

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
ORLANDO DIVISION**

**DAVID HALLER,**

**Plaintiff,**

**-vs-**

**Case No. 6:07-cv-15733-Orl-22DAB**

**ASTRAZENECA PHARMACEUTICALS  
LP, ET AL.,**

**Defendants.**

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**ORDER**

This cause comes before the Court for consideration of AstraZeneca's Motion for Summary Judgment (Doc. 13), to which Plaintiff Haller has responded in opposition (Doc. 15).<sup>1</sup> Oral argument on the motion was held on January 13, 2009. Upon carefully considering the legal memoranda, exhibits, deposition testimony, relevant case law, and the oral argument, the Court determines that AstraZeneca's motion is due to be **GRANTED**.<sup>2</sup>

**I. BACKGROUND**

Seroquel, a prescription drug manufactured and sold by AstraZeneca Pharmaceuticals, was first approved for use in the United States by the Food and Drug Administration (FDA) in 1997.<sup>3</sup>

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<sup>1</sup> Both the motion and the response were filed under seal because they contained information designated as confidential by one or both parties.

<sup>2</sup> AstraZeneca set forth numerous grounds for summary judgment in its motion; however, given the Court's ruling on specific medical causation, it was unnecessary to reach the majority of the issues AstraZeneca raised.

<sup>3</sup> See Ex. 5 to Doc. 1113, *In re Seroquel Prods. Liab. Litig.*, Case No. 6:06-md-1769-Orl-22DAB.

The drug, known chemically as quetiapine fumarate, is still on the market today as one of a number of medications known as second-generation, or “atypical,” antipsychotics. Although initially indicated to treat the “manifestations of psychotic disorders,” including schizophrenia,<sup>4</sup> Seroquel has since been approved for various uses in patients suffering from bipolar disorder.<sup>5</sup>

Several years ago, people who had been prescribed Seroquel by their doctors began filing lawsuits against AstraZeneca, primarily alleging that they had developed diabetes and other related disorders as a result of their ingestion of the drug. In July 2006, the Judicial Panel on Multidistrict Litigation transferred ninety-two actions involving alleged injuries resulting from the use of Seroquel to this Court for consolidated and coordinated pretrial proceedings.<sup>6</sup> Since that time, this consolidated action has grown to include the personal injury claims of several thousand people from across the nation, including the plaintiff in the present case, David Haller.

David Haller is a 47-year-old resident of Largo, Florida. Born in Pennsylvania, he was adopted at six months old,<sup>7</sup> and remained in his adoptive parents’ household until he was twenty-two.<sup>8</sup> Haller had a troubled childhood; he only completed formal education through the third grade due to behavioral problems,<sup>9</sup> and spent much of his teens in and out of juvenile detention centers and

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<sup>4</sup> *Id.*

<sup>5</sup> See Exs. 21, 27, 29 to Doc. 1113, *In re Seroquel Prods. Liab. Litig.*, Case No. 6:06-md-1769-Orl-22DAB.

<sup>6</sup> See *In re Seroquel Prods. Liab. Litig.*, 447 F. Supp. 2d 1376 (J.P.M.L. 2006).

<sup>7</sup> Haller Dep. (Feb. 11, 2008) 351:22-24.

<sup>8</sup> *Id.* at 187:10-188:3.

<sup>9</sup> *Id.* at 84:19-85:16.

psychiatric hospitals.<sup>10</sup> Haller moved to Florida in 1983, and was formally diagnosed with bipolar disorder by a department of corrections psychiatrist in 1987.<sup>11</sup> Beginning shortly after his arrival in Florida, and continuing through 2002, Haller accumulated a lengthy criminal record,<sup>12</sup> leading to incarceration on numerous occasions,<sup>13</sup> and involuntary commission to psychiatric hospitals on at least seven separate occasions.<sup>14</sup>

Haller's non-psychiatric health history indicates that he suffers from several chronic conditions, including gastroesophageal reflux disease, high cholesterol and high blood pressure,<sup>15</sup> and has experienced significant weight fluctuations throughout much of his adult life.<sup>16</sup> In addition,

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<sup>10</sup> Jocelyn Haller Dep. 51:25-54:17, 68:3-69:7.

<sup>11</sup> Haller Dep. (Feb. 11, 2008) 60:20-61:13.

<sup>12</sup> *Id.* at 267:9-287:11.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* at 205:14-20.

<sup>15</sup> Haller Dep. (July 15, 2008) 24:22-25:4, 47:20-24; Expert Report of Israel Jack Abramson, Ex. 19 to Doc. 1160 (*In re Seroquel Prods. Liab. Litig.*, Case No. 6:06-md-1769-Orl-22DAB) at 4 (noting history of hypertension, hyperlipidemia and obesity); Expert Report of Brian Tulloch, M.D., Ex. 22 to Doc. 1160 (*In re Seroquel Prods. Liab. Litig.*, Case No. 6:06-md-1769-Orl-22DAB) at 10 (noting past medical history of hypertension, gastroesophageal reflux disease, psychogenic vomiting, chronic obstructive pulmonary disease, cirrhosis, hyperlipidemia, obesity, substance abuse and heavy cigarette smoking).

<sup>16</sup> Haller's weight history was discussed by one of his experts, Dr. Abramson, at the *Daubert* hearing. See *Daubert* Hr'g Tr. 10, Jan. 14, 2009 (Doc. 31)(noting that Haller was obese and experienced "fluctuations in his weight" throughout the 1990s), 20 (observing that "Mr. Haller did show fluctuations in his weight prior to administration of Seroquel" and acknowledging that he was "overweight or significantly overweight prior to the initiation of Seroquel therapy"), 92-4 (detailing various weight gains and losses from 1988 to 1993), 102 (agreeing that Haller "had been obese throughout the course of his life at various times").

Haller has a history of alcohol abuse,<sup>17</sup> has smoked at least a half a pack of cigarettes a day since he was twelve years old,<sup>18</sup> and does not exercise.<sup>19</sup>

Haller was first prescribed Seroquel in October 2002 by Nurse Practitioner Dee Burke at Directions for Mental Health in Clearwater, Florida.<sup>20</sup> Haller has remained on varying doses of the drug since that time,<sup>21</sup> and was still taking the drug as recently as July 2008.<sup>22</sup> Haller was diagnosed with diabetes and placed on medication in August 2004, when he was admitted to the hospital for abdominal pain.<sup>23</sup> In February 2006, however, Haller's diabetes medication was discontinued,<sup>24</sup> and, according to his present primary care physician, he has not had any diabetic symptoms since she began treating him in July 2005.<sup>25</sup>

Haller initiated this lawsuit against AstraZeneca in October 2006, asserting claims for strict product liability, negligence, fraud and civil conspiracy.<sup>26</sup> AstraZeneca now seeks summary judgment as to each of Haller's claims. It is this motion to which the Court now turns.

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<sup>17</sup> Haller Dep. (Feb. 11, 2008) 223:10-17.

<sup>18</sup> *Id.* at 112:6-113:17.

<sup>19</sup> *Id.* at 49:22-51:2.

<sup>20</sup> *See* Directions for Mental Health Psychiatric Eval. Oct. 1, 2002, at Doc. 13, Ex. 13.

<sup>21</sup> *See* Medication Flow Sheets, Doc. 15, Exs. 4, 5.

<sup>22</sup> Haller Dep. (July 15, 2008) 28:25-31:1.

<sup>23</sup> Doc. 13, Ex. 20 (Morton Plant Hospital record indicating diagnosis of new onset diabetes).

<sup>24</sup> Bacha Dep. 63:21-64:4.

<sup>25</sup> *Id.* at 37:9-12, 71:17-20, 79:13-80:15.

<sup>26</sup> Haller's breach of warranty claims were earlier dismissed by stipulation. *See* Doc. 12.

## II. SUMMARY JUDGMENT STANDARD

On a motion for summary judgment, the movant bears the initial burden of showing that no genuine issue of material fact remains for trial. *Celotex v. Catrett*, 477 U.S. 317, 33 (1986); *see also Zivojinovich v. Barner*, 525 F.3d 1059, 1066 (11th Cir. 2008). To avoid summary judgment, the opposing party must come forward with specific facts in dispute that are material and of a substantial nature. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Conclusory allegations, evidence that is not significantly probative, and personal opinions will not suffice to defeat a motion for summary judgment. *Johnson v. Fleet Fin., Inc.*, 4 F.3d 946, 949 (11th Cir. 1993). Though the opposing party must present specific evidence showing a question of material fact, the Court must draw all reasonable factual inferences in favor of the opposing party. *Anderson v. Liberty Lobby*, 477 U.S. 242, 249-50 (1986).

## III. ANALYSIS<sup>27</sup>

The overarching issue raised by AstraZeneca's summary judgment motion is whether Haller can carry his burden of establishing medical causation. Indeed, because establishing medical causation is critical to each of Haller's claims, AstraZeneca is entitled to judgment as a matter of law as to all claims set forth in the complaint if Haller fails to establish a genuine issue of material fact with regard to whether his ingestion of Seroquel caused him to develop diabetes.

In order to establish medical causation in a toxic tort case such as this one, a plaintiff must show both that exposure to the alleged toxic substance can cause a particular disease (general causation), and that exposure to the alleged toxic substance was a cause of his or her individual injury

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<sup>27</sup> The parties have stipulated that all of Haller's claims are substantively governed by Florida law. *See* Joint Pretrial Statement, Doc. 19 at 20.

(specific causation). See Mary Sue Henefin, et al., *Reference Guide on Epidemiology, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE* 444 (Federal Judicial Center, 2d ed. 2000); see also *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1237 (11th Cir. 2005) (“Plaintiffs must prove the toxicity of the ephedrine/caffeine combination and that it had a toxic effect on them . . .”). Thus, in this action, Haller must show both that Seroquel can generally cause diabetes and that Seroquel was a specific cause of his diabetes. Having carefully reviewed the record in this case, however, the Court finds that even assuming there is a triable issue with regard to general causation, Haller has failed to come forward with evidence establishing a genuine issue of material fact as to whether Seroquel was the specific cause of his injury.<sup>28</sup>

**A. Admissibility of Expert Testimony on Specific Causation**

At the outset, the Court notes that in federal court, expert opinions must meet the admissibility guidelines announced by the United States Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592-93 (1993). In *Daubert*, the Supreme Court set forth a non-exhaustive list of relevant factors to consider in determining whether the methodology employed by an expert is reliable. *Id.* at 593-94. The factors include whether the methods can be tested or have been subject to peer review, the potential rate of error, and whether the methods are generally accepted. *Id.* Applying these principles in *Tuscaloosa v. Harcros Chemicals, Inc.*, 158 F.3d 548, 562 (11th Cir. 1998), the Eleventh Circuit held that expert testimony may be admitted if three

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<sup>28</sup> On January 26, 2009, Plaintiffs filed a motion seeking additional discovery with respect to recent correspondence between AstraZeneca and the FDA, suggesting that such discovery may uncover evidence pertinent to the Court’s consideration of this summary judgment motion. See Doc. 41. In the Court’s view, any evidence uncovered by additional discovery related to the FDA correspondence likely would relate only to general medical causation, and, as such, would not impact the Court’s decision herein.

requirements are met. First, the expert must be qualified to testify competently regarding the matter he or she intends to address. *Id.* Second, the methodology used must be reliable as determined by the *Daubert* inquiry. *Id.* Third, the testimony must assist the trier of fact through the application of expertise to understand the evidence or determine a fact in issue. *Id.* This final requirement entails an evaluation of whether the testimony is relevant, i.e., it “has a justified scientific relationship to the pertinent facts.” *McDowell v. Brown*, 392 F.3d 1283, 1299 (11th Cir. 2004).

Two experts have offered specific causation testimony in Haller’s case: Dr. Brian Tulloch, an endocrinologist, and Dr. I. Jack Abramson, a psychiatrist. After extensively reviewing their testimony, however, the Court determines that neither expert’s specific causation testimony is admissible under *Daubert*, as the following discussion demonstrates.

**1. Dr. Brian Tulloch**

As will be discussed in detail, Dr. Tulloch employed a flawed methodology in arriving at his opinions. Further, on the merits, the causation opinions he reached are speculative and unreliable. In order to fully appreciate the deficiencies in Dr. Tulloch’s methodology, one must understand what those opinions are, how he reached them, and how they have evolved over the course of this lawsuit. Accordingly, a considerable amount of history is necessary.

Dr. Tulloch’s Expert Report

In his expert report, Dr. Tulloch noted the following medical history for Haller: hypertension, gastroesophageal reflux disease, psychogenic vomiting, chronic obstructive pulmonary disease, cirrhosis, hyperlipedemia, obesity, substance abuse (including alcohol and cocaine), and heavy cigarette use (up to 40 cigarettes per day). Additionally, Dr. Tulloch’s report noted that Haller’s “psychiatric history includes references to bipolar disorder in 1987, [m]ixed personality disorder

noted in 1996, [s]chizoaffective disorder, bipolar type, depression, suicide attempts and post traumatic stress disorder.”<sup>29</sup> This is extremely significant; as will be discussed in greater detail, many of the things Dr. Tulloch listed are causative factors for diabetes.

The heart of Dr. Tulloch’s report, at least as far as specific causation is concerned, consists of the following two paragraphs:

In reviewing the relationship between [Haller’s] weight and the onset of abnormal blood sugars there is good evidence of weight gain from 230 lbs in January 2001 to May 2004 when the weight was recorded as 251 lbs[,] an increase of 21 lbs, and he then was diagnosed with diabetes mellitus. Soon after the initiation of Metformin and presumably an appropriate diet, however, his weight was reduced to 218 lbs by February 2005, and thenceforth the weight remained fairly stable while sugars remained under excellent control.

The main detectable relationship between Seroquel and abnormal glucose physiology therefore seems to be following a 21 lb weight gain when clearly abnormal sugars are registered. Based on reasonable medical probability the excess weight gain experienced following the administration of the atypical antipsychotic drug Seroquel was a cause of [Haller’s] developing diabetes. However[,] soon after the diagnosis of diabetes was established the weight returned to his previous level and his sugars stabilized with evidence of good glucose control measured with HbA1c values essentially in the normal range.<sup>30</sup>

#### Dr. Tulloch’s Deposition

On October 15, 2008, Dr. Tulloch was deposed about his specific causation opinions regarding Haller.

At the outset, Dr. Tulloch admitted that before rendering his opinions in the case, he did not physically examine Haller, he did not speak with him, he did not review all of the medical records he was provided regarding Haller, he did not read the depositions of any of Haller’s treating

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<sup>29</sup> Doc. 13, Ex. 22 at 10.

<sup>30</sup> *Id.* at 11.



physicians, and he did not read Haller's deposition.<sup>31</sup> Dr. Tulloch conceded that by not reviewing all of the medical records and any of the treating physicians' depositions, he might possibly miss explanations for Haller's weight gain and diabetes other than his use of Seroquel.<sup>32</sup> Dr. Tulloch also admitted that he had not comprehensively reviewed the medical literature on Seroquel.<sup>33</sup> In fact, he read only a "small portion" of the literature on Seroquel and diabetes.<sup>34</sup> Similarly, he read only a "small portion" of the literature on Seroquel and weight gain, and much of that was "summarizing."<sup>35</sup>

At the time of his deposition, Dr. Tulloch knew of no scientific evidence to support the conclusion that Seroquel directly affected Haller's pancreas or the cells of his pancreas, i.e., that it directly caused diabetes.<sup>36</sup> He gave the same answer to the question regarding persons in general.<sup>37</sup>

Dr. Tulloch admitted that his report appeared to be incorrect regarding the date on which Haller began using Seroquel. The correct date was October of 2002, rather than February of that year.<sup>38</sup> Dr. Tulloch further admitted that he did not know what dose of Seroquel Haller was taking

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<sup>31</sup> Tulloch Dep. 486:9-488:12.

<sup>32</sup> *Id.* at 487:7-11.

<sup>33</sup> *Id.* at 607:5-17.

<sup>34</sup> *Id.* at 608:16-24.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 492:7-12.

<sup>37</sup> *Id.* at 492:13-23.

<sup>38</sup> *Id.* at 503:19-504:7.

during 2002 and the first five months of 2003.<sup>39</sup> Consequently, he conceded that his opinions concerning Haller's weight from the time he commenced taking Seroquel until May 2003 could not relate to the dose of Seroquel Haller was taking.<sup>40</sup>

Based on information presented to Dr. Tulloch at his deposition, it appeared that Haller was still taking Seroquel as of July 2008.<sup>41</sup> Dr. Tulloch admitted that Haller's psychiatrist had elected to keep him on Seroquel despite the fact that Haller was diagnosed with diabetes.<sup>42</sup> The excess weight gain Dr. Tulloch believed resulted from the Seroquel was 21 pounds.<sup>43</sup> Dr. Tulloch believed this weight was gained during the period January 2001 to May 2004.<sup>44</sup> However, Dr. Tulloch admitted that the 21 pound weight gain was based on a beginning weight that was recorded nearly two years before Haller began taking Seroquel.<sup>45</sup>

Dr. Tulloch admitted he did not know how much Haller weighed when he started taking Seroquel.<sup>46</sup> He admitted it was possible Haller might have weighed 251 pounds when he began

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<sup>39</sup> *Id.* at 504:10-22.

<sup>40</sup> *Id.* at 505:2-506:4.

<sup>41</sup> *Id.* at 513:1-4.

<sup>42</sup> *Id.* at 559:5-10.

<sup>43</sup> *Id.* at 513:21-514:1, 517:12-16.

<sup>44</sup> *Id.* at 517:4-16.

<sup>45</sup> *Id.* at 519:24-520:14.

<sup>46</sup> *Id.* at 525:9-24, 527:15-528:3.

taking the drug.<sup>47</sup> Dr. Tulloch further admitted that the beginning number (230 pounds) for his weight gain calculation was not a reliable indicator of what Haller weighed just before he began taking Seroquel.<sup>48</sup> Dr. Tulloch conceded that it was speculative to say how much weight Haller gained when he was on Seroquel.<sup>49</sup> He specifically admitted that he didn't know how much weight Haller gained in the first year he was on the drug.<sup>50</sup>

Dr. Tulloch agreed with the opinion expressed by Dr. Wirshing, another of Plaintiffs' experts, to the effect that persons who gained weight on Seroquel gained about 9 pounds during the first couple of months of treatment, then reached a plateau.<sup>51</sup>

Other causes of Haller's weight gain were his sedentary lifestyle and his psychosis.<sup>52</sup> Dr. Tulloch could not rule out those factors as the sole cause of Haller's weight gain when he was on Seroquel.<sup>53</sup> Dr. Tulloch did not try to rule out alternative causes for Haller's weight gain because he did not feel he needed or had to do that.<sup>54</sup>

Dr. Tulloch agreed that the complications from diabetes that he described in his report could have been solely caused by pre-existing obesity, years of smoking, metabolic syndrome, and

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<sup>47</sup> *Id.* at 525:19-21.

<sup>48</sup> *Id.* at 525:25-526:11.

<sup>49</sup> *Id.* at 527:5-14.

<sup>50</sup> *Id.* at 562:13-16.

<sup>51</sup> *Id.* at 565:10-566:2.

<sup>52</sup> *Id.* at 545:4-7.

<sup>53</sup> *Id.* at 545:10-13.

<sup>54</sup> *Id.* at 548:13-17.

uncontrolled hypertension that preceded Haller's ingestion of Seroquel.<sup>55</sup> Dr. Tulloch further agreed with the statement that "it would be scientifically and medically impossible . . . to look at a complication and say that it came from the diabetes as opposed to it came from the hypertension or the metabolic syndrome or the smoking or the obesity[.]"<sup>56</sup> Referring to the two most common causes of death in diabetics - stroke and heart attack - Dr. Tulloch also agreed that he "wouldn't be able to look at a given individual and say his death was due to the effect of the diabetes or the effect of . . . 20 years of smoking cigarettes or his obesity[.]"<sup>57</sup> With specific reference to the coronary artery disease and myocardial infarction Haller presented after his diagnosis of diabetes, Dr. Tulloch could not rule out that those things were solely caused by Haller's smoking, pre-existing obesity, hypertension and metabolic syndrome.<sup>58</sup> Dr. Tulloch repeatedly proclaimed that the Seroquel usage was the proverbial "straw that broke the camel's back," i.e., that it was an "additive" or "contributing" factor.<sup>59</sup> In other words, he said, Seroquel was "one of the list,"<sup>60</sup> "probably a contributing factor,"<sup>61</sup> and "one of the contributing factors."<sup>62</sup>

Dr. Tulloch made crystal clear at his deposition that the sole basis for his opinion that

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<sup>55</sup> *Id.* at 534:4-536:24.

<sup>56</sup> *Id.* at 534:17-23.

<sup>57</sup> *Id.* at 537:18-22.

<sup>58</sup> *Id.* at 539:2-11.

<sup>59</sup> *Id.* at 534:23-25, 537:25, 544:5-6, 546:21-547:1.

<sup>60</sup> *Id.* at 543:13.

<sup>61</sup> *Id.* at 544:5.

<sup>62</sup> *Id.* at 571:18.

Seroquel caused the development of diabetes in Haller was the temporal relationship between Haller's taking Seroquel and his subsequent weight gain, and the weight gain's temporal relationship with the development of diabetes.<sup>63</sup>

Dr. Tulloch made equally clear that Haller would have developed diabetes at some point even if he had never taken Seroquel.<sup>64</sup> His opinion was that Seroquel somehow accelerated the development of diabetes because of the weight gain.<sup>65</sup> He had not attempted to quantify the acceleration, but based his conclusions on the "correlation" between the weight gain and the appearance of abnormal blood sugar.<sup>66</sup>

Although Dr. Tulloch's report does not note this fact, Haller is 5'6" tall.<sup>67</sup> In January of 2001, at age 40, less than two years before he began taking Seroquel, he weighed 230 pounds.<sup>68</sup> This gave him a body mass index of 37.1, which qualified him as morbidly obese.<sup>69</sup>

Medical records discussed at Dr. Tulloch's deposition established that Haller gained 58 to 60

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<sup>63</sup> *Id.* at 491:19-492:6, 541:7-15.

<sup>64</sup> *Id.* at 541:18-23, 598:20-599:4.

<sup>65</sup> *Id.* at 541:24-542:3.

<sup>66</sup> *Id.* at 542:4-6.

<sup>67</sup> *Id.* at 519:8-9.

<sup>68</sup> *Id.* at 519:10-12.

<sup>69</sup> *Id.* However, Haller's last recorded weight before he starting taking Seroquel was approximately 180 pounds on April 26, 2002. At that time, his BMI was 29. Because it is unknown how much Haller weighed when he began taking Seroquel, his BMI on that date is likewise unknown.

pounds during the period January 1997 to January 2001.<sup>70</sup> Dr. Tulloch's opinion was that Haller gained that weight by "taking in more calories than he burned."<sup>71</sup> Dr. Tulloch added: "Some people eat more when they're depressed, some people eat more when they're in particular sets of circumstances."<sup>72</sup> Medical records further established that Haller gained 80 pounds during the 16-year period ending January 2001; he increased from 150 pounds to 230 pounds.<sup>73</sup> Dr. Tulloch admitted that because he did not interview Haller, take a medical history from him, or have him fill out a questionnaire, he couldn't "have any specificity" about what caused his weight gain during that time period.<sup>74</sup> Dr. Tulloch further conceded that before Haller took Seroquel, he had a much bigger weight gain than he ever had the entire time he was on Seroquel.<sup>75</sup> Given these weight gains, Dr. Tulloch agreed that more probably than not, he would expect such a person to continue to gain weight whether or not they took Seroquel.<sup>76</sup> However, Dr. Tulloch conceded that Haller lost weight for the first year and a half he was on Seroquel.<sup>77</sup> He agreed that Haller lost 20 pounds in the first year he

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<sup>70</sup> *Id.* at 549:5-550:9, 566:6-10.

<sup>71</sup> *Id.* at 549:20-550:4.

<sup>72</sup> *Id.* at 550:5-7.

<sup>73</sup> *Id.* at 550:13-551:6, 566:11-15.

<sup>74</sup> *Id.* at 551:7-13.

<sup>75</sup> *Id.* at 552:6-9.

<sup>76</sup> *Id.* at 567:2-6.

<sup>77</sup> *Id.* at 568:3-570:6.

was on Seroquel and 23 pounds during the second year.<sup>78</sup> In an effort to explain this “pattern” of weight loss, Dr. Tulloch speculated that once Haller was diagnosed with diabetes, he became serious about his situation and reduced his caloric intake.<sup>79</sup> He also suggested that the drug Metformin, prescribed for Haller for his diabetes, might explain the weight loss.<sup>80</sup> Dr. Tulloch further agreed that Haller lost 51 pounds in 2005 while he was taking Seroquel, despite the fact that his dosage increased.<sup>81</sup> Dr. Tulloch also conceded that this history did not support a dose-response relationship between Seroquel and weight gain.<sup>82</sup> Dr. Tulloch was then confronted with the fact that Haller’s weight “popped back up to 245” in August 2006.<sup>83</sup> When asked if he attributed that particular weight gain to Seroquel, Dr. Tulloch opined that the drug was a “contributing factor” or “one of the potential confounding factors,” whereas in the instances where Haller lost weight while on Seroquel “other factors were dominant.”<sup>84</sup> Dr. Tulloch posited other contributing factors for the weight gain in 2006: hypokinesia (inactivity) and excess caloric intake.<sup>85</sup> When asked to quantify how much of the weight gain was attributable to Seroquel and how much to the other factors, Dr. Tulloch admitted he could

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<sup>78</sup> *Id.* at 573:16-21.

<sup>79</sup> *Id.* at 574:2-6.

<sup>80</sup> *Id.* at 574:10-13.

<sup>81</sup> *Id.* at 577:1-20.

<sup>82</sup> *Id.* at 578:4-7.

<sup>83</sup> *Id.* at 579:19-23.

<sup>84</sup> *Id.* at 580:4-9.

<sup>85</sup> *Id.* at 580:15-17.

not do so.<sup>86</sup> He further conceded that as to any of the weight gains by any of the plaintiffs in the cases in which he was testifying, he could not say how much of the weight gain was due to Seroquel and how much was due to diet, lack of exercise and other factors.<sup>87</sup> Ultimately, Dr. Tulloch conceded that in every year since Haller began taking Seroquel, he had “a major weight loss.”<sup>88</sup> Dr. Tulloch also agreed that as of April 2008, Haller weighed the same as he did two years before he began taking Seroquel.<sup>89</sup>

When asked, “So weight gain while he was on Seroquel did not cause [Haller] to have diabetes, correct?”, Dr. Tulloch replied, “Okay. I’ll buy that.”<sup>90</sup>

Dr. Tulloch agreed that Haller had hypertension before he began taking Seroquel, that his hypertension had at times been uncontrolled, and that hypertension can cause diabetes.<sup>91</sup> Even though scientists have quantified the risk of developing diabetes in persons who are hypertense, Dr. Tulloch did not attempt to quantify the contribution of hypertension to Haller’s diabetes.<sup>92</sup> Nevertheless, Dr. Tulloch claimed he was able to rule out, to a reasonable degree of medical probability, hypertension as the sole cause of Haller’s diabetes “[b]ecause he had so many other

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<sup>86</sup> *Id.* at 580:18-22.

<sup>87</sup> *Id.* at 580:23-581:3.

<sup>88</sup> *Id.* at 583:6-10. Dr. Tulloch attempted to retreat from this damaging concession at the subsequent *Daubert* hearing discussed *infra*.

<sup>89</sup> *Id.* at 583:17-19.

<sup>90</sup> *Id.* at 586:7-9.

<sup>91</sup> *Id.* at 598:3-12.

<sup>92</sup> *Id.* at 598:13-19.



factors.”<sup>93</sup>

Dr. Tulloch was aware that Haller was a long-time alcohol abuser.<sup>94</sup> He conceded that alcoholic pancreatitis is a cause of diabetes.<sup>95</sup> He also agreed there was “a lot of evidence” that Haller had a sedentary lifestyle and that sedentary lifestyle is a contributing cause of diabetes.<sup>96</sup> Scientists have quantified the risk of diabetes in people who have a sedentary lifestyle, but Dr. Tulloch had not attempted to quantify that factor as a contributing cause of Haller’s diabetes.<sup>97</sup>

Dr. Tulloch further admitted that he knew Haller was taking Depakote and Lithium contemporaneously with Seroquel, and that Depakote is associated with weight gain.<sup>98</sup> Dr. Tulloch did not determine what contribution Depakote or Lithium made to Haller’s weight.<sup>99</sup> He characterized them as “one of the components on the saddle of the camel,” but didn’t think one could ascribe accurate numbers to that component with reasonable medical probability.<sup>100</sup> In other words,

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<sup>93</sup> *Id.* at 599:11-13.

<sup>94</sup> *Id.* at 599:19-21.

<sup>95</sup> *Id.* at 599:22-25.

<sup>96</sup> *Id.* at 601:2-11.

<sup>97</sup> *Id.* at 601:12-19.

<sup>98</sup> *Id.* at 601:20-602:6. Dr. Tulloch indicated at the deposition that he was unaware that Lithium was associated with weight gain. *Id.* at 601:25-602:1. However, he allowed that Lithium was a sedative and that prescribing it for persons with manic-depressive psychosis could cause them to gain weight. *Id.* at 601:25-602:6. In any event, by the time of the *Daubert* hearing, Dr. Tulloch was willing to concede that Lithium could cause weight gain. *Daubert* Hr’g Tr. 63-64, 71, Jan. 15, 2009 (Doc. 1216, *In re Seroquel Prods. Liab. Litig.*, Case No. 6:06-md-1769-Orl-22DAB).

<sup>99</sup> Tulloch Dep. 602:7-13.

<sup>100</sup> *Id.*

he couldn't determine the number of pounds attributable to Depakote and Lithium.<sup>101</sup>

Dr. Tulloch agreed with the statement that “as a medical and scientific matter, [he couldn't] blame weight gain on . . . Seroquel when an equal amount of weight loss occurred while the patient was on Seroquel.”<sup>102</sup> He further conceded that before Haller had diabetes during the time period in 2003 when he was on Seroquel, he lost 20 pounds.<sup>103</sup> He also agreed that “a weight loss during the first year that a person like . . . Haller was on Seroquel is not the pattern [he] would expect to see if Seroquel caused weight gain.”<sup>104</sup>

Dr. Tulloch admitted that Haller's weight decreased after he was diagnosed with diabetes.<sup>105</sup> Dr. Tulloch made no effort to ascertain what was occurring in Haller's life after he started taking Seroquel that would affect his weight.<sup>106</sup>

When asked to describe the pattern of weight gain Seroquel causes, Dr. Tulloch stated he didn't have any pattern in mind.<sup>107</sup> Dr. Tulloch also could not say how much weight he would expect Seroquel to cause someone to gain.<sup>108</sup> He even noted that some patients on atypicals such as Seroquel

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<sup>101</sup> *Id.* at 14-17.

<sup>102</sup> *Id.* at 572:5-14.

<sup>103</sup> *Id.* at 572:15-20.

<sup>104</sup> *Id.* at 572:21-25.

<sup>105</sup> *Id.* at 554:18-23.

<sup>106</sup> *Id.* at 554:24-555:6.

<sup>107</sup> *Id.* at 555:7-9. Dr. Tulloch did mention risk ratios.

<sup>108</sup> *Id.* at 560:20-25. Again, he referred to risk ratios.

do not gain weight at all.<sup>109</sup>

#### Motion Practice Following Dr. Tulloch's Deposition

On November 3, 2008, after Dr. Tulloch was deposed, AstraZeneca filed a Motion to Exclude the Specific-Causation Testimony of Plaintiffs' Case-Specific Causation Witnesses.<sup>110</sup> Therein, AstraZeneca argued that the testimony of Plaintiffs' expert medical causation witnesses, including Dr. Tulloch, must be excluded on *Daubert* grounds. The first ground AstraZeneca raised for exclusion was that Dr. Tulloch and the other experts had based their causation opinions on the "mere temporal relationship" between Plaintiffs' use of Seroquel and their alleged injuries.<sup>111</sup> AstraZeneca noted that "the Eleventh Circuit has held that admissible expert causation testimony cannot be based merely on 'temporal relationship.'"<sup>112</sup> AstraZeneca raised the following other arguments for exclusion: (1) "all of Plaintiffs' case-specific experts failed to consider and then rule out each Plaintiff's pre-existing obesity, substantial overweight, and many other risk factors and alternative causes for their alleged diabetes injuries"; (2) "none of Plaintiffs' case-specific witnesses even tried quantitatively to assess the relative contribution of each Plaintiff's many other pre-existing risk factors for diabetes"; (3) "none of Plaintiffs' case-specific experts even offers an opinion that meets Florida's 'more likely than not standard of causation' including its 'but for' test"; and (4) "all five of Plaintiffs' specific-causation witnesses compound the errors in their scientific and unreliable

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<sup>109</sup> *Id.* at 561:17.

<sup>110</sup> *See* Doc. 1134, *In re Seroquel Prods. Liab. Litig.*, Case No. 6:06-md-1769-Orl-22DAB. The motion and all exhibits were filed under seal due to the parties' confidentiality concerns.

<sup>111</sup> *Id.* at 3.

<sup>112</sup> *Id.* (citing *McClain*, 401 F.3d at 1243).

causation opinions by relying on little more than cursory review of *insufficient medical facts* about Plaintiffs - including misleading summary charts of cherry-picked data *prepared by Plaintiffs' counsel* and spoonfed to these putative experts, which is impermissible.”<sup>113</sup>

On the same day it filed the *Daubert* motion, AstraZeneca filed a summary judgment motion directed at Haller's claims.<sup>114</sup> The company raised causation as its very first argument, stating:

[A]ll of Plaintiff's claims fail for lack of proof on the essential element of causation - including both general and specific "medical causation." Plaintiffs' expert testimony on medical causation should be excluded, as explained in AstraZeneca's *Daubert* motions incorporated by reference. Indeed, the specific-causation testimony of Plaintiff's two case-specific experts, Drs. Tulloch and Abramson, is clearly inadmissible under *Daubert*. Without expert evidence of both general and specific medical causation, all of Plaintiff's claims fail. *See Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1322 (11th Cir. 1999). Even apart from admissibility under *Daubert*, Plaintiff has no evidence that meets Florida's "'more likely than not' standard of causation," including its "but for" test. *Gooding v. University Hosp. Bldg., Inc.*, 445 So.2d 1015, 1018 (Fla. 1984); *Colville v. Pharmacia & Upjohn Co.*, 565 F. Supp. 2d 1314, 1322 (N.D. Fla. 2008).<sup>115</sup>

#### Dr. Tulloch's Declaration

In the face of these criticisms, on November 21, 2008, Dr. Tulloch prepared a 12-page declaration addressing his causation opinions regarding the four Plaintiffs - including Haller - about which he had been asked to serve as an expert.<sup>116</sup> This declaration was filed in opposition to

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<sup>113</sup> *Id.* at 4-5.

<sup>114</sup> *See* Doc. 13.

<sup>115</sup> *Id.* at 2.

<sup>116</sup> Ex. 22 to Doc. No. 1160, *In re Seroquel Prods. Liab. Litig.*, Case No. 6:06-md-1769-Orl-22DAB. The response and all exhibits were filed under seal due to confidentiality concerns.

AstraZeneca's specific causation *Daubert* motion.

In his declaration, Dr. Tulloch noted that his expert report stated he reserved the right to supplement his opinions because document production was ongoing.<sup>117</sup> Dr. Tulloch further stated that at and after his depositions, he was provided "additional medical records which reflect additional data involving Plaintiffs' weights and blood sugars prior to and during their use of Seroquel and diagnosis of diabetes."<sup>118</sup> Accordingly, Dr. Tulloch stated, his declaration was "supplement[ing]" and "clarify[ing]" his opinions based on "new records and data."<sup>119</sup>

In his declaration, Dr. Tulloch reiterated that Haller's weight was not recorded when he started taking Seroquel in October of 2002.<sup>120</sup> Dr. Tulloch further noted weights of 226 pounds on March 13, 2003, 247 pounds on June 23, 2003, and a peak of 251 pounds in May of 2004.<sup>121</sup> Dr. Tulloch thus stated that Haller gained at least 25 pounds since the first weight was recorded on Seroquel.<sup>122</sup> Dr. Tulloch admitted in his declaration that Haller's weight "fluctuated."<sup>123</sup> He further noted that Haller began losing weight in the months following May of 2004.<sup>124</sup>

Dr. Tulloch commented on the fact that in June of 2004, Haller had to be hospitalized for

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<sup>117</sup> Tulloch Decl. at 3.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> *Id.* at 8.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

elevated blood sugars and “suspected pancreatitis, another condition associated with Seroquel use and which Mr. Haller’s treating physician Dr. Sreenath questioned as being drug induced.”<sup>125</sup> Dr. Tulloch noted that Haller lost weight during and after this hospitalization.<sup>126</sup>

Dr. Tulloch stated that Haller was diagnosed with uncontrolled diabetes on August 6, 2004, when he weighed 225 pounds.<sup>127</sup> Dr. Tulloch noted that the 25-pound weight gain while Haller was on Seroquel was more than 10% of Haller’s body weight and “increases his risk of diabetes.”<sup>128</sup> Continuing, Dr. Tulloch stated: “As with many other drug exposure-disease relationships, the exact mechanism is not always known, yet the causal association is accepted in the medical and scientific communities. It is my opinion that is the case here and that but for the exposure to Seroquel, Mr. Haller would not have developed diabetes in August 2004.”<sup>129</sup>

Dr. Tulloch also discussed the issue of multiple risk factors, quantification of each risk factor in each individual plaintiff, and AstraZeneca’s criticisms of his “straw/camel” analogy.<sup>130</sup> Dr. Tulloch asserted that “it is impossible to attribute a percentage of risk for each risk factor in a given individual” (as opposed to a population).<sup>131</sup> He stated that risk factors may “interact synergistically

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<sup>125</sup> *Id.* at 8-9.

<sup>126</sup> *Id.* at 9.

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

<sup>130</sup> *Id.* at 10.

<sup>131</sup> *Id.*

in different ways in different patients.”<sup>132</sup> Acknowledging that “each of these patients had other risk factors for diabetes,” he opined that “their risk profiles were relatively stable prior to the addition of Seroquel as a new risk factor for diabetes.[.]”<sup>133</sup> Further, noted Dr. Tulloch, these patients “did not develop diabetes despite having other risk factors for diabetes until after exposure to Seroquel.”<sup>134</sup> Hence, opined Dr. Tulloch, “but for exposure to Seroquel, these individuals would not have developed diabetes when they did.”<sup>135</sup>

As for his methods, Dr. Tulloch asserted that he reached his opinions “using methodology consistent with the methods used by clinicians in clinical practice when evaluating a referred patient’s history and clinical course and when asked to give second opinions and consultations to other physicians based on the patient’s records and diagnostic testing.”<sup>136</sup> Dr. Tulloch stated that his “methodology with regard to each opinion was the same: [he] reviewed medical histories and the notes of physical examinations performed by other physicians; [he] gathered and scrutinized clinical data, including weight recordings and results of laboratory tests; [he] reviewed and analyzed existing peer-reviewed published literature and the manufacturer’s own clinical trials, all supporting the view that Seroquel can cause diabetes; and [he] considered the role other risk factors might have played

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<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at 10-11.

<sup>135</sup> *Id.* at 11.

<sup>136</sup> *Id.*

in the development of diabetes in each individual's case."<sup>137</sup> "Ultimately," Dr. Tulloch concluded that, "but for ingestion of Seroquel, . . . David Haller would not have developed diabetes at the time of [his] respective diagnos[is]."<sup>138</sup>

Although in his deposition he made abundantly clear that his specific causation opinion as to Haller rested on a single ground - temporality - Dr. Tulloch concluded his declaration by listing five different bases for his opinion: (1) "the temporal association of ingestion of Seroquel with the onset of diabetes"; (2) "the fact that other risk factors had not brought about the onset of diabetes prior to the introduction of Seroquel"; (3) "the presence of a biologically plausible mechanism whereby Seroquel can cause diabetes"; (4) "the demonstration in the literature of a significantly increased risk of diabetes as a result of Seroquel ingestion"; and (5) "the consistency in the clinical courses of the individuals here compared with those of patients in literature and clinical trials."<sup>139</sup>

#### Dr. Tulloch's Testimony at the *Daubert* Hearing

The Court held a *Daubert* hearing on January 15, 2009. Dr. Tulloch testified at that hearing. On direct examination, when asked for his opinion regarding whether Haller's "use of Seroquel was a substantial contributing cause of his development of diabetes in August of 2004," Dr. Tulloch replied: "I believe it was a contributing factor. . . . [At my deposition] my simple concept was that of the final straw that breaks the camel's back. I acknowledged all of the risk factors that this man

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<sup>137</sup> *Id.* at 11-12.

<sup>138</sup> *Id.* at 12.

<sup>139</sup> *Id.*



had. And then I pointed out that he got Seroquel at a certain date. On three separate occasions after that he developed pancreatitis, which is a known complication of Seroquel. And then some months after that he developed high blood sugar, compatible with diabetes.”<sup>140</sup>

When questioned about the materials he reviewed in reaching his opinion, Dr. Tulloch noted that Haller had “voluminous medical and other records.”<sup>141</sup> Dr. Tulloch stated he “skimmed through most of those, and then also a summary that puts all of those together”; he also stated some of the information had been put on a “flow sheet.”<sup>142</sup> Dr. Tulloch noted that he relies on summaries of medical records in his regular medical practice, and remarked, “[t]hat’s the only way I survive[.]”<sup>143</sup> Dr. Tulloch then reiterated his oft-used “straw/camel” analogy: “I believe that if one adds up the circumstances, the final straw arrived, that broke the camel’s back, of his blood sugar on the 6th of August in 2004.”<sup>144</sup>

Dr. Tulloch referred to Exhibit 19, which he described as “a serial listing of [Haller’s] weights

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<sup>140</sup> *Daubert Hr’g Tr.* 15.

<sup>141</sup> *Id.* at 16.

<sup>142</sup> *Id.*

<sup>143</sup> *Id.* As a follow-up question, Plaintiffs’ counsel asked Dr. Tulloch if he had reviewed individual medical records, as opposed to summaries of those records. *Id.* at 17. Dr. Tulloch replied, “I skimmed through most of the ones that were there, sir. That’s - - it’s a form [of] masochism that we don’t entertain very often.” *Id.*

<sup>144</sup> *Id.* at 16.

from 1985 until 2008.”<sup>145</sup> At the outset, Dr. Tulloch admitted that Haller’s weight “does oscillate.”<sup>146</sup> Dr. Tulloch testified that in 2002 Haller was given Seroquel, and “from that time there’s an apparent dramatic rise in weight.”<sup>147</sup> At a later point in his testimony, Dr. Tulloch reiterated: “There is a dramatic increase in body weight, which occurs from his first exposure to Seroquel in October of 2002, and that high weight is maintained until his development of diabetes in August of 2004.”<sup>148</sup>

During his direct examination, Dr. Tulloch noted that Haller developed pancreatitis in November of 2003, January of 2004, and July of 2004.<sup>149</sup> He also admitted that Haller had a “fairly dramatic rise” in weight in 1997.<sup>150</sup>

Dr. Tulloch testified that prior to using Seroquel, Haller had the following risk factors for diabetes: he was psychotic; at least from the year 1997, he was overweight; he was a smoker; he had high blood pressure; he had high cholesterol; he had a sedentary lifestyle; and he was on Depakote

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<sup>145</sup>*Id.* at 18. As a visual representation of Haller’s weight gain and loss over time, Exhibit 19 is seriously flawed, as will be discussed further *infra*.

<sup>146</sup> *Id.*

<sup>147</sup>*Id.* at 19. After stating that Haller had an “apparent dramatic rise in weight” following his ingestion of Seroquel, Dr. Tulloch implicitly acknowledged the misleading nature of Exhibit 19 by volunteering: “I would point out that the points, the time points there are a little bit apart. They go from 2002 to 2003. So where it looks like a very steep curve, we’re missing a few months in between.” *Id.* Later in his deposition, Dr. Tulloch resurrected this point in the course of repeating his claim that Haller had a “massive weight gain” after he began taking Seroquel. *Id.* at 64. This time, Dr. Tulloch stated, “But in your favor, I pointed out that the time scale is a little bit modified in that massive rise, that there’s several months in there that don’t show.” *Id.*

<sup>148</sup> *Id.* at 22.

<sup>149</sup> *Id.* at 19.

<sup>150</sup> *Id.*

from 1997-2000.<sup>151</sup> Dr. Tulloch added that the blood pressure medications Haller was using when he developed diabetes were not the sort that precipitate diabetes or pose a dramatic risk factor for diabetes.<sup>152</sup> Dr. Tulloch also noted that even though Haller had all those risk factors, he did not develop diabetes during time frame 1997-2000, nor did he after he began taking Risperdal.<sup>153</sup>

When Dr. Tulloch was asked, “[A]re you able to say, with a reasonable degree of medical certainty, that any of the risk factors [discussed], other than the Seroquel, was not the sole cause of his development of diabetes in August of 2004?”, he replied: “Well, yes, sir. You know, in these additive risk factor issues, that simple concept of that final straw that breaks the camel’s back is the best analogy I can use. Yes, sir.”<sup>154</sup> When asked if his opinion that Seroquel caused Haller to develop diabetes in August of 2004 was based simply on the fact that he developed diabetes while on the drug, Dr. Tulloch reiterated his “final straw” analogy.<sup>155</sup> Plaintiffs’ counsel then asked, “So your opinion then that Mr. Haller’s diabetes was caused by Seroquel is not based merely on the temporal relationship between his use of Seroquel and his diagnosis of diabetes?”<sup>156</sup> Dr. Tulloch replied, “No, sir. We have and will discuss a number of other mechanisms by which Seroquel can

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<sup>151</sup> *Id.* at 19-21.

<sup>152</sup> *Id.* at 20-21.

<sup>153</sup> *Id.* at 21.

<sup>154</sup> *Id.*

<sup>155</sup> *Id.* at 21-22.

<sup>156</sup> *Id.* at 22.

cause a rise in blood sugar, damage to the pancreatitis [sic], and the development of diabetes.”<sup>157</sup>

When asked if he had “any opinion as to whether Seroquel was a substantial contributing cause of Mr. Haller’s development of diabetes in August of 2004,” Dr. Tulloch replied: “I have summarized for you, sir. I believe Seroquel causes weight gain, Seroquel causes a rise in glucagon, Seroquel causes insulin resistance, Seroquel is - - use of Seroquel is associated with high levels of diabetes. And I think that would summarize both the outcome and some of the contributing factors.”<sup>158</sup> Apparently recognizing the non-responsiveness of this answer with respect to specific (as opposed to general) causation, Plaintiffs’ counsel tried again: “So we’re absolutely clear, is it your opinion that Mr. Haller’s use of Seroquel was a substantial contributing cause of his development of diabetes in August of 2004?”<sup>159</sup> Dr. Tulloch replied: “The final straw that broke the camel’s back. Yes, sir.”<sup>160</sup> Wrapping up the direct examination, Plaintiffs’ counsel asked Dr. Tulloch, “Is it your opinion that . . . Mr. Haller would not have developed diabetes in August of 2004, but for his use of Seroquel?”<sup>161</sup> Dr. Tulloch replied, “You are pushing me hard, sir, but certainly it was the final straw that broke the camel’s back, yes, sir.”<sup>162</sup>

Dr. Tulloch was subjected to vigorous cross-examination. At the outset, AstraZeneca’s counsel elicited that in this case and the other three in which Dr. Tulloch was testifying, Dr. Tulloch

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<sup>157</sup> *Id.* at 22-23.

<sup>158</sup> *Id.* at 28.

<sup>159</sup> *Id.*

<sup>160</sup> *Id.*

<sup>161</sup> *Id.* at 29.

<sup>162</sup> *Id.*

was willing to give an opinion after reviewing only a portion of the medical records.<sup>163</sup> Defense counsel then established that in most cases in which Dr. Tulloch has testified, he has been able to obtain an independent history and had the ability to examine patients.<sup>164</sup> In his clinical practice, he always takes a medical history and does a physical examination.<sup>165</sup> Dr. Tulloch further testified that apart from the situation where someone shows him data “casually in the hall” and he “helps” that person make a diagnosis, if a diagnosis is going to be made in his name, he must see the patient before rendering a diagnosis of diabetes.<sup>166</sup> Dr. Tulloch essentially admitted he did not follow his regular method in analyzing Haller’s case; he formed his opinions without talking to Haller and obtaining a medical history.<sup>167</sup>

Dr. Tulloch conceded that even though Haller was prescribed Seroquel in October of 2002, Dr. Tulloch formed his opinions in this case without knowing what dose of Seroquel Haller was on until May of 2003, some eight months after he started taking Seroquel.<sup>168</sup> Dr. Tulloch also admitted his prior testimony that Haller did not always take his Seroquel and that he wasn’t compliant with many of his medications.<sup>169</sup>

Dr. Tulloch further conceded that he had testified in deposition that he didn’t know how much

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<sup>163</sup> *Id.* at 33.

<sup>164</sup> *Id.* at 42-43.

<sup>165</sup> *Id.* at 43.

<sup>166</sup> *Id.*

<sup>167</sup> *Id.* at 43-44.

<sup>168</sup> *Id.* at 44-45.

<sup>169</sup> *Id.* at 45.

weight Haller gained in the first year he was on Seroquel, and that it was speculative to say how much weight Haller gained while on the medication.<sup>170</sup> However, Dr. Tulloch countered that the information “has been summarized very nicely in Exhibit 19.”<sup>171</sup>

AstraZeneca’s counsel established that Dr. Tulloch did not review any of Haller’s treating physicians’ depositions.<sup>172</sup> More to the point, she elicited that Dr. Tulloch formed his opinions without knowing that Haller’s treating physician testified in 2008 that Haller was not diabetic.<sup>173</sup> In fact, Dr. Tulloch admitted that he was learning that information for the first time at the *Daubert* hearing.<sup>174</sup> Dr. Tulloch also conceded that Haller is still taking Seroquel and Haller’s sugars are currently “absolutely well controlled” while he’s on Seroquel.<sup>175</sup>

As for his testimony on direct regarding Haller’s prior episodes of pancreatitis, Dr. Tulloch admitted that he testified in deposition that there is not enough scientific evidence to conclude that Seroquel is a cause of pancreatitis, that his expert report was wrong to say it was causal, and that all he could say was that there was an association based on case reports.<sup>176</sup> Dr. Tulloch agreed that an association is not causation, “[u]nless it’s been shown to be a mechanistic way . . . in an experimental

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<sup>170</sup> *Id.* at 45-46.

<sup>171</sup> *Id.* at 46.

<sup>172</sup> *Id.* at 47.

<sup>173</sup> *Id.*

<sup>174</sup> *Id.* at 48.

<sup>175</sup> *Id.*

<sup>176</sup> *Id.* at 48-50.

setting with animals or in a clinical setting[.]”<sup>177</sup>

Dr. Tulloch reiterated that to a reasonable degree of medical probability, Haller would have developed diabetes whether or not he ever took Seroquel.<sup>178</sup> This is because Haller had many other risk factors for diabetes: obesity, hypertension, smoking, sedentary lifestyle and psychosis.<sup>179</sup> In fact, Dr. Tulloch made clear that all of the plaintiffs about which he was expressing causation opinions would have gotten diabetes at some point in time, even if they had never taken Seroquel.<sup>180</sup> Dr. Tulloch posited that this might not have happened until age 105, but he admitted that they could have gotten diabetes at age 25 if they made bad lifestyle choices, became pregnant, or were exposed to certain medications, including some antipsychotics and blood pressure medicines.<sup>181</sup> On the other hand, he indicated, if they made really good lifestyle choices, they might live to 105.<sup>182</sup>

Although Dr. Tulloch was extremely reluctant to agree that it was “speculative” to say when these plaintiffs - including Haller - would get diabetes, he gave an answer that effectively conceded the point.<sup>183</sup> Invoking his “straw/camel” analogy, Dr. Tulloch stated, “I don’t know what speculative means. I leave the analogy, sometimes at 25, if everything is bad, sometimes at 105, if the guardian angel is kind, and somewhere in between the straws stack up hard. . . . I’m avoiding the word

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<sup>177</sup> *Id.* at 50.

<sup>178</sup> *Id.* at 54.

<sup>179</sup> *Id.* at 55.

<sup>180</sup> *Id.*

<sup>181</sup> *Id.* at 55-56.

<sup>182</sup> *Id.* at 56.

<sup>183</sup> *Id.*

‘speculative,’ because I don’t know what it means legally.’<sup>184</sup>

Defense counsel then examined Dr. Tulloch about the declaration he submitted after AstraZeneca filed its summary judgment and *Daubert* motions. Specifically, counsel brought up the statement in Dr. Tulloch’s declaration that Haller would not have developed diabetes in August of 2004 absent ingestion of Seroquel.<sup>185</sup> Dr. Tulloch responded, “Without that being the final straw, yes, ma’am.”<sup>186</sup> Regarding Dr. Tulloch’s theory that Haller’s Seroquel use accelerated the onset of his diabetes,<sup>187</sup> Dr. Tulloch admitted he had not attempted to quantify the acceleration of Haller’s diabetes, because he can’t.<sup>188</sup> In that regard, Dr. Tulloch stated, “You are trying very hard to get me to quantify a lot of things, ma’am, and I wouldn’t, because I couldn’t, because it’s not good science. That’s correct.”<sup>189</sup> Dr. Tulloch was then asked, “And you could not say how much [of] Mr. Haller’s development of diabetes was accelerated, right? . . . [B]ecause it would be speculative?”<sup>190</sup> He responded, “The final straw, yeah. The final straw that breaks the camel’s back. That’s the date it

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<sup>184</sup> *Id.* at 57.

<sup>185</sup> *Id.* at 58.

<sup>186</sup> *Id.*

<sup>187</sup> When asked if he believed that Seroquel somehow accelerated Haller’s development of diabetes through weight gain, Dr. Tulloch responded, “Well, and the other mechanisms we have discussed; the change in the pancreatitis, the change in the blood sugar, the change in the peripheral fat cells.” *Id.* Defense counsel then confronted Dr. Tulloch with his deposition testimony in which he agreed that “Seroquel somehow accelerated the development of the diabetes because of the weight gain[.]” *Id.* at 58-59.

<sup>188</sup> *Id.* at 59.

<sup>189</sup> *Id.*

<sup>190</sup> *Id.*



happened. That's what happened to his weight. There are the other mechanisms. But that's it. Those are the facts."<sup>191</sup> Pressing the point, AstraZeneca's attorney asked, "You couldn't say without . . . taking Seroquel . . . whether he would have gotten diabetes on August 1 of 2004, or August 1 of 2003, or August 1 of 2005, right?"<sup>192</sup> Dr. Tulloch replied:

Ma'am, you're trying to paint me into a corner that I don't think there is good data for. What I have said was that this man developed it under the circumstances. Now you're taking that came[l]'s back that's broken and saying, Tulloch, pull off one straw at a time and tell me when the diabetes would have gone away. That's not good science. What I can say is that those circumstances resulted in him having a blood sugar that was compatible with diabetes and with a hemoglobin A1C that showed the sugars had been way off for a good period of time.

Now, ask me to take away Seroquel, well, it would still have happened, but it may not have happened until many years later, ma'am.

\* \* \*

Q: Without taking Seroquel, if he's not taking Seroquel, you can't say whether he would have gotten diabetes in August of 2003, August of 2004, or August of 2005, right?

\* \* \*

A: No. You're trying to make me speculate, and I don't know what the legal issue of speculation is, so I'm trying to avoid that.

He developed diabetes, we saw it. And the factors were there; weight gain, Seroquel and all the things that Seroquel does to the body. Now you're saying, Tulloch, take away that straw, and I'm reluctant to commit myself, because you're understanding my problem.

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<sup>191</sup> *Id.*

<sup>192</sup> *Id.* at 59-60.

Q: *I'm saying you can't. You can't say whether - - if he's not taking Seroquel, whether he would have developed diabetes in August of 2003 or August of 2004 or August of 2005. You can't say, right, because of all the lifestyle choices?*

A: Ma'am, but the facts are the facts. He had a medication, which by epidemiological data causes weight gain, diabetes, and by a chemical data, causes pancreatitis and hypothalamic change and all the rest of it.

Q: You can't say?

A: Okay. *You need me to say yes, I'll say yes.* But do you understand the circumstances? I don't want to speculate the facts where he got diabetes. And he gained a lot of weight with that medication.<sup>193</sup>

Defense counsel then queried Dr. Tulloch regarding paragraph 21 of his declaration. Dr. Tulloch agreed that the declaration listed five different things as bases for his causation opinions: (1) temporal association; (2) other risk factors had not brought about the onset of diabetes; (3) mechanism; (4) literature; and (5) consistency.<sup>194</sup> However, AstraZeneca's counsel pointed out that in his deposition, Dr. Tulloch admitted that the only basis for his opinion that Seroquel caused the development of diabetes was its temporal relationship with weight gain, and the weight gain's temporal relationship with diabetes.<sup>195</sup>

Dr. Tulloch agreed that the mentally ill have increased levels of diabetes.<sup>196</sup> He acknowledged that when Haller gained weight in the 2002-2003 time period, he was taking the following other drugs

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<sup>193</sup> *Id.* at 60-61 (emphasis added).

<sup>194</sup> *Id.* at 62.

<sup>195</sup> *Id.* at 62-63.

<sup>196</sup> *Id.* at 63.

besides Seroquel: Depakote, Lithium and Risperdal.<sup>197</sup> He further agreed that with all these medications, there is a temporal relationship between the drug and weight gain;<sup>198</sup> nevertheless, Dr. Tulloch maintained that Haller’s biggest weight change began when he started taking Seroquel.<sup>199</sup> Dr. Tulloch also noted that the other medications were exposed to him before “this massive weight gain.”<sup>200</sup>

Regarding the “string of things” Dr. Tulloch brought up on direct examination “about mechanism, about glucagon, about insulin physiology,” AstraZeneca’s attorney pointed out to Dr. Tulloch that in his deposition, which took place “just a month or so” before he filed his declaration, Dr. Tulloch admitted that he knew of no scientific evidence that would allow him to conclude that Seroquel directly affects the pancreas, or the cells of the pancreas, or has any other direct effect on people.<sup>201</sup> Dr. Tulloch conceded that he had given that testimony, but reiterated that he had promised if he received new data, he would share it.<sup>202</sup> In that regard, he stated: “And then in the airplane last night, I came over and I found three amylases which [were] dramatically in excess of normal,” so he

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<sup>197</sup> *Id.*

<sup>198</sup> *Id.* at 64; *see also id.* at 71 (acknowledging that Haller has been on Depakote, Lithium and Risperdal, and that those drugs are known to cause weight gain).

<sup>199</sup> *Id.* at 64.

<sup>200</sup> *Id.* As previously noted, in apparent recognition of the visually misleading nature of his weight time-line (Exhibit 19), Dr. Tulloch added: “But in your favor, I pointed out that the time scale is a little bit modified in that massive rise, that there’s several months in there that don’t show.” *Id.*

<sup>201</sup> *Id.* at 64-65.

<sup>202</sup> *Id.* at 65-67.

added pancreatitis to the list.<sup>203</sup> He asserted that at the time of his deposition, he had not noticed that data.<sup>204</sup> When asked the follow-up question, “In fact, that’s because you didn’t do a thorough review of [Haller’s] medical records before his [sic] deposition?”, Dr. Tulloch replied, “Our time is limited, ma’am, that’s correct.”<sup>205</sup>

Addressing mechanism, Dr. Tulloch testified that “the most probable mechanism” by which Haller got diabetes was “weight gain.”<sup>206</sup> AstraZeneca’s attorney then asked, “With all this other mechanism stuff, for Mr. Haller you testified it was weight gain, right?”<sup>207</sup> Dr. Tulloch answered, “Again, I go back to that additive issue. Seroquel causes weight gain, but Seroquel causes all the other issues as well. We have shown it in animals. We’ve hypothesized it to be there in humans. And as the data becomes stronger, so my opinion on the other mechanisms also become[s] stronger.”<sup>208</sup>

Defense counsel then addressed the issue of Haller’s weight fluctuations. She pointed out that in his deposition, Dr. Tulloch testified that he attributed an “excess weight gain” of 21 pounds to Seroquel.<sup>209</sup> Dr. Tulloch conceded, however, that before Haller began taking Seroquel, he had a

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<sup>203</sup> *Id.* at 67.

<sup>204</sup> *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> *Id.* at 66. Defense counsel brought out that in his deposition, Dr. Tulloch did not use the qualifier “probable.” *Id.*

<sup>207</sup> *Id.*

<sup>208</sup> *Id.*

<sup>209</sup> *Id.* at 67-68. In apparent recognition that this number had evolved, to say the least, Dr. (continued...)

period of weight gain in which he gained 80 pounds; 60 pounds of that was during the four-year period from January of 1997 to January of 2001.<sup>210</sup> Dr. Tulloch then volunteered, “I think if you go back to ‘94, you could make the weight gain even more.”<sup>211</sup> Dr. Tulloch acknowledged that this was a “big weight gain.”<sup>212</sup> Additionally, he conceded that he testified in his deposition that such a weight gain was not normal.<sup>213</sup> Dr. Tulloch admitted that he didn’t have any information regarding how Haller gained all that weight before he began taking Seroquel.<sup>214</sup>

Dr. Tulloch agreed that Haller was mentally ill and that sometimes people eat more when they’re depressed.<sup>215</sup> When asked if he had agreed in deposition that Haller’s “sedentary lifestyle and underlying psychoses were causes of his weight gain,” Dr. Tulloch answered, “Contributing factors, yes, ma’am.”<sup>216</sup> Defense counsel then forced Dr. Tulloch to concede that he had used the word “causes” in his deposition, not “contributing factors.”<sup>217</sup> When asked, “And there are many reasons

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<sup>209</sup>(...continued)

Tulloch volunteered, “Well, I think the mass [sic; presumably, “math”] may not be quite that way, but let’s leave it as weight gain. The specifics are arguable, depending on when one starts the weight gain issue.” *Id.* at 67.

<sup>210</sup> *Id.* at 68.

<sup>211</sup> *Id.*

<sup>212</sup> *Id.*

<sup>213</sup> *Id.* at 70.

<sup>214</sup> *Id.*

<sup>215</sup> *Id.*

<sup>216</sup> *Id.*

<sup>217</sup> *Id.* at 70-71.

that you know that account for Mr. Haller's weight gain, right?", Dr. Tulloch stated, "Yes, ma'am. And Seroquel was the final straw that broke the camel's back."<sup>218</sup>

AstraZeneca's attorney then returned to the subject of Dr. Tulloch's methodology. She established that in Dr. Tulloch's own clinical practice, when a patient presents with weight gain, Dr. Tulloch asks them what they eat, what their diet is, whether they exercise, what calories they take in, what calories they burn, and what medications they are taking, in order to determine why they gained the weight.<sup>219</sup> Defense counsel then asked,

Q: You didn't do that with Mr. Haller?

A: I didn't see Mr. Haller.

Q: You didn't follow your own method to figure out what the cause of Mr. Haller's weight gain was, did you?

A: I didn't have access to him, ma'am.

Q: You didn't even take - - send him a questionnaire, right?

A: No, ma'am.

Q: You didn't have - - because you didn't take a medical history from Mr. Haller, or even send him a questionnaire to fill out, or even read his deposition, right, you didn't have any specificity about what was causing the weight gain he experienced before he took Seroquel, or while he was on Seroquel?

A: Other than the access to his chart. That's correct, ma'am.<sup>220</sup>

Defense counsel then asked Dr. Tulloch whether it was fair to say he had not ruled out

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<sup>218</sup> *Id.* at 71.

<sup>219</sup> *Id.*

<sup>220</sup> *Id.* at 71-72.

alternative causes for Haller's weight gain.<sup>221</sup> Dr. Tulloch replied, "Again, association with a medication that's been associated with weight gain in a whole lot of settings was one of the options. If your question is, did I have access to what else might have caused the weight gain, you're correct, ma'am, I did not have access to this man."<sup>222</sup> Counsel then pointed out that in his deposition, Dr. Tulloch agreed that he "did not rule out the alternative causes for [the plaintiffs'] weight gain, because [he] didn't feel that [he] needed to or had to."<sup>223</sup> Dr. Tulloch reiterated that he "didn't have access to [these plaintiffs]."<sup>224</sup>

Continuing this line of questioning, AstraZeneca's counsel asked:

Q: You cannot say how much of Mr. Haller's weight gain was due to Seroquel, and how much was due to diet, and how much was due to his lack of exercise or other factors, correct?

A: Yes, ma'am.

Q: For example, you can't say whether Seroquel caused him to gain zero, one, two, twenty. You can't say, right?

A: Ma'am, no. I think one has to point to Reference 19, and to show that from the time that he had access to Seroquel, and if one just eyeballs those numbers, then weight went, within the next few months, from 180 to 245.

\* \* \*

Q: You cannot say how much of his weight gain was due to Seroquel and how much was due to all these other factors, like diet, exercise, and psychosis, and so on, correct?

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<sup>221</sup> *Id.* at 72.

<sup>222</sup> *Id.*

<sup>223</sup> *Id.* at 73.

<sup>224</sup> *Id.*

A: Yes, ma'am. But if Seroquel was the only variable that was added to everything else that had been stable, then one would have to assume that Seroquel was responsible for a fairly major part of that.

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Q: [In your deposition] you were asked, "As to any of the weight gains by any of the plaintiffs in these cases, you cannot say how much of the weigh[t] was due to Seroquel and how much was due to diet, and how much was due to lack of exercise or other factors. Correct?" And your answer was: "That's correct." Right?

A: That's correct again. Ma'am, you read my deposition.<sup>225</sup>

On the subject of alternative causes, AstraZeneca's attorney raised the point that Haller's weight fluctuations appeared to correlate to his alternating periods of incarceration and release. On that point, Dr. Tulloch agreed that Haller got out of prison in September of 2002, something Dr. Tulloch conceded was "a huge change in his life circumstances."<sup>226</sup> Haller started taking Seroquel the very next month.<sup>227</sup> Dr. Tulloch admitted that in prison, food is controlled and that when Haller got out, he could eat what he wanted.<sup>228</sup> Counsel then inquired:

Q: You can't quantify the amount of weight gain Mr. Haller had after he started taking Seroquel, upon his release from prison, that would be due to change in diet from prison food to cooking on his own, right?

A: No, ma'am. Without asking him. And even there, if he was on a medication that stimulated his appetite, he may not have been

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<sup>225</sup> *Id.* at 73-74.

<sup>226</sup> *Id.* at 75-76.

<sup>227</sup> *Id.* at 76.

<sup>228</sup> *Id.*



aware that he was eating because of the effect of the medication. And we have shown that there is mechanisms [sic] by which these medications stimulate appetite.

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Q: [B]efore forming your opinions, did you ever look back at his weight to see if in fact he actually had a pattern of losing weight while he was in prison and gaining it back when he got out?

A: Ma'am, I did acknowledge when we were last together that he had in fact had oscillations in his weight. And we are looking at another one. The reason why I believe Seroquel contributed was the association between his massive weight gain and the onset of Seroquel. [sic, presumably "diabetes"]<sup>229</sup>

Dr. Tulloch testified he was aware that Haller was also in prison from April 1993 until January 1995, and that he lost 63 pounds during that time period.<sup>230</sup> He further conceded that by January 15, 2001, "after a longer period of freedom," Haller's weight had gone back up to 230 pounds, and that all of this occurred before Haller began taking Seroquel.<sup>231</sup>

Regarding his deposition testimony that Haller had a major weight loss every year while he was on Seroquel, Dr. Tulloch agreed that he had given that testimony; however, he stated "that's clearly not correct, because I may not have had 2008 data. But from 2008 there was another weight spike that went up to 230."<sup>232</sup> Nevertheless, Dr. Tulloch agreed that Haller weighed 230 pounds in

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<sup>229</sup> *Id.* at 77.

<sup>230</sup> *Id.* at 77-78.

<sup>231</sup> *Id.* at 78.

<sup>232</sup> *Id.* at 79.

January of 2001, before he took Seroquel, and weighed the same in August of 2008.<sup>233</sup> Additionally, Dr. Tulloch conceded that in 2005, Haller's Seroquel dosage was increased from 400 mg to 600 mg, yet Haller lost 51 pounds that year, reducing his weight from 235 pounds to 184 pounds.<sup>234</sup> Dr. Tulloch offered the following explanation: "Under the finger of somebody saying, you have diabetes, therefore, you get your act under control."<sup>235</sup>

When confronted with his deposition testimony in which he admitted that Haller's weight gain while he was on Seroquel did not cause him to have diabetes, Dr. Tulloch agreed that he had said that, but added: "I can't say that in the current setting. I have shown you how much he gained weight when he was exposed to Seroquel, with all the other issues that were present. And we have shown that while his weight was high, with all the other medications that had been present, this man developed diabetes following a period of pancreatitis. So if [sic] that context, I might have been thinking of it in a different context. But I think we have shared the data today, and now we have a nice simple graph to show the weights in relationship to the diagnosis."<sup>236</sup>

Dr. Tulloch agreed that Haller was morbidly obese, with a BMI of 37.1, before he started taking Seroquel.<sup>237</sup> Dr. Tulloch also agreed with his prior deposition testimony that weight gain in

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<sup>233</sup> *Id.*

<sup>234</sup> *Id.* at 80.

<sup>235</sup> *Id.*

<sup>236</sup> *Id.* at 83.

<sup>237</sup> *Id.* at 83-84.

someone with a BMI of 37.1 does not increase the risk of developing diabetes.<sup>238</sup> Additionally, before he began taking Seroquel, Haller had uncontrolled hypertension, smoked heavily for decades, had a sedentary lifestyle, and had high cholesterol or hyperlipidemia.<sup>239</sup> Dr. Tulloch essentially agreed that Haller was psychotic and that a significant percentage of mentally ill patients taking Seroquel would be expected to develop diabetes because of the background incidence of diabetes in the mentally ill, even assuming no effect of Seroquel.<sup>240</sup>

Dr. Tulloch agreed that Haller had “many, many causes of diabetes that pre-dated his Seroquel use.”<sup>241</sup> He conceded that Haller’s obesity, hypertension, smoking, psychosis, sedentary lifestyle, and hyperlipidemia all were causes of his diabetes.<sup>242</sup> He further admitted that these things can be the sole cause of diabetes in some people.<sup>243</sup>

AstraZeneca’s counsel next addressed the association between Seroquel and particular weight gain.

Q: . . . Is it your testimony today that you cannot say one way or the other whether Seroquel caused one pound or two pounds or five pounds or ten pounds or twenty pounds of weight gain in Mr. Haller, right?

A: I can accept that it is difficult to quantitate. I point out that in

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<sup>238</sup> *Id.* at 87-88.

<sup>239</sup> *Id.* at 84-85.

<sup>240</sup> *Id.* at 84 (“That camel’s back is being loaded[.]”).

<sup>241</sup> *Id.*

<sup>242</sup> *Id.* at 85. At first, Dr. Tulloch tried to characterize these things as “contributing factors.” *Id.* However, when pressed, he conceded they were “causes.” *Id.*

<sup>243</sup> *Id.*

every other patient there's been reports of weight gain that have been summarized in some of the literature, including by Dr. Brecker.

In this man, there was significant weight gain, which is about 65 pounds, when he started taking Seroquel. And as a physician, I have got to accept there might have been other factors as well. *But the temporal relationship is very impressive, 65 pounds when he started Seroquel.*

Q: So you agree with me that you cannot say that one pound or two pound[s] or five pound[s] or ten pounds?

A: Of that 65 pounds was Seroquel, yes, ma'am. I'm always open to there being - - if it was 65 pounds, there might have been other factors for some of them.<sup>244</sup>

Concluding her examination, AstraZeneca's counsel got Dr. Tulloch to agree that in his expert report he calculated Haller's weight gain after he began taking Seroquel at 21 pounds, that he upped that figure to 25 pounds in his declaration, and that at the *Daubert* hearing, for the first time, he increased that figure to 65 pounds.<sup>245</sup> Finally, she elicited that Haller stopped taking diabetes medications in 2006 and he continues to take Seroquel today.<sup>246</sup>

On redirect, Dr. Tulloch testified that the fact that Haller's blood sugars are now under control does not mean he is not diabetic.<sup>247</sup> Dr. Tulloch also stated he did not need to examine Haller to recognize that he satisfied the criteria for diabetes.<sup>248</sup> He asserted that "in a lot of these referrals, [he]

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<sup>244</sup> *Id.* at 91-92 (emphasis added).

<sup>245</sup> *Id.* at 92-93.

<sup>246</sup> *Id.* at 93.

<sup>247</sup> *Id.*

<sup>248</sup> *Id.* at 95.

look[s] at the numbers.”<sup>249</sup> He also reiterated that even though Haller gained a tremendous amount of weight before he took Seroquel, he didn’t develop diabetes while he was on other drugs that can cause weight gain.<sup>250</sup> Finally, when asked if anything defense counsel brought up regarding his deposition had changed his testimony or opinions at the *Daubert* hearing, Dr. Tulloch replied: “[N]o, sir. [Defense counsel] and I entertained one another at great length over many evenings, and I think we shared data. Which I then - - I promised her I would update. And as I had access to more and more, my opinions fine-tuned, but they’re pretty well similar.”<sup>251</sup>

### Analysis

In this particular case, there are so many *Daubert* problems associated with Dr. Tulloch’s opinions that it is difficult to know where to begin. The Court will first address methodology, then turn to the substance of Dr. Tulloch’s opinions.

The Court accepts as a general proposition that a physician need not necessarily examine a patient, interview that patient, or speak with the patient’s treating physician(s) in order to render opinions regarding diagnosis, prognosis, course of treatment and perhaps even causation.<sup>252</sup> In other words, the Court does not deem it necessarily fatal that an expert medical witness has relied on medical records alone to reach a specific causation opinion. However, Haller’s particular circumstances expose the failings of applying *to this specific case* what might otherwise be

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<sup>249</sup> *Id.*

<sup>250</sup> *Id.* at 96.

<sup>251</sup> *Id.* at 98.

<sup>252</sup> The Court leaves for another day the question of whether the same general process used by medical professionals to reach opinions regarding diagnosis, prognosis, and course of treatment can be used equally well to determine the cause of diabetes in any given individual.

considered a generally acceptable methodology.

The lynchpin of Dr. Tulloch's causation opinions is that Haller had a "dramatic weight gain" after he started taking Seroquel, and that this particular weight gain constituted the straw that broke the camel's back and led to Haller's diabetes. However, in Haller's particular case, there were other factors at work that could have caused Haller's weight gain. Specifically, the month before he began taking Seroquel, Haller was released from prison, and he had a demonstrated history of weight loss while in prison and weight gain during periods of release. Additionally, Haller had a history of sometimes dramatic weight gains and losses throughout his life. These fluctuations occurred before he began taking Seroquel and have continued while he is on the drug. Given this background, simple logic and common sense dictated that Dr. Tulloch do more than merely "skim" Haller's medical records and summaries to ascertain the cause of Haller's alleged weight gain after he began taking Seroquel. At a minimum, he should have conducted some further inquiry concerning Haller's diet, caloric intake, and any other life activities that could have explained Haller's weight gain. In other words, he should have applied the same scientific rigor to Haller's case that he employs in his own clinical practice to ascertain the cause of a patient's weight gain.<sup>253</sup> This was particularly critical given the fact that Dr. Tulloch did not know what Haller weighed when he began taking Seroquel. This "guess" at Haller's weight, and weight change, is impermissible under *Daubert*.

Apart from weight gain, Haller had many pre-existing and concurrent factors that could have

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<sup>253</sup> See *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001) (upholding district court's exclusion of orthopedic surgeon's specific medical causation testimony based on, *inter alia*, physician's failure to conduct physical examination of plaintiff, something that was inconsistent with diagnostic methodology doctor employed in his own practice).

caused his diabetes. Some of those factors were alcohol and drug abuse and a 40-cigarette-a-day smoking habit. Again, simple logic and common sense dictated that Dr. Tulloch conduct some inquiry concerning whether Haller was continuing these habits and, if so, what potential role they played in Haller becoming diabetic. In the circumstances of this case, Dr. Tulloch was required to do more than skim Haller's medical records.

Further, the fact that Haller is still taking Seroquel and yet is no longer diabetic, at least in the opinion of his treating physician, suggests that Dr. Tulloch should have contacted Haller's treating physician - or at least read that doctor's deposition - before reaching his opinions in this case. It is telling that Dr. Tulloch learned about the treating physician's opinion for the first time at the *Daubert* hearing.

Beyond these deficiencies in Dr. Tulloch's general approach, his review of Haller's medical records was apparently hurried, cursory, and incomplete. This led to significant errors. Perhaps the most important of these is the ever-changing weight increase figure Dr. Tulloch attributed to Haller's use of Seroquel. In his expert report, Dr. Tulloch provided a number of 21 pounds. By the time of his declaration, that number had increased, to at least 25 pounds. At the *Daubert* hearing, it had more than tripled, to 65 pounds. This is a startling progression. And this is no trivial matter, since Dr. Tulloch attributes Haller's diabetes onset to the weight he gained after he began taking Seroquel. The fact that these figures all come from Haller's medical records and that Dr. Tulloch could not get this figure right in his initial report - or even in his subsequent declaration - shows that he did not employ the kind of methodology that *Daubert* requires.<sup>254</sup>

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<sup>254</sup>Similarly, Dr. Tulloch initially missed by eight months the date on which Haller started  
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Another glaring example is Exhibit 19, the weight vs. time graph Dr. Tulloch relied on at the *Daubert* hearing. As a visual representation of Haller's weight gain and loss over time, Exhibit 19 is seriously flawed, for at least two reasons. First, the graph is grossly misleading because the horizontal date axis is not scaled. For example, the distance on the chart between 1-22-97 and 8-26-00 (a 3 ½ year interval) is the same as between 6-23-04 and 6-24-04 (a 1-day interval). This results in an artificially steep slope at some points on the chart. Second, the graph is comprised of two stapled-together segments, and the lines signifying weight increments on the vertical axis are misaligned from the first to the second segment. The Court is at a loss to conceive how a graph so visually misleading could be considered an aid to the Court. Further, this demonstrates that the reliability problems associated with Dr. Tulloch's methodology were not confined to the early stages of his involvement in the case, but instead continued all the way through the *Daubert* hearing.

Beyond the problems associated with the way in which Dr. Tulloch reached his opinions, the stark fact is that the grounds for his causation opinion have been a veritable moving target.<sup>255</sup> And what is most troubling is that the underpinnings of his opinions have changed in direct response to AstraZeneca's motion practice.

The most significant example is the basis for Dr. Tulloch's opinion that Seroquel caused Haller's diabetes. As previously noted, in his deposition, Dr. Tulloch made crystal clear that the sole basis for his opinion that Seroquel caused the development of diabetes in Haller was the temporal relationship between Haller's taking Seroquel and his subsequent weight gain, and the weight gain's

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<sup>254</sup>(...continued)  
taking Seroquel.

<sup>255</sup>The Court has already covered the changing weight gain figures.



temporal relationship with the development of diabetes. AstraZeneca subsequently filed its summary judgment and *Daubert* motions demonstrating that, under binding Eleventh Circuit precedent, temporal connection alone was legally insufficient. Then, despite his clear and unequivocal deposition testimony, and in a transparent attempt to thwart exclusion of his opinions on *Daubert* grounds and entry of summary judgment in AstraZeneca's favor, Dr. Tulloch submitted his declaration listing four additional grounds for his causation opinion. Finally, by the time of the *Daubert* hearing, Dr. Tulloch had added pancreatitis to the causation mix.

At the *Daubert* hearing, Dr. Tulloch characterized this remarkable evolution in his opinions as mere "fine-tun[ing]" and asserted that his most recent opinions were "pretty well similar."<sup>256</sup> This is simply wishful thinking on Dr. Tulloch's part; such characterizations grossly understate the significant changes associated with his expert opinions over the course of this case. This is not the relatively unremarkable situation where an expert witness merely tweaks an opinion in response to new considerations. At the very least, the drastic changes in Dr. Tulloch's opinions illustrate that he reached his initial conclusions prematurely and based on incomplete data, then later gathered what additional information he could to shore up his initial opinions. This approach smacks of post-hoc rationalization and is devoid of the intellectual rigor that *Daubert* demands. Put bluntly, this is not how good science is done. Because Dr. Tulloch's opinions were seriously flawed from their inception due to inadequate methodology, *Daubert* requires their exclusion.

The Court now turns to the substance of Dr. Tulloch's specific medical causation opinions. Dr. Tulloch's opinions would not assist the trier of fact in this case because there is too great an

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<sup>256</sup> *Daubert* Hr'g Tr. 98.

analytical leap between the particular facts of Haller's case and Dr. Tulloch's specific causation opinions. In that respect, Dr. Tulloch's proposed expert testimony is both unreliable and does not satisfy *Daubert's* "fit" requirement. See *McDowell v. Brown*, 392 F.3d 1283, 1298-99 (11th Cir. 2004) (discussing *Daubert's* reliability and relevance prongs).

Clearly, from a plaintiff's standpoint, Haller's particular case is a difficult one in terms of specific causation. Unfortunately, in an effort to surmount those difficulties, Plaintiffs' counsel and Dr. Tulloch have overreached significantly in terms of their causation theory. In fact, the Court has not seen a clearer case of an expert being maneuvered by counsel to elicit an opinion with which he is not really comfortable. This was evidenced by Dr. Tulloch's direct examination at the *Daubert* hearing. Whenever Plaintiffs' counsel invoked the magic words "but for" and "substantial contributing factor," Dr. Tulloch always qualified his answer with the "straw/camel" analogy. At the end of his direct examination, he even went so far as to protest that Plaintiffs' counsel was "pushing [him] hard[.]"<sup>257</sup> This suggests to the Court that Dr. Tulloch recognized just how far out on a limb he is with his specific causation opinions regarding Haller.

Distilled to essentials, what emerges intact from Dr. Tulloch's testimony is that Haller had a number of factors that cause diabetes, that some or all of those factors could have been the cause of Haller's diabetes onset, and that it is sheer speculation to say that Seroquel was a "but for" cause of Haller's diabetes or a factor that contributed "substantially" to the disease. It is abundantly clear that any one or all of a host of things besides Seroquel could have (1) caused Haller to gain weight after he began taking Seroquel (assuming he actually did so), and (2) caused Haller to be diagnosed

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<sup>257</sup> *Id.* at 29.

with diabetes in August of 2004.

As previously discussed, in paragraph 21 of his declaration, Dr. Tulloch listed five bases for his specific causation opinions: (1) “the temporal association of ingestion of Seroquel with the onset of diabetes”; (2) “the fact that other risk factors had not brought about the onset of diabetes prior to the introduction of Seroquel”; (3) “the presence of a biologically plausible mechanism whereby Seroquel can cause diabetes”; (4) “the demonstration in the literature of a significantly increased risk of diabetes as a result of Seroquel ingestion”; and (5) “the consistency in the clinical courses of the individuals here compared with those of patients in literature and clinical trials.”<sup>258</sup>

Standing alone, the first factor - temporal connection - is legally insufficient. *McClain*, 401 F.3d at 1243. The second listed ground - that other risk factors had not yet caused diabetes - is also unpersuasive. This observation is largely temporal proximity in disguise. It posits that arguably the last additive factor - Seroquel - is necessarily the one that caused or substantially contributed to causing the disease. This overlooks Dr. Tulloch’s own testimony regarding the slow progression of diabetes and the additive nature of the factors that can cause it. Moreover, it is equally plausible that the additive effects of, or an incremental increase in, one or more of the other risk factors was the actual tipping point. The third and fourth factors - biologically plausible mechanism and literature demonstrating a connection between Seroquel and diabetes - relate to *general* causation and carry little if any relevance to the question of whether Seroquel caused diabetes in Haller’s *specific* case.<sup>259</sup>

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<sup>258</sup> Tulloch Decl. at 12.

<sup>259</sup> It is important to note Dr. Tulloch’s particular word choice regarding the third factor: “the presence of a biologically plausible mechanism *whereby Seroquel can cause diabetes*[.]” (Tulloch Decl. at 12 (emphasis added).) As phrased, this factor relates to general causation. *Cf. McClain*, 401 (continued...)

The last factor - consistency with other patients in literature and clinical trials - has not been shown to apply at all to Haller. Dr. Tulloch has failed to demonstrate that Haller's specific history is comparable to those of patients involved in clinical trials or discussed in the literature.<sup>260</sup>

Consequently, it appears that Haller is left with temporal connection. Toward the end of his cross-examination during the *Daubert* hearing, Dr. Tulloch seemed to have retreated to this position, when he stated: "In this man, there was significant weight gain, which is about 65 pounds, when he started taking Seroquel. And as a physician, I have got to accept there might have been other factors as well. *But the temporal relationship is very impressive, 65 pounds when he started Seroquel.*"<sup>261</sup> However, even if, as an abstract proposition, temporal proximity alone could establish specific causation, in this particular case it cannot. This is because there is no factual and logical support for Dr. Tulloch's temporal connection opinion.

Dr. Tulloch does not know how much Haller weighed when he began taking Seroquel. Hence, he has no basis whatsoever apart from sheer speculation to say that Haller experienced a "massive weight gain" after he began taking the drug. Further, despite Dr. Tulloch's insistence that it was Seroquel that caused Haller to gain weight, Haller's weight fluctuated dramatically in the years

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<sup>259</sup>(...continued)

F.3d at 1243 (discussing biological plausibility regarding chemical exposure to particular persons as a matter of individual causation).

<sup>260</sup>As previously noted, Dr. Tulloch raised a sixth ground - episodes of pancreatitis - at the *Daubert* hearing. However, Dr. Tulloch conceded at that hearing that there was, at most, merely an "association" (as distinguished from "causation") between Seroquel and pancreatitis. Further, given Haller's history of alcohol abuse, Dr. Tulloch did not address the equally plausible notion that Haller's pancreatitis could have been caused by alcohol abuse.

<sup>261</sup> *Daubert Hr'g Tr.* 92 (emphasis added).

before he started taking Seroquel, and he gained *and lost* weight while he was on the drug, including during the time period before he was diagnosed with diabetes.<sup>262</sup> Additionally, Haller began taking Seroquel the month after he got out of prison and he had a demonstrated history of gaining weight following release from incarceration. Combine these circumstances with all of the pre-existing and concurrent risk factors Haller had for diabetes, and it becomes clear that it is simply impossible to say that it was Seroquel that caused Haller to gain weight, or that a weight gain after Haller began taking Seroquel caused Haller to become diabetic.<sup>263</sup> Dr. Tulloch effectively acknowledged as much during the *Daubert* hearing when he was forced to concede that (1) Haller had many causes of diabetes that pre-dated his Seroquel use; (2) without taking Seroquel, Haller might have gotten diabetes in any one of three years (2003, 2004 or 2005);(3) there were many reasons that accounted for Haller's weight gain; (4) he couldn't really say how much of Haller's weight gain was due to Seroquel and how much was attributable to other factors, such as diet, exercise and psychosis; and (5) he couldn't say how much of the 65 pounds he claims Haller gained while on Seroquel was

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<sup>262</sup>Dr. Tulloch's theory that Haller lost weight on Seroquel because he got serious about his health following his diabetes diagnosis ignores the fact that Haller lost weight during several periods after he began taking Seroquel but *before* he was diagnosed with diabetes. It is also worth noting that Haller lost weight while on the psychotropic medication Depakote, which Dr. Tulloch conceded had been associated with weight gain. Finally, Dr. Tulloch's contention that Haller's diabetes risk profile was "relatively stable" before the introduction of Seroquel is simply unsupportable given Haller's history.

<sup>263</sup> While Dr. Tulloch may not be required to definitively exclude every possible alternative cause for Haller's diabetes, he must at least adequately consider each proffered alternative cause, Mary Sue Henefin, et al., *Reference Guide on Medical Testimony*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 476 (Federal Judicial Center, 2d ed. 2000), and explain why it was not the sole cause, *Cooper*, 259 F.3d at 202. Although Dr. Tulloch acknowledged Haller's other risk factors, he did little more. It is apparent from the foregoing discussion that he failed to adequately consider those other factors and provide logical, non-speculative reasons why they were not the sole cause of Haller's diabetes.

attributable to the drug, as opposed to other factors.

Further, even if one accepts any of Dr. Tulloch's weight gain figures (21, 25 or 65 pounds) as accurate, a weight increase of that magnitude does not square with Dr. Wirshing's opinion, to the effect that persons who gained weight on Seroquel gained about nine pounds during the first couple of months of treatment, then reached a plateau. Because Dr. Tulloch stated he agreed with Wirshing on that point, his weight gain opinion is internally inconsistent.

Finally, even using Dr. Tulloch's "straw/camel" analogy, the Court is unpersuaded that a contributing factor as figuratively insubstantial as a straw equates to a *substantial* contributing factor. In the Court's view, Dr. Tulloch's testimony is sufficient only to raise the *possibility* that Seroquel caused Haller's diabetes. In other words, Dr. Tulloch has no factual or logical basis for claiming that the "final straw" in this case was some contributing factor other than the introduction of Seroquel.

The Court thus concludes that Dr. Tulloch has employed a flawed methodology in reaching his specific medical causation opinions. Moreover, those opinions are impermissibly conjectural and speculative; they require too great a leap of faith. For these reasons, Dr. Tulloch's proposed expert testimony fails both the reliability and relevance prongs of *Daubert*. The predominant lesson of *Daubert* is that federal courts are not simply to take the expert's "word for it." Because Dr. Tulloch's specific causation opinions in this case amount to no more than the *ipse dixit* of an expert witness, they must be excluded.

## **2. Dr. I. Jack Abramson**

As a preliminary issue, AstraZeneca's complaints about Dr. Abramson's qualifications to render a diabetes causation opinion are well-taken. Under the Federal Rules of Evidence, a witness may qualify as an expert "by knowledge, skill, experience, education or training." Fed. R. Evid. 702.

There is a relative dearth of Eleventh Circuit law on the subject of qualification of medical experts, and other circuits have expressed conflicting views. Compare *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001) (“[M]erely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issue.”), and *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1113 (5th Cir. 1991) (concluding that an “M.D. degree . . . alone is not enough to qualify [an expert] to give an opinion on every conceivable medical question.”), *abrogated on other grounds by Daubert v. Merrill Dow Pharms., Inc.*, 509 U.S. 579 (1993), with *Mitchell v. U.S.*, 141 F.3d 8, 15 (1st Cir. 1998) (“The fact that the physician is not a specialist in the field in which he is giving his opinion affects not the admissibility of his opinion but the weight the jury may place on it.” (quoting *Payton v. Abbott Labs*, 780 F.2d 147, 155 (1st Cir. 1985))), and *Baerman v. Reisinger*, 363 F.2d 309, 310 (D.C. Cir. 1966) (noting that “[i]t is settled law that a physician is not incompetent to testify as an expert merely because he is not a specialist in the particular field of which he speaks. The training and specialization of the witness goes to the weight rather than admissibility of the evidence, generally speaking.” (internal quotations omitted)), and *Harris v. Smith*, 372 F.2d 806, 813-14 (8th Cir. 1967) (“It is a well-established principle that the testimony of a qualified medical doctor cannot be excluded simply because he is not a specialist in a particular school of medical practice.”).

Despite the lack of firm guidance on the extent of specialization required to render a medical causation opinion, the Court agrees with AstraZeneca that Dr. Abramson’s education, training and experience simply do not render him qualified to express a diabetes causation opinion in Haller’s

case. Dr. Abramson has never diagnosed diabetes in a patient,<sup>264</sup> does not treat any of his patients for diabetes,<sup>265</sup> and admits that if he observes an elevated blood sugar in a patient he sends them either to a primary care physician or specialist.<sup>266</sup> He further has no specialized training in endocrinology and, although he asserts that he could practice primary care if he wanted to, he has not held himself out as a primary care physician at any time during the last eighteen years.<sup>267</sup>

Moreover, Dr. Abramson admits to being unqualified to discuss “the typical progression of diabetes in a particular individual,” or “to evaluate whether a patient’s clinical course is consistent with the typical development of diabetes.”<sup>268</sup> He furthermore admitted the following at the *Daubert* hearing:

Q. In your practice, if you see a patient in a limited circumstance, where you might see a high glucose reading, as part of your practice, you don’t undertake to determine the cause of that high blood glucose level; you don’t undertake to determine how long the high glucose level has been present; you don’t undertake to determine what the proper treatment regimen is; and you don’t follow the patient to see how the patient responds to treatment? Those are all true statements, in a general sense, aren’t they?

A. Yes.<sup>269</sup>

Dr. Abramson testified that he generally knew the diagnostic criteria for diabetes, but also

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<sup>264</sup> Abramson Dep. 35:7-15; *Daubert* Hr’g Tr. 35, Jan. 14, 2009 (Doc. 31).

<sup>265</sup> Abramson Dep. 36:2-4; *Daubert* Hr’g Tr. 36.

<sup>266</sup> Abramson Dep. 35:16-22; *Daubert* Hr’g Tr. 35-36.

<sup>267</sup> *Daubert* Hr’g Tr. 37-38.

<sup>268</sup> *Id.* at 38-39.

<sup>269</sup> *Id.* at 45-46.



acknowledged that “a specialty endocrinologist would have more knowledge about the intricacies of diabetes and diabetes management than I would.”<sup>270</sup> He also admitted that he did not have expertise in diagnosing the cause of diabetes in particular individuals,<sup>271</sup> and that he would have to defer to the date of diagnosis in the medical records in order to give an opinion as to when a particular patient actually developed diabetes.<sup>272</sup> In all, Dr. Abramson simply does not possess the requisite knowledge, skill, experience, education or training to render an opinion on the cause of Haller’s diabetes.

Apart from being unqualified to render a specific causation opinion in this case, Dr. Abramson offers testimony that raises other *Daubert* concerns. Although his testimony does not appear to suffer from the same methodological infirmities observed with respect to Dr. Tulloch, many of the relevance and reliability concerns raised by Dr. Tulloch’s testimony are equally applicable to Dr. Abramson. The most visible indicator of unreliability in Dr. Abramson’s opinion is his sole reliance on the temporal association between Haller’s Seroquel ingestion and his subsequent weight gain and diabetes diagnosis. As previously noted with respect to Dr. Tulloch’s testimony, merely demonstrating a temporal connection between a drug and a disease diagnosis is insufficient to prove a causal connection. *McClain*, 401 F.3d at 1243.

Dr. Abramson attempted to sidestep this legal hurdle on a few occasions by specifically stating that he was not relying solely on the temporal connection between Haller’s Seroquel ingestion

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<sup>270</sup> *Id.* at 105-06.

<sup>271</sup> Abramson Dep. 141:4-7.

<sup>272</sup> *Id.* at 193:14-194:3 (stating that he was “not evaluating [Haller’s] blood work and saying he has diabetes or he doesn’t have diabetes”).

and his subsequent weight gain and diabetes diagnosis;<sup>273</sup> however, the record demonstrates that a temporal connection was the only evidence Dr. Abramson had to go on.

First, Dr. Abramson acknowledged that the “exact mechanism” by which Seroquel can cause diabetes is “unknown.”<sup>274</sup> He was further “unprepared” to say that it was Haller’s significant weight gain on Seroquel that led to his ultimate diabetes diagnosis,<sup>275</sup> and stated at the *Daubert* hearing that, although a “variety of mechanisms” had been proposed, “the medical state of the art at this point is still trying to figure that question out definitively.”<sup>276</sup> Therefore, having not even formulated a theory about how Seroquel contributed to Haller’s diabetes, Dr. Abramson repeatedly fell back on his temporality observation, as the following exchange at his deposition exemplifies:

Q. So, in this case, what is your opinion as to how Seroquel caused Mr. - - was a cause for Mr. Haller developing diabetes?

A. I don’t know the exact mechanism of the cause of Mr. Haller developing diabetes. However, I do know that he did not have the diabetes prior to taking Seroquel, and his weight was much lower than it was after he started taking the Seroquel, and within a short time after the prescription for the Seroquel was given and he began taking the medication, his weight shot up and he began to show evidence of glucose disregulation, ultimately culminating with the diagnosis of diabetes.<sup>277</sup>

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<sup>273</sup> *Id.* at 341:4-15 (denying that it was solely a “temporal relationship between taking Seroquel, and getting diabetes” that was the basis of his opinion); *Daubert* Hr’g Tr. 30 (stating that “[i]t’s not just a temporal relationship”).

<sup>274</sup> Abramson Dep. 198:1-199:15.

<sup>275</sup> *Id.*

<sup>276</sup> *Daubert* Hr’g Tr. 87.

<sup>277</sup> Abramson Dep. 198:8-17. Dr. Abramson relied on similar observations both in his expert report and at the *Daubert* hearing as well. *See* Ex. 19 to Doc. 1160 (*In re Seroquel Prods. Liab. Litig.*, (continued...))

Further undermining the reliability of his opinion, Dr. Abramson was unable to offer any testimony, other than that based on mere temporal relationship, to explain why it was not one or more of the numerous other risk factors in Haller's life, as opposed to Seroquel, that caused him to develop diabetes. Indeed, Dr. Abramson noted that Haller had many pre-existing risk factors for diabetes, including his "weight issue," "lipid problems," hypertension, sedentary lifestyle, psychiatric disorder, heavy smoking habit, and ingestion of other medications linked to weight gain.<sup>278</sup> Furthermore, Dr. Abramson recognized that Haller was "overweight or significantly overweight" prior to his first ingestion of Seroquel.<sup>279</sup> In all, he agreed that Haller was at a "substantial risk" for developing diabetes before he ever took Seroquel.<sup>280</sup>

Dr. Abramson further acknowledged that all of Haller's pre-existing risk factors "may have

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<sup>277</sup>(...continued)

6:06-md-1769-Orl-22DAB) at 6 (concluding that Haller "did have risk factors for diabetes and after being on Seroquel for some time his weight increased dramatically and he began to show evidence of elevated blood glucose"); *Daubert* Hr'g Tr. 10-11 (testifying that Mr. Haller did not develop diabetes "through the '90's" when he exhibited "significant risk factors for diabetes," but "[w]ithin a short time after receiving Seroquel," his weight "significantly increased," he had some "elevated random blood glucose levels," and "was ultimately diagnosed with diabetes").

<sup>278</sup> *Daubert* Hr'g Tr. 28; *see also id.* at 31 (Haller had "a whole constellation of risk factors that predisposed him to developing diabetes."), 72-75 (recounting Haller's obesity, waist measurement, mental illness, family history, high cholesterol, and high triglycerides as pre-existing risk factors for diabetes), 80-82 (recounting Haller's other medications, sedentary lifestyle, hypertension, alcohol and drug abuse, smoking habits and stress as additional risk factors); Abramson Dep. 220:7-226:25 (same).

<sup>279</sup> *Daubert* Hr'g Tr. 20.

<sup>280</sup> Abramson Dep. 227:4-9 (further stating that "the analogy I would make is that he was an egg shell in terms of his diabetes risk").

played some role” in his development of diabetes,<sup>281</sup> and that none of these risk factors was the sole cause of his diabetes.<sup>282</sup> Indeed, Dr. Abramson admitted that “there isn’t any way to tell with regard to diabetes, whether a risk factor was an actual cause of any particular person’s diabetes.”<sup>283</sup> Moreover, Dr. Abramson was unsure of whether Haller’s pre-existing risk factors alone could have caused him to develop diabetes, consistently testifying that he could not say to a reasonable degree of medical certainty that Haller would not have gotten diabetes had he never taken Seroquel.<sup>284</sup> In fact, he stated that it was “impossible” to say whether Haller would or would not have developed diabetes “under any circumstances.”<sup>285</sup>

Despite these admissions, Dr. Abramson was curiously confident in his opinion that Seroquel

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<sup>281</sup> *Daubert Hr’g Tr.* 30.

<sup>282</sup> *Id.* at 29-30 (noting that “a disease state like diabetes is a complicated multifactorial disease where all these risk factors may play a role”).

<sup>283</sup> Abramson Dep. 334:23-335:2.

<sup>284</sup> *Daubert Hr’g Tr.* 83 (stating that Haller “may or may not” have developed diabetes without the addition of Seroquel), 85 (testifying that he could not say “that absent Seroquel, that [Haller] would not have developed diabetes”), 86 (agreeing that Haller “could have developed diabetes without taking Seroquel and he could have developed it at the time that he did”); Abramson Dep. 227:24-228:11 (testifying that Haller “may very well have developed diabetes even if he didn’t take Seroquel”), 267:8-14 (agreeing that there was no way that he could rule out that Haller would have gotten diabetes even if he never took Seroquel); 304:19-25 (agreeing that Seroquel was “an exciting factor that pushed him over the edge, so to speak”); 324:1-19 (testifying that he couldn’t say “to a reasonable degree of medical certainty” that Haller would not have developed diabetes without Seroquel); 340:7-10 (agreeing that Haller “could have developed diabetes without taking Seroquel, and he could have developed it at the time that he did”); 342:8-14 (admitting that it was a “possibility” that Haller could have developed diabetes without taking Seroquel, and that he couldn’t say that it was Seroquel alone that “pushed [Haller] over the edge.”).

<sup>285</sup> Abramson Dep. 307:16-308:3.

was a “substantial contributing cause” of Haller’s diabetes,<sup>286</sup> and that the addition of Seroquel to Haller’s pre-existing diabetes risk factors “unleashed - - or was a significant contributing factor that appears to have almost broken the camel’s back.”<sup>287</sup> His testimony at the *Daubert* hearing illuminated the basis for this opinion:

Mr. Haller had certain risk factors for diabetes and did not develop the disease. His weight fluctuated over time prior to the administration of the Seroquel, and he did not develop the disease. After the administration of the Seroquel, his general weight had shifted upwards, and after a time, began to show evidence of glucose dysregulation. That’s all.<sup>288</sup>

As the Court noted with regard to Dr. Tulloch’s reliance on the same reasoning, however, an observation that other risk factors had not yet caused diabetes until Seroquel was added to the mix is largely a temporal proximity in disguise.<sup>289</sup>

Therefore, having formed no theory as to the mechanism by which Seroquel caused Haller’s diabetes, and having failed to substantiate his opinion with anything other than a mere observation of temporal association, Dr. Abramson has not met the standard of reliability required under *Daubert*. Accordingly, his specific causation testimony is inadmissible in this case.<sup>290</sup>

### **C. Motion for Summary Judgment**

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<sup>286</sup> *Daubert* Hr’g Tr. 31.

<sup>287</sup> *Id.* at 21.

<sup>288</sup> *Id.* at 30.

<sup>289</sup> *See supra* p. 51.

<sup>290</sup> The Court notes that exclusion of both experts’ testimony is itself a basis for granting summary judgment; Haller has no other expert upon whose testimony he can rely to establish specific causation, and “[t]his type of proof *requires* expert testimony.” *McClain*, 401 F.3d at 1237 (emphasis added).

Even if the experts' testimony was admissible, their opinions are insufficient to establish a triable issue as to whether Seroquel caused Haller's diabetes, as the following discussion demonstrates.

Florida product liability actions, whether sounding in negligence or strict liability, require proof of proximate cause. *West v. Caterpillar Tractor Co., Inc.*, 336 So. 2d 80, 87 (Fla. 1976) (plaintiff must demonstrate proximate cause in order to hold manufacturer liable on theory of strict liability in tort); *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1295 (11th Cir. 2005) (Florida products liability law requires showing of proximate cause to sustain action based on negligence theory). Although the Florida courts have injected several different factors into the proximate cause analysis over the years,<sup>291</sup> the Supreme Court of Florida captured the essence of these factors when it held in *Jones v. Utica Mutual Insurance Co.*, 463 So. 2d 1153 (Fla. 1985), that "[i]n the ordinary negligence context, a defendant is liable for injury produced or substantially produced in a natural and continuous sequence by his conduct, such that 'but for' such conduct, the injury would not have occurred." *Id.* at 1156.

The test announced in *Jones* may not be suitable, however, for situations outside the "ordinary

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<sup>291</sup> See *McCain v. Florida Power Corp.*, 593 So. 2d 500, 502 (Fla. 1992) ("The proximate causation element . . . is concerned with whether and to what extent the defendant's conduct foreseeably and substantially caused the specific injury that actually occurred."); *Sardell v. Malanio*, 202 So. 2d 746, 747 (Fla. 1967) (approving of the district court's finding that in order to establish proximate cause "there must be such a natural, direct and continuous sequence between the negligent act and the injury that it can reasonably be said but for the act the injury would not have occurred.") (internal quotations omitted); *Loftin v. Wilson*, 67 So. 2d 185, 191 (Fla. 1953) ("Defendant's conduct in an action for personal injuries is considered a cause of the event if it was a material and substantial factor in bringing it about."); *Cone v. InterCounty Tel. & Tel. Co.*, 40 So. 2d 148, 149 (Fla. 1949) ("[W]hen the loss is not a direct result of the negligent act complained of, or does not follow in natural ordinary sequence from such act but is merely a possible, as distinguished from a natural and probable, result of the negligence, recovery will not be allowed.").

negligence context,” such as those cases in which there is evidence of more than one cause of an injury. Indeed, it has long been recognized that “if damages are caused by the concurring force of a defendant’s negligence and some other force for which he is not responsible, the defendant is nevertheless responsible if his negligence is one of the proximate causes of the damage.” *De La Concha v. Pinero*, 104 So. 2d 25, 27 (Fla. 1958). In *Stahl v. Metropolitan Dade County*, 438 So. 2d 14 (Fla. 3d DCA 1983), the court suggested that “[i]n [] so-called ‘concurrent cause’ cases . . . , the Florida courts have abandoned *sub silentio* the ‘but for’ test and have employed instead a ‘substantial factor’ test for the obvious reason that adherence to the ‘but for’ test in this limited type of case leads to anomalous and unacceptable results.” *Id.* at 18. According to the court, the “substantial factor” test required consideration of whether the defendant’s conduct was a “material and substantial factor in bringing [the injury] about.” *Id.* at 19 (quoting *Loflin v. Wilson*, 67 So. 2d 185, 191 (Fla. 1953)). Importantly, the *Stahl* court noted that the “substantial factor” test was to be applicable “only in those concurring cause cases where each of the said concurring causes could have alone produced the plaintiff’s injury.” *Stahl*, 438 So. 2d at 19.

The Florida Standard Civil Jury Instructions<sup>292</sup> reflect the principles enunciated in *Jones* and *Stahl*. For example, Instruction 5.1(a) teaches that proximate cause should be considered under the

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<sup>292</sup> The Supreme Court of Florida issued an opinion formally approving and authorizing the publication of the Standard Jury Instructions for use in the Florida courts on April 19, 1967, recognizing that although “it would be inappropriate for the Court at this time to consider the recommended instructions with a view to adjudging that the legal principles embodied in the recommended instructions correctly state the law of Florida . . . [t]he Court is confident that the forms of instructions recommended by the Committee [on Standard Jury Instructions] state as accurately as a group of experienced lawyers and judges could state the law of Florida in simple understandable language.” *In re Standard Jury Instructions*, 198 So. 2d 319, 319 (Fla. 1967). The Florida Supreme Court periodically issues opinions adopting revisions to the instructions that are recommended by the Supreme Court Committee on Standard Jury Instructions.

following test:

Negligence is a legal cause of [loss] [injury] [or] [damage] if it directly and in natural and continuous sequence produces or contributes substantially to producing such [loss] [injury] [or] [damage], so that it can reasonably be said that, but for the negligence, the [loss] [injury] [or] [damage] would not have occurred.

Fla. Std. Jury Instr. (Civ.) 5.1(a). Likewise, instruction 5.1(b) incorporates the “substantial factor” test into a concurring cause instruction, as follows:

In order to be regarded as a legal cause of [loss] [injury] [or] [damage], negligence need not be the only cause. Negligence may be a legal cause of [loss] [injury] [or] [damage] even though it operates in combination with [the act of another] [some natural cause] [or] some other cause if such other cause occurs at the same time as the negligence and if the negligence contributes substantially to producing such [loss] [injury] [or] [damage].

Fla. Std. Jury Instr. (Civ.) 5.1(b). The Note on Use accompanying instruction 5.1 indicates that instruction 5.1(a), incorporating the “but for” test, “is to be given in all cases.” Note on Use, Fla. Std. Jury Instr. 5.1. Furthermore, instruction 5.1(b) is to be given “when the court considers it necessary,” and “does not set forth any additional standard for the jury to consider in determining whether negligence was a legal cause of damage but only negates the idea that a defendant is excused from the consequences of his negligence by reason of some other cause concurring in time and contributing to the same damage.” *Id.*

As Haller notes in his response to the motion, the concurring cause instruction has been mandated in cases where the facts supported a theory that the defendant’s negligence acted only in combination with other factors to cause an injury. *See Hart v. Stern*, 824 So. 2d 927, 930 (Fla. 5th DCA 2002) (“[I]n medical malpractice cases, concurrent causes occur when the injury is caused by the negligence of a health care provider *acting upon and combined with* the plaintiff’s pre-existing physical condition.”) (emphasis added); *Thomason v. Gordon*, 782 So. 2d 896, 898 (Fla. 5th DCA



2001) (accident victim entitled to concurring cause instruction where evidence showed car accident “acted in combination with” pre-existing back condition to cause injury); *Esancy v. Hodges*, 727 So. 2d 308, 309 (Fla. 2d DCA 1999) (injured passenger in rear-ended vehicle entitled to concurring cause instruction where there was evidence that car accident “combined with” passenger’s pre-existing health condition to cause injury); *Zigman v. Cline*, 664 So. 2d 968, 969 (Fla. 4th DCA 1995) (mandating the concurring cause instruction where an expert witness opined that two concurring causes, neither of which could be considered a sole cause, “conjoined in a ‘constellation’ of circumstances” leading to the plaintiff’s injury). Indeed, the Court notes that these “pre-existing condition” cases raise some question about the *Stahl* court’s proclamation that the substantial factor test applies only where each of the concurring causes alone could have caused the injury.

After careful analysis of Florida’s case law and standard jury instructions regarding causation, the Court concludes that Florida’s concurring cause rules are, at best, unsettled. In particular, it is unclear whether, as *Stahl* states, the “substantial factor” test applies “only in those concurring cause cases where each of the said concurring causes could have *alone* produced the plaintiff’s injury,” 438 So.2d at 19 (emphasis added), or whether, as Florida Standard Jury Instruction 5.1(b) and the pre-existing condition cases cited above can be read to suggest, causation is satisfied where the plaintiff establishes that the defendant’s negligence substantially contributed to the plaintiff’s injury, even though such negligence was one of perhaps many concurring causes that *acted in combination* to cause the injury. Ultimately, however, the lack of clarity in the law does not hinder the Court’s decision in this case, as the record does not create a triable issue under either of these two tests. The testimony of Haller’s specific causation experts, Drs. Tulloch and Abramson, confirms that there is no evidence in the record from which a reasonable juror could conclude that Seroquel contributed

substantially to producing Haller's injury.

Dr. Tulloch's causation mantra is the "straw/camel" analogy. However, to reiterate, a contributing factor as figuratively insubstantial as a straw does not equate to a *substantial* contributing factor. No matter how many times Plaintiffs' counsel attempts to join the magic causation phrases "but for" and "substantial contributing factor" to Dr. Tulloch's testimony, the fact remains that those phrases are undercut by to Dr. Tulloch's "straw/camel" analogy. Dr. Tulloch's testimony is sufficient only to raise the *possibility* that Seroquel caused Haller's diabetes. Further, as previously shown, Dr. Tulloch's specific causation opinions truly boil down to temporal proximity and that concept alone is insufficient to create a genuine issue of fact regarding causation. *McClain*, 401 F.3d at 1243. Finally, based on the record before the Court, given all of the possible and equally plausible causes for diabetes *in Haller's specific case* (if Haller even has that disease), no reasonable jury could conclude that Seroquel was the "but for" cause of, or even a factor that contributed *substantially* to, diabetes in Haller.

Similarly, Dr. Abramson observed that Haller had numerous preexisting risk factors for diabetes that, by themselves, put him at substantial risk for developing diabetes. He furthermore opined that all of these risk factors may have played a role in Haller's ultimate diabetes diagnosis, and admitted that there was simply no way to tell whether any given risk factor was a cause of Haller's disease. Critically, Dr. Abramson consistently testified that he could not say with any certainty that Haller would not have gotten diabetes at the time that he did even if he had never taken Seroquel. Indeed, the *only* evidence supporting Dr. Abramson's opinion that Seroquel was a substantial factor in Haller's diabetes was the mere temporal connection between Haller's first ingestion of Seroquel and his subsequent weight gain and diabetes diagnosis.

In all, the experts' testimony neither establishes a genuine issue of material fact with respect to whether Haller's ingestion of Seroquel was a specific cause of his diabetes, nor sets forth reliable opinions upon which a jury could make an informed factual determination. At best, Drs. Tulloch and Abramson could only speculate as to whether Seroquel actually contributed to Haller's weight gain during the time he was taking the drug. As the Supreme Court of Florida held in *Gooding v. University Hospital Building, Inc.*, 445 So. 2d 1015 (Fla. 1984), "[a] mere possibility of [] 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." *Id.* at 1018 (quoting *Prosser, Law of Torts* § 41 (4th ed. 1971)). Therefore, because Haller has not established a triable issue with regard to specific medical causation, and each of Haller's claims is fundamentally premised on a causal connection between his Seroquel ingestion and his diabetes, AstraZeneca is entitled to summary judgment as to all claims set forth in the complaint.

The Court stresses that its ruling herein is strictly confined to the application of Florida law to the specific facts of Mr. Haller's case. Other cases presenting potentially distinguishable facts,<sup>293</sup> or which arise under the laws of other states,<sup>294</sup> may fare differently. Accordingly, this opinion is in no way intended to prevent a full and fair evaluation of the specific facts of each of the other cases involved in this litigation.

#### IV. CONCLUSION

Based on the foregoing, it is **ORDERED** as follows:

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<sup>293</sup> E.g., cases in which the drug was prescribed off-label.

<sup>294</sup> The Court has not reviewed the law of causation applicable in any other state, and, as such, cannot predict the fate of any cases to which the laws of states other than Florida apply.

1. AstraZeneca's Motion for Summary Judgment (Doc. 13), filed under seal on November 3, 2008, is **GRANTED**.

2. The Clerk shall enter a final judgment providing that the Plaintiff, David Haller, shall take nothing on his claims against the Defendants, AstraZeneca Pharmaceuticals LP and AstraZeneca LP, and that the Defendants shall recover their costs of action. Two other parties, AstraZeneca AB and AstraZeneca PLC, were originally named as defendants in this action but never entered appearances.

3. The Clerk is directed to **CLOSE** the file in Case No. 6:07-cv-15733-Orl-22DAB. **DONE** and **ORDERED** in Chambers, in Orlando, Florida on February 6, 2009.

  
ANNE C. CONWAY  
United States District Judge

Copies furnished to:

Counsel of Record