based its ruling on two alternative grounds. First, the court held that the testimony of Dr. Marks, Guinn's only evidence on the issue of specific causation, did not satisfy the requirements of Rule 702 of the Federal Rules of Evidence and therefore should be excluded. Second, the district court held that even if Dr. Marks' testimony were admissible, it did not support the conclusion that it was more likely than not that Seroquel substantially contributed to causing Guinn's diabetes. We affirm the district court's order granting both AstraZeneca's *Daubert* and summary judgment motions.

I. BACKGROUND

A. Procedural History

Guinn brought suit against AstraZeneca in the District of Massachusetts, claiming to have developed diabetes as a result of taking Seroquel. Guinn asserted claims against AstraZeneca for strict products liability, negligence, fraud, and civil conspiracy. Guinn contended that while her prescribers were unaware of any increased risk of hyperglycemia or diabetes associated with Seroquel, AstraZeneca knew Seroquel caused weight gain in approximately one-quarter to one-third of patients. According to Guinn, despite AstraZeneca's knowledge of the relationship between Seroquel and weight gain, the company marketed Seroquel as having no effect on patients' weight and failed to include adequate warnings on Seroquel's labels as required by United States Food and Drug Administration (FDA) regulations. Guinn further contended Seroquel is no more effective than other antipsychotics which she claims pose less of a risk of weight gain.

The Judicial Panel on Multidistrict Litigation transferred Guinn's case and 91 other actions involving Seroquel to the Middle District of Florida for coordinated pretrial proceedings in July 2006. At the time of the district court's summary judgment order, the consolidated action had grown to include the claims of several thousand plaintiffs.

B. Facts

Seroquel, chemically known as quetiapine fumarate, is an antipsychotic medication manufactured and distributed by AstraZeneca. Seroquel has been approved by the FDA for use in the treatment of bipolar disorder and schizophrenia. Guinn was prescribed Seroquel from May 2002 through April 2007.

1. Dr. Marks' Expert Report

Dr. Marks, Guinn's expert witness on specific causation, first gave her opinion in an expert report submitted to the district court.¹ Dr. Marks began her discussion of Guinn with a review of her medical records dating back to 1998. Dr. Marks noted that the first weight she had available for Guinn was 194 pounds in March 1999. According to Dr. Marks' report, Guinn reached a peak weight of 205 pounds in January 2000 and thereafter her weight, though fluctuating, generally decreased until June 2002, when she reached her lowest weight of 155 pounds. It was at approximately this time that Guinn began taking Seroquel. Guinn then gained weight until she was diagnosed with diabetes with a weight of

¹ Specific causation refers to the issue of whether the plaintiff has demonstrated that the substance actually caused injury in her particular case. Specific causation is often distinguished from general causation, which refers to the more general issue of whether a substance has the potential to cause the plaintiff's injury. *See Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir. 2007) (discussing the distinction between specific and general causation).

198 pounds in February 2006. Dr. Marks summarized her review of Guinn's medical records by stating she gained approximately forty pounds during her five years of taking Seroquel.

After reviewing Guinn's weight history, Dr. Marks concluded, "based on reasonable medical probability[,] that Seroquel was a cause of [Guinn's] diabetes."

Dr. Marks explained that "exposure to a medication which caused weight gain worsened her underlying insulin resistance and likely accelerated the onset of diabetes in such a predisposed individual."

2. Dr. Marks' Deposition and AstraZeneca's *Daubert* Motion

In Dr. Marks' deposition, AstraZeneca provided Dr. Marks with additional information regarding Guinn's medical history and more fully examined Dr. Marks' opinion on causation given this new information. The additional medical history discussed at the deposition revealed that Guinn had already had a number of risk factors for diabetes before she began taking Seroquel. Guinn had struggled with obesity, a significant risk factor for diabetes, and experienced dramatic weight fluctuations since her teenage years. In fact, Guinn's weight fluctuated before, during, and after her use of Seroquel, with her highest recorded

weight during each period being roughly equivalent.² Guinn also had a sedentary lifestyle, a poor diet, a significant family history of diabetes, hypertension, hyperlipidemia, schizophrenia, and prediabetes, all of which, in addition to her age of 61, put her at an increased risk for developing diabetes. Dr. Marks stated she was not aware of all of Guinn's risk factors at the time she wrote her initial report because she had only reviewed medical records provided to her by Guinn's attorneys dating back to 1998.³

At the deposition, Dr. Marks expanded on her theory of causation. She reiterated her belief that Seroquel caused Guinn's diabetes through the mechanism of weight gain. When asked what steps she had taken to determine whether Seroquel had caused Guinn's weight gain, she replied that she had considered only the medical literature showing that Seroquel can cause weight gain and the temporal proximity of Guinn's use of the medication. Dr. Marks stated she had made no attempt to quantify the amount of weight gain she attributed to Seroquel and had done nothing to rule out other factors as the sole cause of Guinn's weight

² Guinn's highest recorded weights before, during and after her use of Seroquel were 208, 205, and 206, respectively. As an example of Guinn's previous weight fluctuations, she reported weighing 111 pounds in 1986, 208 pounds in 1994, and 155 pounds in 2002.

³ Dr. Marks did not know whether the copy of Guinn's medical records provided to her by Guinn's attorneys was complete.

gain. Dr. Marks further acknowledged that Seroquel does not cause weight gain in approximately two-thirds of the patients who take the drug.

When asked what she had done to rule out Guinn's other risk factors as the sole cause of Guinn's diabetes, Dr. Marks stated she knew of no methodology for ruling out alternative causes and thus had not attempted to do so. In fact, Dr. Marks agreed Guinn's other risk factors alone were sufficient to explain the onset of her diabetes. Dr. Marks stated, however, she had "no way of ruling out the Seroquel any more than [she] c[ould] rule out any other risk factors."

Dr. Marks also stated she could not rule out the possibility that Guinn had diabetes before ever taking Seroquel. According to Dr. Marks, the development of diabetes is a slow, incremental process that occurs gradually over many years. Dr. Marks explained that about half of the patients who are diagnosed with diabetes have actually had the disease for approximately five years prior to diagnosis. Dr. Marks stated that although there was some evidence indicating Guinn may have had diabetes before taking Seroquel, she believed the evidence was ultimately inconclusive.⁴

⁴ Dr. Marks explained that Guinn had two glucose readings shortly before she began taking Seroquel that were above the threshold for a diagnosis of diabetes. These readings, however, were unreliable because they were taken during circumstances that could have skewed the results. Dr. Marks stated that, if she had been Guinn's physician, she would have conducted follow-up testing to determine whether Guinn had diabetes at that time.

AstraZeneca filed a *Daubert* motion seeking to exclude Dr. Marks' testimony based primarily on statements made at Dr. Marks' deposition.

AstraZeneca first argued that Dr. Marks had failed to adequately consider and rule out other potential causes of Guinn's diabetes. AstraZeneca further contended that Dr. Marks' methodology was unreliable because it was based primarily on the temporal proximity of Guinn's ingestion of Seroquel to her diagnosis of diabetes.

3. Dr. Marks' Declaration

Soon after AstraZeneca filed its *Daubert* motion, Dr. Marks submitted a declaration to supplement her initial expert report. Dr. Marks explained that although she had received additional medical records and data regarding Guinn since her initial report, including information provided to her during her deposition, "[t]he additional records produced d[id] not substantially alter [her] conclusions."

Likely in response to AstraZeneca's criticisms, Dr. Marks' declaration provided a more complete explanation of her methodology. Dr. Marks explained that she based her conclusion on:

the totality of the evidence[,] including the temporal association of ingestion of Seroquel with the onset of diabetes, a stable risk factor profile without the diagnosis of diabetes prior to use of Seroquel, clinical evidence of a pattern of overall weight gain while on Seroquel prior to diagnosis of diabetes, . . . evidence of a significantly increased

risk of diabetes as a result of Seroquel ingestion reported in the peer-reviewed literature, and the consistency in the clinical presentations of [Guinn] compared with those of patients in literature and clinical trials.

Dr. Marks also reiterated that “it [was] not possible or practical to quantify the risk of each risk factor in each individual plaintiff.”

4. The *Daubert* Hearing

Dr. Marks’ theory of causation was more fully explored in a *Daubert* hearing conducted before the district court. On direct examination, Dr. Marks again stated that she had considered all of Guinn’s risk factors for diabetes but that there was no scientific way to determine whether one of the risk factors may have been the sole cause of her diabetes. Dr. Marks, however, did not elaborate on how she had considered Guinn’s other risk factors in forming her opinion that Seroquel substantially contributed to Guinn’s diabetes. Instead, she testified that “[a]ll the [risk] factors work together.”

On cross examination, Dr. Marks acknowledged that Guinn’s other risk factors were sufficient to explain the onset of her diabetes.⁵ In fact, Dr. Marks testified that, given Guinn’s risk profile, it was “very likely that she would develop type II diabetes whether she took Seroquel or not.”

⁵ Dr. Marks also acknowledged, as she had stated earlier in her deposition, that Guinn may have had diabetes before ever taking Seroquel. Dr. Marks’ deposition was admitted into evidence at the *Daubert* hearing and used by AstraZeneca during cross examination.

Dr. Marks also acknowledged on cross examination that specific events in Guinn's life could have caused Guinn to gain weight during the time she took Seroquel. Prior to taking Seroquel, Guinn had lost a significant amount of weight due to a lack of appetite associated with a period of mental illness. Dr. Marks explained that she had not been aware of this cause of Guinn's weight loss at the time she initially formed her opinion. Dr. Marks acknowledged that as Seroquel improved Guinn's mental condition, Guinn reverted to her ordinary eating habits, which, combined with her sedentary lifestyle, were alone sufficient to explain Guinn's weight gain. Moreover, during the time Guinn was taking Seroquel, she gained approximately ten pounds in the six months after she quit smoking, something Dr. Marks stated is a known cause of weight gain. Guinn also had two serious back injuries during the time she took Seroquel, requiring steroid injections and surgery. Dr. Marks acknowledged that her failure to include Guinn's injuries in her report "was an oversight" and that Guinn's injuries and consequent recovery time could have contributed to her weight gain.

Dr. Marks again stated on cross examination that she had not attempted either to quantify the amount of Guinn's weight gain that could be attributed to Seroquel or to rule out other factors as the sole cause of Guinn's weight gain. When Dr. Marks was asked if she had used any methodology to determine whether

Guinn's weight gain while on Seroquel was caused by the medication rather than normal weight fluctuations, Dr. Marks once again replied she knew "of no method to prove that Seroquel caused the weight gain." Dr. Marks also stated that although she ordinarily would have a detailed conversation with a patient regarding issues such as diet and exercise to determine the cause of a patient's weight gain, she did not personally examine or speak with Guinn when forming her opinion.

C. The District Court's Order

After the *Daubert* hearing, the district court entered an order granting summary judgment in favor of AstraZeneca. The court held Guinn had failed to establish a genuine issue of material fact on the issue of specific causation based on two separate grounds.

First, the district court granted summary judgment on the basis of its exclusion of Dr. Marks' testimony, Guinn's only evidence on the issue of specific causation. The court held that Dr. Marks failed to satisfy the reliability requirement of Federal Rule of Evidence 702, as elucidated in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786 (1993). The district court stated "Dr. Marks was unable to articulate any scientific methodology for assessing whether, and to what extent, Seroquel contributed to Guinn's weight

gain and diabetes.” *Guinn v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1239, 1243 (M.D. Fla. 2009). The court also found that Dr. Marks’ opinion on causation “amounts to nothing more than inadmissible *ipse dixit*, as ‘the only connection between the conclusion and the existing data is the expert’s own assertions.’” *Id.* (quoting *McDowell v. Brown*, 392 F.3d 1283, 1300 (11th Cir. 2004)). The court ultimately held that excluding Dr. Marks’ testimony was a basis for granting summary judgment because “Guinn has no other expert upon whose testimony she can rely to establish specific causation, and ‘this type of proof *requires* expert testimony.’” *Id.* at 1243 n.25 (quoting *McClain v. Metabolife Int’l Inc.*, 401 F.3d 1233, 1237 (11th Cir. 2005)).

Second, the district court held that, even if Dr. Marks’ testimony was admissible, her statements were insufficient to establish a genuine issue of material fact with respect to specific causation. The court noted Dr. Marks testified that factors other than Seroquel could have caused Guinn’s weight gain, Guinn’s pre-existing risk factors alone could have caused her diabetes, and Dr. Marks had made no attempt to determine the relative contribution of the various potential causes of Guinn’s weight gain and diabetes. The district court held that, given this testimony, no reasonable juror could conclude that Seroquel more likely than not played a role in causing Guinn’s diabetes.

II. STANDARD OF REVIEW

This Court reviews a district court's decision regarding the admissibility of expert testimony for an abuse of discretion. *United States v. Frazier*, 387 F.3d 1244, 1258 (11th Cir. 2004). We review a district court's grant of summary judgment de novo. *Midrash Sephardi, Inc. v. Town of Surfside*, 366 F.3d 1214, 1222–23 (11th Cir. 2004).

III. DISCUSSION

As explained above, the district court based its order granting summary judgment on two separate holdings. Because alternative holdings are accorded precedential value in this Circuit, *Bravo v. United States*, 532 F.3d 1154, 1162–63 (11th Cir 2008), we will address each of the district court's rulings in turn.

A. The Admissibility of Dr. Marks' Expert Testimony

Rule 702 of the Federal Rules of Evidence governs the admission of expert testimony. This Circuit applies a three-part inquiry to determine whether an expert has met the requirements of Rule 702. *Frazier*, 387 F.3d at 1260. Under this test, a court must consider whether: (1) the expert is sufficiently qualified to testify on the issues he intends to address; (2) the expert's methodology is "sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or

specialized expertise, to understand the evidence or to determine a fact in issue.”
Id. (citing *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998)).

Neither the district court nor the parties in this case dispute that Dr. Marks is qualified to testify as an expert on diabetes causation. There is also no dispute that expert testimony regarding the cause of Guinn’s diabetes would assist the trier of fact because the testimony “concerns matters that are beyond the understanding of the average lay person.” *See id.* at 1262 (citing *United States v. Rouco*, 765 F.2d 983, 995 (11th Cir 1985)). Dr. Marks’ testimony is thus admissible under Rule 702 if her methodology is sufficiently reliable.

1. The Methodology of Differential Diagnosis

On appeal, Guinn contends Dr. Marks’ testimony is reliable because she employed the scientifically accepted methodology of differential diagnosis. Differential diagnosis “is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999); *see also McClain*, 401 F.3d at 1252 (describing differential

diagnosis as “a process of identifying external causes by a process of elimination”).⁶

Although a reliable differential diagnosis need not rule out all possible alternative causes, it must at least consider other factors that could have been the sole cause of the plaintiff’s injury. As the Fourth Circuit explained in *Westberry*, a “differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.” 178 F.3d at 265; *see also In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 759 (3d Cir.1994) (“[A]t the core of differential diagnosis is a requirement that experts at least consider alternative causes—this almost has to be true of any technique that tries to find a cause of something.”). As other circuits have recognized, an expert “must provide a reasonable explanation as to why ‘he or she has concluded that [any alternative cause suggested by the defense] was not the sole cause’” of the plaintiff’s injury. *Best v. Lowe’s Home Ctrs., Inc.*, 563 F.3d 171, 179 (6th Cir. 2009) (quoting *Paoli*, 35 F.3d at 758 n.27); *see also Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 694 (8th Cir. 2001) (stating an expert must “be

⁶ Technically, differential diagnosis refers to a method of determining which of two diseases a patient suffers from, whereas differential etiology is a term used to describe the process by which the cause of an injury is determined. Following the trend among federal courts, however, we will use the term differential diagnosis to refer to both concepts. *See McClain*, 401 F.3d at 1252.

able to explain why other conceivable causes are excludable”); *Westberry*, 178 F.3d at 265 (holding an expert must provide some explanation of why other potential causes were not the sole cause); *Kanneankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 808 (3d Cir. 1997) (holding that after a defendant identifies a plausible alternative cause, it is “necessary for the plaintiff’s expert to offer a good explanation as to why his or her conclusion remains reliable”).

When properly conducted, differential diagnosis can be a reliable methodology under *Daubert*. See *Best*, 563 F.3d at 178 (“An overwhelming majority of the courts of appeals . . . have held that a medical opinion on causation based upon a reliable differential diagnosis is sufficiently valid to satisfy the [reliability] prong of the Rule 702 inquiry.”); *Westberry*, 178 F.3d at 262 (finding differential diagnosis “has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results”); *Paoli*, 35 F.3d at 758 (same). However, “an expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient.” *McClain*, 401 F.3d at

1253.⁷ We therefore must examine whether Dr. Marks correctly applied the differential diagnosis methodology.

2. Dr. Marks' Application of the Differential Diagnosis Methodology

The district court did not abuse its discretion by finding that Dr. Marks' differential diagnosis was unreliable under *Daubert* because she failed to adequately consider possible alternative causes of Guinn's weight gain and diabetes. Dr. Marks has presented two possible ways in which she has considered alternative causes. First, in her supplemental declaration, Dr. Marks stated she believed other potential causes were not solely responsible because Guinn had gained weight and developed diabetes soon after taking Seroquel when Guinn's other risk factors remained constant.⁸ Dr. Marks' reliance on the temporal proximity of the introduction of an additional risk factor, however, does not satisfy the requirement that a differential diagnosis consider possible alternative causes on the facts of this case.

⁷ Guinn's contention that the shortcomings found in Dr. Marks' analysis should go to the weight and credibility of her testimony rather than its admissibility since Dr. Marks conducted a differential diagnosis is therefore without merit.

⁸ At the *Daubert* hearing, Guinn's counsel similarly characterized Dr. Marks' conclusions by stating that Dr. Marks "ruled all those other risk factors out as being the [sole] cause of the diabetes on the day it occurred because they hadn't caused it earlier."

Temporal proximity is generally not a reliable indicator of a causal relationship. This Circuit has held that “[t]he temporal connection between exposure to chemicals and an onset of symptoms, standing alone, is entitled to little weight in determining causation.” *McClain*, 401 F.3d at 1254 (quoting *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 278 (5th Cir. 1998)); *see also, e.g., Black v. Food Lion, Inc.*, 171 F.3d 308, 313 (5th Cir. 1999) (holding that using temporal proximity to establish causation “is not an exercise in scientific logic but in the fallacy of post-hoc propter-hoc reasoning, which is as unacceptable in science as in law.”); *Cartwright v. Home Depot U.S.A., Inc.*, 936 F. Supp. 900, 906 (M.D. Fla. 1996) (“It is well settled that a causation opinion based solely on a temporal relationship is not derived from the scientific method and is therefore insufficient to satisfy the requirements of Fed. R. Evid. 702.”). Although temporal proximity may constitute probative evidence in certain circumstances, *see Westberry*, 178 F.3d at 265, several factors make it especially unreliable in this case.

First, the temporal relationship at issue in this case does not strongly suggest that Seroquel played a role in causing Guinn’s diabetes. According to Dr. Marks’ testimony, the development of diabetes occurs gradually over many years, and approximately half of the patients who are diagnosed with diabetes

have actually had the disease for about five years prior to diagnosis. Because Guinn was diagnosed with diabetes only four years after beginning to take Seroquel, the temporal relationship in this case does not provide strong evidence of causation; in fact, it appears to equally indicate that Guinn may have already developed diabetes before ever taking Seroquel.

Second, Guinn's numerous other risk factors for diabetes make it hard to draw any inferences from the temporal proximity of Guinn's weight gain to her diagnosis of diabetes. Dr. Marks states these other risk factors were likely not the sole cause of Guinn's diabetes because they remained constant during the time she took Seroquel. Dr. Marks, however, does not explain why having a stable risk profile makes it unlikely that preexisting factors caused Guinn's diabetes when such factors put her at an extremely high risk for diabetes. Moreover, one important risk factor—Guinn's age—did not remain constant.

Third, not only do Guinn's numerous risk factors for diabetes make it hard to draw any inference regarding causation, but the various other potential causes of Guinn's weight gain also make it hard to conclude that Seroquel even caused Guinn to gain weight. The record indicates many other events, including back surgery, quitting smoking, recovering from mental illness, and normal weight fluctuations, may have played a role in Guinn's weight gain during the time she

was taking Seroquel. Although it would be unreasonable to require Dr. Marks to conclusively rule out all alternative causes, she has provided no explanation of how she concluded that, based on reasonable medical probability, Seroquel played a role in Guinn's weight gain despite these other possible explanations.

After considering the nature of the temporal relationship at issue in this case, we conclude Dr. Marks did not adequately consider possible alternative causes simply by noting the temporal proximity between Guinn's ingestion of Seroquel and subsequent development of diabetes. We do not hold that a temporal relationship can never be used to consider alternative causes of a plaintiff's injury; instead, we merely find that temporal proximity is not sufficient on the facts of this case.

Dr. Marks provided a second possible explanation of her consideration of alternative causes by testifying that "[a]ll the [risk] factors [for diabetes] work together." Here Dr. Marks appears to be contending that since diabetes can have multiple concurrent causes, she need not analyze the role played by each cause.

An expert, however, cannot merely conclude that all risk factors for a disease are substantial contributing factors in its development. "The fact that exposure to [a substance] may be a risk factor for [a disease] does not make it an actual cause simply because [the disease] developed." *Cano v. Everest Minerals*

Corp., 362 F. Supp. 2d 814, 846 (W.D. Tex. 2005). “[A]lthough the differential diagnosis technique is well accepted . . . [, a finding] that all possible causes are causes does not appear to have gained general acceptance in the medical and scientific communities.” *Id.* While multiple factors can work together to cause diabetes, Dr. Marks was still required to provide some analysis of why she concluded that, more likely than not, Seroquel substantially contributed to Guinn’s weight gain and such weight gain was among the factors that substantially contributed to her diabetes.

3. Deviation from Standard Diagnostic Practices

The reliability of Dr. Marks’ methodology is further called into question by her failure to conduct the standard diagnostic techniques she normally used to rule out potential alternative causes. *See Best* , 563 F.3d at 179; *Paoli*, 35 F.3d at 760. Dr. Marks admitted that although she would normally conduct an interview to determine the cause of a patient’s weight gain, she had only reviewed selections from Guinn’s medical records prepared by her attorneys. Not only does this cast doubt on Dr. Marks’ differential diagnosis, but it also violates a primary purpose of *Daubert*: to ensure the expert “employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S. Ct. 1167, 1176 (1999).

4. Connection between Dr. Marks' Conclusion and the Facts

The district court did not abuse its discretion by alternatively holding that, even if Dr. Marks' differential diagnosis methodology was acceptable, her testimony was unreliable because her conclusions were not logically supported by the facts of this case. As the Supreme Court explained in *General Electric Company v. Joiner*, “nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which 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.” 522 U.S. 136, 146, 118 S. Ct. 512, 519 (1997); *see also McDowell v. Brown*, 392 F.3d 1283, 1301–02 (11th Cir. 2004) (“[A]n expert opinion is inadmissible when the only connection between the conclusion and the existing data is the expert’s own assertions”).⁹

In determining that the existing data did not support Dr. Marks' conclusions, the district court noted Dr. Marks' testimony established the

⁹ Guinn's argument that the district court erred by applying the wrong state law causation standard when excluding Dr. Marks' testimony improperly conflates *Daubert's* reliability requirement with the showing necessary to survive summary judgment. *See City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 564–65 (11th Cir. 1998) (holding that courts should avoid “the confusion and conflation of admissibility issues with issues regarding the sufficiency of the plaintiff's evidence to survive summary judgment”). Under *Joiner*, the facts of the case must merely support the expert's conclusions, which may or may not satisfy the plaintiff's ultimate burden on causation.

following facts: Dr. Marks knew of no method to determine whether Guinn's weight gain was due to Seroquel or normal fluctuations in weight Guinn had experienced throughout her life; it was "hard to know for sure" whether the point in time Guinn developed diabetes had anything to do with Seroquel; Guinn had numerous pre-existing health conditions that could have caused her weight gain; Guinn had numerous risk factors for diabetes; these risk factors were sufficient to cause Guinn's diabetes; Dr. Marks had made no attempt to quantify the relative contribution of Guinn's risk factors; and Guinn likely would have developed diabetes whether or not she ever took Seroquel. *See Guinn*, 598 F. Supp. 2d at 1246–47. Given this evidence, the district court did not abuse its discretion by holding that Dr. Marks' opinion was unsupported by the evidence.

On appeal, Guinn has identified no evidence of specific causation other than Dr. Marks' testimony. The district court therefore did not err by holding that the exclusion of Dr. Marks' testimony is a basis for granting summary judgment in favor of AstraZeneca. *See Allison v. McGhan Medical Corp.*, 184 F.3d 1300, 1304 (11th Cir. 1999); *Haggerty v. The Upjohn Co.*, 950 F. Supp. 1160, 1168 (S.D. Fla. 1996).

B. Failure of Dr. Marks' Testimony to Create a Genuine Issue of Material Fact

Alternatively, the district court did not err by holding that, even if Dr. Marks' testimony were admissible, her statements would not have created a genuine issue of material fact with regard to specific causation. Under Florida law, a plaintiff:

must introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a substantial factor in bringing about the result. A mere possibility of such causation is not enough; and when the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant.

Gooding v. Univ. Hosp. Bldg., Inc., 445 So.2d 1015, 1018 (Fla. 1984) (quoting Prosser, Law of Torts § 41 (4th Ed.1971)); *see also Christopher v. Cutter Labs.*, 53 F.3d 1184, 1191 (11th Cir. 1995) (further discussing the Florida standard for proving causation).

The district court did not err by holding that Dr. Marks' testimony amounted to mere speculation as to whether Seroquel was a substantial contributing factor in causing Guinn's diabetes. Dr. Marks' testimony reveals several facts that cast substantial doubt on whether Seroquel contributed to Guinn's development of diabetes, including the following: approximately two-thirds of all patients who take Seroquel do not experience weight gain; many other factors plausibly could

have caused Guinn's weight gain; about half of all patients have diabetes five years prior to diagnosis (which would have been before Guinn began taking Seroquel); Guinn had multiple risk factors that could have been the sole cause of Guinn's diabetes; and Dr. Marks was unable to determine the relative risk of each factor. Given these facts, the district court did not err by holding that no reasonable juror could find Seroquel was, more likely than not, a substantial contributing factor in causing Guinn's diabetes.¹⁰

IV. CONCLUSION

For the reasons stated above, we hold the district court did not err by excluding Dr. Marks' testimony and holding that Guinn failed to establish a genuine issue of material fact on the issue of specific causation. We therefore affirm the district court.

AFFIRMED.

¹⁰ On appeal, the parties dispute whether Florida law also requires Guinn to show that but for her ingestion of Seroquel, she would not have developed diabetes. As the district court held, however, this issue of Florida law need not be addressed because Guinn has failed to meet her burden under the more lenient substantial contributing factor test.