

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

**IN RE: Seroquel Products Liability
Litigation**

Case No. 6:06-md-1769-Orl-22DAB

ORDER

This cause comes before the Court for consideration of AstraZeneca's Motion to Exclude the General Causation Testimony of Plaintiffs' Generic and Case-Specific Witnesses (Doc. 1112), to which Plaintiffs responded (Doc. 1159).¹ A *Daubert* hearing was held on December 4 and 5, 2008. Upon consideration of the motion and memoranda, as well as the testimony set forth at the hearing, the Court determines that AstraZeneca's motion, as it relates to Dr. Wirshing's general causation testimony, is due to be **DENIED**. The Court reserves ruling on the remainder of the motion.

I. LEGAL STANDARD

AstraZeneca challenges Plaintiffs' experts' testimony under Rules 401, 402, 403, 702 and 703 of the Federal Rules of Evidence. The first two of these rules govern the admissibility of evidence. Specifically, Rule 402 dictates that, in general, "[a]ll relevant evidence is admissible." Fed. R. Evid. 402. Rule 401 defines relevant evidence as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. This rule does not stand

¹ Plaintiffs' response was filed under seal because it contained documents designated by one or both parties as confidential.

alone, however; it must be balanced with Rule 403, which dictates that, “[a]lthough relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.” Fed. R. Evid. 403.

Unlike Rules 401, 402, and 403, which apply to all evidence, Rules 702 and 703² are limited in scope to evidence involving the application of specialized expertise. Fed. R. Evid. 702 governs the admission of expert testimony at trial. The Rule states:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592-93 (1993), laid out the standard for determining the admissibility of experts under Fed. R. Evid. 702. “The trial judge has a two-part duty to ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”³ *Daubert*, 509 U.S. at 589. The *Daubert* Court set forth a non-exhaustive list of relevant factors to consider in determining whether the methodology employed 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.* Since *Daubert*, courts have looked at additional factors, including whether an expert

² Rule 703, relating to the bases of expert testimony and admissibility of underlying facts or data, was nowhere addressed in AstraZeneca’s motion.

³In *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999), the Supreme Court made it clear that *Daubert* applies to all types of expert testimony, scientific or not.

has properly accounted for alternative explanations (*Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 154-55 (1999)), whether the conclusions were reasoned as carefully as they would have been outside of litigation (*Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005)), and whether an accepted premise is being extrapolated to unfounded claims (*Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144-46 (1997)).

The Eleventh Circuit applied *Daubert* in *Tuscaloosa v. Harcross Chemicals, Inc.*, 158 F.3d 548, 562 (11th Cir. 1998), and held that expert testimony may be admitted if three 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.*

The burden of making this showing is on the party offering the expert, and admissibility must be shown by a preponderance of evidence. *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002) (citations omitted). While “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence,” (*Daubert*, 509 U.S. at 596 (citations omitted)), the Court is an essential gatekeeper and in all cases “must take care to weigh the value of [expert testimony] against its potential to mislead or confuse.” *United States v. Frazier*, 387 F.2d 1244, 1263 (11th Cir. 2004). Trial judges have considerable discretion in deciding how to evaluate expert testimony and whether it is reliable and relevant. *Kumho*, 526 U.S. at 152.

II. DISCUSSION

In this *Daubert* motion, AstraZeneca seeks to exclude the general causation testimony of

three of Plaintiffs' experts: Dr. Laura M. Plunkett, a pharmacologist and toxicologist; Dr. Donna Arnett, an epidemiologist; and Dr. William C. Wirshing, a psychiatrist. Each expert generally intends to testify that Seroquel can cause diabetes and other related conditions.⁴ This Order addresses only the admissibility of the general causation opinions of Dr. Wirshing.

A. Dr. William C. Wirshing - Qualifications and Experience

Dr. Wirshing is a psychiatrist whose clinical practice is primarily focused on individuals suffering from schizophrenia and bipolar disorder. He acquired his medical degree from U.C.L.A. in 1982, and thereafter completed an internship with the U.C.L.A. Center for the Health Sciences & Wadsworth V.A. Medical Center in Los Angeles, California. He received his license to practice medicine from the State of California in 1983. Dr. Wirshing went on to complete a three-year residency in psychiatry at U.C.L.A. Neuropsychiatric Institute in Los Angeles. During the final year of his residency he served as Chief Resident in Geropsychiatry at the West Los Angeles Veterans Affairs Medical Center. After his residency, Dr. Wirshing became a Postdoctoral Research Scholar at U.C.L.A., during which time he learned and applied clinical research techniques in patients with severe schizophrenia.

Over the next eighteen years, Dr. Wirshing served in various clinical, teaching and research capacities with the U.C.L.A. School of Medicine and the affiliated West Los Angeles V.A. Medical Center. In 2006, he left U.C.L.A. to serve as Vice President in charge of research and continuing medical education for Exodus Inc. in Culver City, California, where he treats psychiatrically

⁴ All three experts also offer opinions outside the scope of general causation. AstraZeneca has moved to exclude certain of these opinions by separate motion, and the Court will address that motion by separate order.

impaired patients and gives continuing medical education lectures to staff. Dr. Wirshing also currently serves as Clinical Director of Exodus Real Recovery, a chemical dependency treatment center in Agoura Hills, California. In these positions, Dr. Wirshing sees approximately 325 new psychiatric patients each month, supervises doctoral candidates, and teaches over a dozen nursing, social work and nurse practitioner students.

Over the course of his career, Dr. Wirshing has given numerous lectures and has authored or co-authored 98 peer-reviewed publications, 23 book chapters, and over 130 abstracts and other brief publications. He has published “three or four” case reports and articles specifically geared toward the metabolic profile of Seroquel.⁵ In addition, he was involved with early clinical testing of many second generation antipsychotic drugs, including risperidone, olanzapine, ziprazadone and aripiprazole. After Seroquel was approved by the FDA in 1997, AstraZeneca employed Dr. Wirshing for lecture and consultation regarding the drug. At AstraZeneca’s request, Dr. Wirshing gave “generic lectures” on the metabolic consequences of second generation antipsychotics, including Seroquel.⁶ He was also asked to lecture to smaller groups of physicians who were considered “big customers” by AstraZeneca.⁷ Dr. Wirshing’s most recent consultation with AstraZeneca occurred in August 2008.

In addition, Dr. Wirshing was one of nineteen experts invited to present their findings and opinions on the association between Seroquel and diabetes at a major consensus development

⁵ *Daubert* Hr’g Tr. 11, Dec. 5, 2008 (Doc. 1178).

⁶ Wirshing Dep. 130:12-131:9.

⁷ *Id.*

conference in November 2003.⁸ The conference was a joint meeting of the American Diabetes Association, American Psychiatric Association, the American Association of Clinical Endocrinologists and the North American Association for the Study of Obesity,⁹ and resulted in a Consensus Statement published in *Diabetes Care* in early 2004.¹⁰

In his practice, Dr. Wirshing routinely prescribes second generation antipsychotic medications to his patients.¹¹ In particular, he estimates that he has prescribed Seroquel to between 3000 and 5000 patients over the course of his career.¹² He estimates that about 15 to 20 percent of his patients are currently taking Seroquel to control their psychoses.¹³

B. Dr. Wirshing's Causation Opinions

Dr. Wirshing proposes to testify that Seroquel "causes significant substantial and sustained weight gain in a sizable percentage of the population exposed to it."¹⁴ In fact, Dr. Wirshing observes that "on average about between 25 and 30 percent of patients exposed to [Seroquel] will develop clinically pertinent and significant weight gain."¹⁵ In Dr. Wirshing's opinion, this Seroquel-induced weight gain, in turn, leads to an increased risk of glucose intolerance and diabetes, among other

⁸ Declaration of William Wirshing, M.D., Doc. 1159, Ex.2 at 2.

⁹ Wirshing Decl. at 2-3.

¹⁰ See Doc. 1112, Ex. 1.

¹¹ Wirshing Dep. 89:12-17.

¹² *Daubert* Hr'g Tr. 9.

¹³ Wirshing Dep. 90:14-21.

¹⁴ *Daubert* Hr'g Tr. 3-4.

¹⁵ *Id.*

illnesses.¹⁶ Indeed, Dr. Wirshing states that “[o]ne of the most robust correlates of weight gain is the subsequent development of diabetes,”¹⁷ although he admits that “the details of exactly why that is are not known.”¹⁸ Specifically, Dr. Wirshing observes that according to one well-known study, every one kilogram increase in weight leads to a four or five percent increase in risk for developing diabetes.¹⁹

Dr. Wirshing also observes that, with regard to Seroquel’s weight gain potential, “in general, what you see is a pattern of weight gain in approximately a quarter of the population . . . [which is] remarkably consistent across time, patient populations, and exposure.”²⁰ In Dr. Wirshing’s view, this weight gain pattern amounts to a gain of, on average, a pound a week for the first couple of months and then a plateau where weight stabilizes.²¹ Dr. Wirshing additionally observes that this pattern appears to hold true for people of all baseline weights, including those who are already

¹⁶ Expert Report of William C. Wirshing, Doc. 1112, Ex. 20 at 7 (noting that “increased risks for glucose intolerance and even frank diabetes” were among the “number of well-known health consequences to increases in adiposity”); *Daubert* Hr’g Tr. 63 (“There should be no question in anyone’s mind [that Seroquel can cause diabetes through weight gain]. That’s not an arguable fact.”), 117-118 (“[I]t’s axiomatic that if a drug causes weight gain it’s going to increase your risk of diabetes.”); Wirshing Decl. at 5 (observing that “[t]he connection between Seroquel and diabetes has become generally accepted in the medical community”), 9 (referring to the connection between Seroquel-induced weight gain and diabetes as “well-established and recurrently documented”).

¹⁷ *Daubert* Hr’g Tr. 24.

¹⁸ *Id.* at 25.

¹⁹ *Id.* (discussing the Framingham Heart Studies).

²⁰ *Id.* at 54-55.

²¹ Wirshing Dep. 52:3-14; *see also Daubert* Hr’g Tr. 86 (agreeing that the average person on Seroquel gains eight or nine pounds in a couple of months and then plateaus).

obese.²²

C. Admissibility of Dr. Wirshing's Testimony

As noted above, Dr. Wirshing's testimony may be admitted if the following three requirements are met: (1) he is qualified to testify competently regarding the matter he intends to address; (2) the methodology used is reliable as determined by the *Daubert* inquiry; and (3) the testimony will assist the trier of fact. The Court determines that Dr. Wirshing's general causation testimony meets each of the three requirements, as detailed in the following discussion.

1. Qualifications

AstraZeneca does not contest Dr. Wirshing's qualifications to testify as to whether Seroquel causes diabetes and other related metabolic disorders, and, indeed, the Court finds that his extensive training and experience in clinical psychiatry sufficiently qualify him to discuss the observed toxicities of Seroquel. Therefore, Dr. Wirshing is qualified to testify as to general causation.

2. Reliability

AstraZeneca sets forth numerous "reliability" grounds for exclusion of Dr. Wirshing's general causation opinion. At bottom, AstraZeneca believes that Dr. Wirshing's opinion does not meet *Daubert* because it: (1) fails to identify a plausible biological mechanism by which Seroquel can cause diabetes; (2) fails to identify a dose-response relationship between Seroquel and weight gain or diabetes; and (3) is not generally accepted in the relevant scientific community. The Court visits each one of AstraZeneca's contentions in turn.

a. Biological Mechanism

²² Wirshing Dep. 69:12-70:3; *Daubert* Hr'g Tr. 29-30.

AstraZeneca's primary concern with respect to Dr. Wirshing's methodology is that he unreliably premises his opinion on the indirect mechanism of weight gain. In this regard, AstraZeneca believes that Dr. Wirshing makes an unjustified "leap" from the accepted premise that obesity causes diabetes to the unsupported conclusion that any amount of Seroquel-induced weight gain can cause diabetes. AstraZeneca contends that, in doing so, Dr. Wirshing cherry-picks data drawing a connection between Seroquel and weight gain and ignores data on the direct association between Seroquel and diabetes. Furthermore, AstraZeneca believes that Dr. Wirshing's weight gain mechanism is "nothing but pure speculation" because he "cannot demonstrate that, in general, any amount of weight gain associated with Seroquel causes diabetes."²³

For the reasons that follow, the Court believes that Dr. Wirshing's weight gain mechanism constitutes a reliable basis for his opinion. As an initial matter, Dr. Wirshing believes that a direct effect of Seroquel on pancreatic function, glucose metabolism, or circulating lipids, although suggested by the literature and clinical trial data, has not yet been firmly established.²⁴ He further opines that even if these direct mechanisms were established, their influence would likely be "a minor one."²⁵ He also acknowledges that the data directly linking Seroquel and diabetes are

²³ Doc. 1112 at 17-18.

²⁴ Wirshing Dep., 277:25-278:20 (stating that he did not think there were any observational epidemiological studies that show that Seroquel directly causes diabetes, "absent its effect on weight"); *Daubert* Hr'g Tr. 38-39 (explaining confounded data regarding lipid changes in "a decided minority" of Seroquel patients), 47 (pointing to "cumulative and growing evidence to suggest that there are extra adiposity influences, all be they minor, on glucose metabolism"), 82 (testifying that he does not think it has been established that Seroquel exerts a direct toxicity on the pancreas).

²⁵ *Daubert* Hr'g Tr. 41; *see also id.* at 40 ("[T]here are and have been data to suggest that there may be a minor signal that's extra adiposity"), 59-60 (testifying that he does not "think most of the diabetes people are talking about has anything to do with a direct toxic effect" and that extra adiposity

discrepant – some studies show diabetes with Seroquel and some studies do not.²⁶ However, the lack of conclusive evidence as to direct effect or direct association does not hinder Dr. Wirshing’s ultimate opinion or his methodology, given his ultimate conclusion that “the vast majority of the cases of diabetes related to the use of [Seroquel] are through weight gain.”²⁷

In arriving at his conclusion that Seroquel can cause diabetes through weight gain, Dr. Wirshing makes a series of observations based on his review of the literature and available clinical trial data, as well as his extensive clinical experience treating psychiatric patients with Seroquel. Dr. Wirshing begins by observing that Seroquel induces clinically significant weight gain. Indeed, Dr. Wirshing firmly believes that “[t]he fact that Seroquel induces significant and sometimes massive increases in adiposity is indisputable.”²⁸ He bases this conclusion both on clinical data generated by AstraZeneca²⁹ and, more importantly, on his extensive clinical experience with patients

influences on diabetes were “a small portion of the overall equation”).

²⁶ *Daubert* Hr’g Tr. 80. Contrary to AstraZeneca’s contention that Dr. Wirshing “ignored” data on the direct correlation between Seroquel treatment and diabetes, it is clear from the record that Dr. Wirshing considered the studies and clinical data geared toward detecting a direct association between Seroquel and diabetes, *see, e.g.*, Reference Exhibit List, Doc. 1112, Ex. 20, but ultimately discarded them in favor of what he deems to be more conclusive evidence on the association between Seroquel and weight gain.

²⁷ *Daubert* Hr’g Tr. 80; *see also* Wirshing Decl. at 10 (noting that “weight gain adiposity is the most obvious, if not predominant mechanism” by which Seroquel causes diabetes), 12 (observing that the “lion’s share” of the causal connection between Seroquel and diabetes “goes to increases in adiposity”); Wirshing Dep. 38:9-21 (noting that although there are data that “suggest” that Seroquel may have a “minor direct impact on pancreatic functioning[,] . . . [t]he biggest effect is the fact that [Seroquel] makes people gain weight”).

²⁸ Wirshing Decl. at 4.

²⁹ *See id.* at 4-5 (pointing to “literally hundreds of studies” conducted by AstraZeneca that support his conclusion about the relationship between Seroquel and weight gain); *Daubert* Hr’g Tr. 54 (summarizing his observations after reviewing clinical trial data produced by AstraZeneca, *e.g.*,

on Seroquel, many of whom have gained significant amounts of weight.³⁰

Next, Dr. Wirshing observes that it is generally accepted in the medical community that clinically significant weight gain leads to an increased risk of diabetes.³¹ In this regard, Dr. Wirshing maintains that, although the precise mechanism is yet unknown,³² “[t]he causal relationship between weight gain and diabetes is established, robust, and unarguable,”³³ as demonstrated by authoritative texts and published studies.³⁴ He further clarifies that he does not believe that diabetes is caused by just any amount of weight gain, but rather only “clinically pertinent weight gain (i.e., a 7%

Studies 2, 6, 125, and 132). The Court further observes that AstraZeneca’s clinical data, as set forth in the Seroquel label, clearly support Dr. Wirshing’s observation. *See* Doc. 1112, Ex. 13 at 6 (“In schizophrenia trials the proportions of patients meeting a weight gain criterion of $\geq 7\%$ of body weight were compared in a pool of four 3- to 6-week placebo-controlled clinical trials, revealing a statistically significantly greater incidence of weight gain for SEROQUEL (23%) compared to placebo (6%).”).

³⁰ Wirshing Dep. 143:20-144:15 (recounting that “it was just an amazing process to see this happen right before your eyes. You literally just got to watch them get bigger, and . . . as a doctor, as a clinical scientist, . . . it was riveting to me. It was unbelievably compelling.”); *Daubert* Hr’g Tr. 9-11 (noting that he was “among the very first people to recognize the metabolic toxicities of [atypical antipsychotics] . . . because I got to see them every day,” and further stating that Seroquel “cause[s] a very significant and rapid weight gain in patients that I got to see right away”); Wirshing Decl. at 5 (noting that several hundred of the more than 3000 patients he has treated with Seroquel over the past decade have developed diabetes).

³¹ *See* Wirshing Dep. 26:11-27:1 (citing the Framingham Heart Studies for his proposition that “a one pound change in fat translates to a 4 percent increase in the risk of diabetes”); *Daubert* Hr’g Tr. 27-8 (discussing Mokdad, Bowman, Ford, Vinicor, Marks & Koplan, *The Continuing Epidemics of Obesity and Diabetes in the United States*, 286 J.A.M.A. 1195 (2001) in relation to the correlation between weight gain and diabetes risk).

³² *Daubert* Hr’g Tr. 25-27; Wirshing Dep. 33:5-6.

³³ Wirshing Decl. at 5.

³⁴ *See id.* at 5-7 (referencing three “recognized text books” and citing three published studies as support).

increase).”³⁵

Having made scientifically supported observations about the extent to which Seroquel causes significant weight gain, and the extent to which weight gain increases diabetes risk, Dr. Wirshing arrives at the following conclusion: clinically significant weight gain induced *by Seroquel* leads to an increased risk of diabetes, and, in this way, Seroquel can cause diabetes. The Court has no trouble seeing the logic in Dr. Wirshing’s methodology; if Seroquel can cause clinically significant weight gain, and clinically significant weight gain is known to increase one’s risk for diabetes, then it follows that *Seroquel-induced* clinically significant weight gain can cause diabetes. Furthermore, each step in Dr. Wirshing’s methodology has ample scientific support, whether it be literature-based, drawn from AstraZeneca’s clinical trial data, or grounded in first-hand clinical observation. Thus, the Court believes that Dr. Wirshing’s method does not incorporate any “scientific leap” or unjustified “extrapolation,” but rather is the product of decades of clinical experience and sound scientific reasoning.

b. Dose-Response Relationship

AstraZeneca next contends that Dr. Wirshing fails to identify evidence of a dose-response relationship between Seroquel and diabetes. In this regard, AstraZeneca observes that Dr. Wirshing instead improperly relies on a dose-response relationship between Seroquel and weight gain that does not have reliable evidentiary support for doses less than 300 mg.

Dr. Wirshing stated at his deposition that AstraZeneca’s clinical studies “clearly show[] a

³⁵ *Id.* at 13.

dose-response relationship,”³⁶ although he later acknowledged that “[t]here have been studies that haven’t shown a dose-response relationship.”³⁷ Even so, Dr. Wirshing clarified at the *Daubert* hearing that AstraZeneca’s clinical data regarding weight gain in Seroquel users showed a “sigmoidal dose response curve.”³⁸ He explained this curve in general terms as follows: “[A]t subthreshold doses, [the drug] doesn’t have an effect. And then over the linear portion of the curve, it would have increasing effect. And then it plateaus.”³⁹ Specifically with regard to Seroquel, Dr. Wirshing noticed a “pattern of weight gain . . . that is linear below 300 milligrams, that is to say, lower doses below 300 milligrams are associated with lower rates of weight gain,” and then the weight gain “plateaus after 300 milligrams.”⁴⁰ At his earlier deposition, when asked about the response at a dose as low as 50 milligrams, Dr. Wirshing acknowledged that “there’s not, unfortunately, we don’t have any great studies at 50 milligrams.”⁴¹ Even so, he indicated that an extrapolation from the existing data would reveal a weight gain of “just . . . a couple of pounds” at the 50 milligram dose.⁴²

The Court is not persuaded that Dr. Wirshing’s observation of a dose response relationship

³⁶ Wirshing Dep. 104:10-105:15.

³⁷ *Id.* at 283:5-6.

³⁸ *Daubert* Hr’g Tr. 54.

³⁹ *Id.* at 55; *see also id.* at 79 (noting that “there is not an incremental increase [in weight gain] above 300 [milligrams]. You don’t get more weight gain when you add more drug on. You do below, but not above. It’s plateaued at 300.”).

⁴⁰ *Id.* at 54.

⁴¹ Wirshing Dep. at 106:1-3.

⁴² *Id.* at 106:3-5.

between Seroquel and weight gain, rather than Seroquel and diabetes, is fatal to his opinion. Indeed, given his opinion that Seroquel primarily causes diabetes through the mechanism of weight gain, his demonstration of a dose-response relationship in that regard, rather than with respect to a direct causal relationship, appears appropriate. In addition, the Court finds nothing particularly unreliable about Dr. Wirshing's dose-response observations, especially given the fact that he has drawn them from AstraZeneca's own clinical data, and has openly acknowledged the limitations of that data in terms of low-dose toxicity predictions.

c. General Acceptance

AstraZeneca proposes that the views of the FDA and the ADA Consensus Panel represent the "generally accepted wisdom of the medical community,"⁴³ on whether Seroquel causes diabetes. In this regard, AstraZeneca observes that neither entity has concluded that the scientific evidence establishes that Seroquel causes diabetes, and, accordingly, Dr. Wirshing's view that there is a causal connection "stand[s] afar from the mainstream scientific community."⁴⁴ The Court notes, however, that neither the FDA nor the ADA Consensus Panel has concluded that Seroquel does *not* cause diabetes. Indeed, it is apparent from Seroquel's label that the FDA believes that "the relationship between atypical antipsychotic use and hyperglycemia-related adverse reactions *is not completely understood*."⁴⁵ Likewise, the ADA Consensus Panel concluded in 2004 that "[t]he risk [of diabetes] in patients taking . . . [Seroquel] is less clear; some studies show an increased risk for diabetes, while

⁴³ Doc. 1112 at 21.

⁴⁴ *Id.*

⁴⁵ Doc. 1112, Ex. 13 at 3 (emphasis added).

others do not.”⁴⁶

Although *Daubert* suggests that “[w]idespread acceptance can be an important factor in ruling particular evidence admissible,” 509 U.S. at 594, in this instance the Court gives minimal consideration to this factor in light of that fact that there appears to be no general scientific consensus as to the extent of the association between Seroquel and diabetes.

3. Assistance to the Jury

AstraZeneca does not specifically contest Dr. Wirshing’s general causation testimony on the ground that it would not assist the jury, and the Court can likewise find no reason to exclude it on this basis. Indeed, the available scientific data on the relationship between Seroquel, weight gain, and diabetes are highly technical and, in the Court’s view, could not possibly be fairly evaluated by a jury of ordinary citizens without expert assistance. Therefore, Dr. Wirshing’s proposed testimony would undoubtedly be helpful to the jury on the issue of general causation.

4. Admissibility Determination

In view of the above discussion, the Court concludes that Dr. Wirshing’s proposed general causation testimony is admissible. Accordingly, he may testify at trial as to his opinion that Seroquel can cause diabetes and other metabolic disorders.

III. CONCLUSION

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

1. AstraZeneca’s Motion to Exclude the General Causation Testimony of Plaintiffs’

⁴⁶ Doc. 1112, Ex. 1 at 3 (American Diabetes Association, et al., *Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes*, *Diabetes Care* 27:2 (Feb. 2004)(further characterizing data on the risk of diabetes in Seroquel users as “discrepant”).

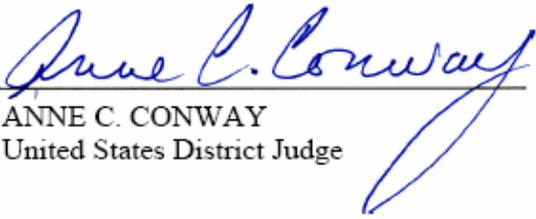
Generic and Case-Specific Witnesses (Doc. 1112) is **DENIED** as to Dr. Wirshing, who shall be permitted to offer general causation testimony consistent with this opinion.

2. The Court reserves ruling as to Drs. Plunkett and Arnett, whose opinions will be evaluated by separate order.

DONE and **ORDERED** in Chambers, in Orlando, Florida on February 11, 2009.

Copies furnished to:

Counsel of Record


ANNE C. CONWAY
United States District Judge