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

I. INTRODUCTION

This cause comes before the Court for consideration of AstraZeneca Pharmaceuticals LP and AstraZeneca LP's ("AstraZeneca") Motion and Supporting Memorandum of Law to Exclude Non-Causation Expert Testimony Under Federal Rules of Evidence 702, 401 and 403 (Doc. No. 1121). By means of this motion, AstraZeneca challenges eight general categories of non-causation testimony as inadmissible under the three cited rules of evidence. Plaintiffs have filed a legal memorandum in opposition to the motion (Doc. No. 1332).[1]

II. APPLICABLE LAW

Rule 702, specifically governing expert testimony, states as follows:

> 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.

Fed. R. Evid. 702.

[1] Plaintiffs' original response (Doc. 1162) was filed under seal because it contained documents designated by one or both parties as confidential. At the Court's direction, Plaintiffs later filed a redacted public version of their response (Doc. 1332).

Rules 401 and 403 are applicable to all evidence and imply a balancing test for admissibility. Rule 401 states: "'Relevant evidence' means 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." On the other side of the balance is Rule 403, which states: "Although 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."

In its motion, AstraZeneca argues that much of the non-causation testimony offered by Plaintiffs' experts falls outside the realm of Rule 702 in that it does not require any scientific, technical, or other specialized knowledge. Indeed, "[e]xpert testimony is properly excluded when it is not needed to clarify facts and issues of common understanding which jurors are able to comprehend for themselves." *Hibiscus Assocs. Ltd. v. Bd. of Trs. of Policemen and Firemen Ret. Sys. of City of Detroit*, 50 F.3d 908, 917 (11th Cir. 1995) (citing *Salem v. U.S. Lines Co.*, 370 U.S. 31, 35 (1962)). Most courts take a liberal approach to this standard, resolving doubts about whether the testimony is within the common understanding of the jury in favor of admissibility. 4 J. Weinstein & M. Berger, *Weinstein's Federal Evidence* § 702.03[2][b], pp. 702-43 & -44 (J. Mc Laughlin ed., 2d ed. 2008).

III. EXPERTS' NON-CAUSATION OPINIONS

As an initial matter, the Court clarifies that this motion relates to the testimony of seven experts: Plaintiffs' three general causation experts and four case-specific experts designated to testify as to specific medical causation in Group One of the Florida cases designated for inclusion in the Initial Trial Pool. The Court now considers the motion only as it applies to the three general

causation experts: Dr. Plunkett, Dr. Arnett and Dr. Wirshing.

A. Dr. Plunkett

Dr. Plunkett is a pharmacologist and a toxicologist. She is not a medical doctor. In addition to her general causation opinions, Dr. Plunkett believes that "Seroquel is not unique in its efficacy" and that, therefore, there are safer alternative therapies that would be as effective as Seroquel but produce fewer side effects. (Doc. No. 1121, Ex. 1 at 9.) Dr. Plunkett also opines that the Seroquel label inadequately warned physicians and consumers of the adverse health effects associated with the drug. (*Id.* at 13.) She further believes that the class-wide warning incorporated into the label in 2004 was inadequate to convey the risks specifically associated with Seroquel. (*Id.*) Moreover, citing foreign regulatory body actions to strengthen the Seroquel label with regard to the hyperglycemia and diabetes risk, Dr. Plunkett opines that AstraZeneca should have been taking similar actions with regard to its labeling in the United States. (*Id.*) Finally, Dr. Plunkett criticizes AstraZeneca's heavy marketing of Seroquel as safe and effective, with fewer side effects than competitors when, in her opinion, the drug was neither of those things. (*Id.*)

B. Dr. Wirshing

Dr. Wirshing is a psychiatrist. In addition to his belief that Seroquel causes clinically significant weight gain, which in turn can lead to increased risk of hyperglycemia, diabetes and impaired glucose and lipid metabolism, Dr. Wirshing also believes that the Seroquel label has always inadequately warned physicians of this "serious and predictable toxicity." (Doc. No. 1121, Ex. 5 at 7.) In particular, Dr. Wirshing opines that the Seroquel label: (a) merely lists weight gain as an adverse side effect of the drug when this information should be a prominent warning; (b) incorporates only a class warning which fails to note the specific toxicities of Seroquel; (c) is "virtually silent"

about Seroquel's detrimental effect on circulating triglycerides; and (d) is "virtually silent" about the demonstrated addictive potential of Seroquel. (*Id.* at 7-10.) Dr. Wirshing further believes that AstraZeneca's marketing materials, which "consistently touted that [Seroquel] is 'weight neutral'," were "palpably inappropriate and inadequate at best and deceptively misleading at worst." (*Id.* at 7.) Dr. Wirshing also opines that AstraZeneca engaged in "'indirect' off label marketing" by mischaracterizing the "true toxic potential of their product," which, in turn, led physicians to "use their product inappropriately and excessively off label." (*Id.* at 9.)

C. Dr. Arnett

Dr. Arnett is an epidemiologist. She is not a medical doctor. In addition to her view that Seroquel causes clinically significant weight gain and other metabolic complications, Dr. Arnett also believes that: (a) "AstraZeneca should have made the data presentation clearer within the New Drug Approval application and included the data regarding metabolic risk within scientific publications of the Phase II and Phase III randomized clinical trials in order to warn the FDA, future patients and physicians about metabolic risks associated with Seroquel"; (b) "the metabolic risks associated with Seroquel outweigh the benefits of treatment"; (c) "AstraZeneca promoted Seroquel as metabolically neutral when there was insufficient evidence to support this claim but substantial evidence that the drug in fact caused weight gain and other metabolic derangements"; and (d) "AstraZeneca withheld support for studies that could have demonstrated Seroquel's metabolic risk relative to other atypical antipsychotics." (Doc. No. 1121, Ex. 7 at 3.)

IV. ANALYSIS

AstraZeneca identifies eight categories of testimony about which Plaintiffs' experts should be precluded from giving their "expert" opinion. Plaintiffs generally respond that the attacks on

Plaintiffs' experts' non-causation testimony are "by and large, based on assessments of credibility, which should instead be left for the trier of fact." (Doc. No. 1332 at 3.) In this regard, Plaintiffs accuse AstraZeneca of "re-cast[ing] each expert as a 'super fact witness,' [and] ignoring the legitimate bases for their testimony." (*Id.* at 4.) Plaintiffs further charge that AstraZeneca has "challenged testimony that was never offered or intended to be admitted at trial." (*Id*).

A. Expert Witness Commentary on Internal Corporate Documents

In general, AstraZeneca observes that all of the experts propose to provide "subjective commentary" on AstraZeneca's internal corporate documents and to "draw negative inferences from them." (Doc. No. 1121 at 6.) In AstraZeneca's view, such commentary should be excluded because: (a) it does not require any scientific, technical or other specialized knowledge; and (b) it invades the province of the jury.

Particularly, AstraZeneca argues that Dr. Plunkett's testimony about the contents of internal documents should be excluded because she relies only on documents that were "pre-selected" by Plaintiffs' counsel, and, therefore, she "did not conduct the requisite full and proper investigation of the facts underlying her opinion." (*Id.* at 14.) Plaintiffs respond that Dr. Plunkett plans to use internal corporate documents to demonstrate to the jury that the association between Seroquel and weight gain "was known to AstraZeneca at the inception of Seroquel development" and "the null hypothesis that Seroquel would be associated with extraordinary weight gain was confirmed within AstraZeneca prior to the inception of marketing[.]" (Doc. No. 1332 at 13.) In other words, Dr. Plunkett appears to be proposing to use internal corporate documents to demonstrate what AstraZeneca knew about the association between Seroquel and diabetes and when AstraZeneca first knew it.

Likewise, AstraZeneca maintains that Dr. Wirshing should be precluded from commenting on internal corporate documents because the "counsel-selected collection" of documents provided to Dr. Wirshing "does not approach a complete, or even representative, record of AstraZeneca documents concerning Seroquel." (Doc. No. 1121 at 21.) Plaintiff clarifies that Dr. Wirshing's relevant opinion in this regard is "[a] comparison of the evidence available to [AstraZeneca] and practicing psychiatrists related to the description of diabetes[-]related side effects in Seroquel's labeling over time." (Doc. No. 1332 at 18.) In view of this opinion, Plaintiffs argue that Dr. Wirshing reviewed a "substantial collection" of internal documents and that his "explanation of the scientific, technical information in the internal documents is critical to the jury's understanding of the distinctions between information that was available to [AstraZeneca] and information that was ultimately communicated to doctors." (*Id.* at 19.)

Similarly, AstraZeneca seeks exclusion of Dr. Arnett's interpretation of internal corporate documents because she looked at "only a fraction" of the thousands of documents provided to her by counsel. (Doc. No. 1121 at 26.) Furthermore, according to AstraZeneca, she did not review any corporate depositions and did not look at materials related to documents she cited in her report. (*Id.*) Accordingly, AstraZeneca argues, Dr. Arnett does not have a sufficient factual basis for her opinion regarding the contents of internal corporate documents, nor is she permitted to rely exclusively on information that was pre-screened by Plaintiffs' counsel. (*Id.* at 26-27.) Plaintiffs respond that, to the contrary, Dr. Arnett reviewed a "substantial collection" of AstraZeneca's internal documents before forming her opinions in this case. (Doc. No. 1332 at 27.) Furthermore, Plaintiffs believe that her testimony about "the distinctions between information that was available to [AstraZeneca] and information that was ultimately communicated to prescribing healthcare providers" will assist jurors

in "appreciat[ing] the significance of highly technical, scientific information contained in internal documents[.]" (*Id.*)

The Court determines that Drs. Plunkett, Wirshing and Arnett may appropriately rely on and discuss AstraZeneca's internal corporate documents for the specific purposes identified by Plaintiffs in their response to the motion. To rule otherwise would unduly restrict Plaintiffs' experts from explaining the bases of their opinions. AstraZeneca's criticisms regarding the universe of documents the experts considered go to the weight to be accorded these experts' opinions, rather than their admissibility. Accordingly, AstraZeneca's motion will be denied on this point as to these witnesses. However, Plaintiffs' counsel may not simply use these expert witnesses to provide a narrative history of AstraZeneca's marketing and labeling practices, or to make points that are within the province of counsel, rather than an expert witness. Instead, the testimony regarding the company's internal documents must relate to specific and otherwise permissible opinions articulated by the expert.

B. Expert Testimony Regarding State of Mind, Motives or Ethics

AstraZeneca observes that Dr. Wirshing proposes to testify regarding the state of mind, motives and intent underlying the actions of AstraZeneca and its employees. AstraZeneca believes that such testimony is inadmissible under Rule 702 of the Federal Rules of Evidence, citing similar district court decisions in other multidistrict litigation as support.

Specifically, AstraZeneca seeks to exclude what it deems as Dr. Wirshing's "various negative opinions about AstraZeneca's corporate ethics, its motives and intentions, and whether AstraZeneca's actions meet certain legal thresholds." (Doc. No. 1121 at 22) (citing pp. 6-9 of Dr. Wirshing's expert report). In AstraZeneca's view, such testimony should be excluded because it is speculative and "constitute[s] no more than the articulation of his personal beliefs." (*Id.*) Plaintiffs have not directly

responded to AstraZeneca's arguments regarding Dr. Wirshing.

The Court determines that Dr. Wirshing may not render any opinions regarding the state of mind, intent, motives or ethics of AstraZeneca or any of its employees. These matters are not the proper subject of expert opinion; they are matters to be argued by counsel based on the evidence. However, Dr. Wirshing is not precluded from testifying about matters from which counsel may make those arguments, provided the testimony is appropriately within the realm of his expertise.

C. Expert Testimony Regarding Foreign Regulatory Actions

AstraZeneca next argues that Dr. Plunkett should not be permitted to address regulatory actions taken by foreign countries with regard to Seroquel because: (a) such testimony is irrelevant and would confuse the jury; and (b) such regulatory actions do not require expert interpretation. (Doc. No. 1121 at 8-9, 15) In response, Plaintiffs state that Dr. Plunkett does not intend to testify about whether AstraZeneca complied with foreign labeling regulations. (Doc. No. 1332 at 16.)

In accordance with this Court's earlier decision affirming Magistrate Judge Baker's ruling on AstraZeneca's motion *in limine* seeking exclusion of evidence and argument about foreign Seroquel labels and regulatory actions, *see* Doc. 1348, Dr. Plunkett may not testify regarding foreign labeling regulations or foreign regulatory actions regarding Seroquel. Introducing evidence of foreign regulatory schemes and compliance with those schemes would inject unnecessary confusion and add yet another layer of complexity to this case. Accordingly, this evidence is inadmissible under Fed. R. Evid. 403. However, as this Court previously noted with respect to Judge Baker's ruling on the motion *in limine*:

> [Magistrate Judge Baker's] decision does not necessarily preclude Plaintiffs from introducing evidence regarding the *information* the foreign regulators communicated to AstraZeneca regarding the dangers of Seroquel. Rather, it excludes evidence of the

> regulators' *decisions and actions* - including requiring label changes - regarding Seroquel. In other words, during direct examination of witnesses in their main case, Plaintiffs may not introduce evidence of what the foreign regulators decided about Seroquel or what actions they required AstraZeneca to take regarding the drug. However, the information the foreign agencies imparted to AstraZeneca regarding the drug's safety *may* be admissible during Plaintiffs' main case on such issues as notice, knowledge and scienter . . . . However, the Court stresses that a final determination regarding the admissibility of this more limited class of evidence - the information foreign regulators communicated to AstraZeneca regarding the dangers of Seroquel - must await the trial of this case.

Doc. 1348 at 9-11 (citations and footnotes omitted). Therefore, to the extent Plaintiffs intend to offer Dr. Plunkett's testimony to impart to the jury the information that foreign regulators communicated to AstraZeneca regarding Seroquel's safety profile, such testimony *may* be admissible. The Court will issue a final admissibility determination, should it be required, at the time Dr. Plunkett's trial testimony is taken.

D. Expert Testimony Regarding Submissions to FDA

AstraZeneca seeks to exclude the testimony of Drs. Plunkett and Arnett regarding the content and form of AstraZeneca's submissions to the FDA because: (a) the experts are not qualified to comment on adherence to FDA regulations; and (b) expert assistance with facts about the disclosure of information to FDA is unnecessary. (Doc. No. 1121 at 9, 17 & 24-25.)

Specifically, AstraZenenca maintains that Dr. Plunkett impermissibly speculates that certain information was not conveyed to the FDA because she was not able to identify any supporting documents at her deposition. (*Id.* at 17.) On this issue, Plaintiffs clarify that Dr. Plunkett will not offer an opinion about whether AstraZeneca defrauded the FDA. (Doc. No. 1332 at 16.) Nevertheless, Plaintiffs say Dr. Plunkett will use AstraZeneca's FDA disclosures to "assist the jury in understanding both the mechanism by which Seroquel can cause diabetes, and why Seroquel's

chemical structure made [AstraZeneca's] placement of information about diabetes[-]related side [-] effects in its label inappropriate." (*Id.* at 15.)

AstraZeneca also attacks Dr. Arnett's opinion that AstraZeneca did not properly present metabolic risk data contained within the New Drug Application it submitted to FDA. (Doc. No. 1121 at 24.) AstraZeneca maintains that Dr. Arnett has no relevant experience with the regulations and guidelines regarding preparation of an NDA, nor regarding the NDA review process conducted by FDA. (*Id.* at 25.) Furthermore, AstraZeneca argues, Dr. Arnett did not review the initial labeling for Seroquel or FDA's reviews of the NDA. (*Id.* at 25-26.) Accordingly, the company maintains Dr. Arnett's methodology is flawed. Finally, AstraZeneca maintains that the jury can assess the NDA on its own, without the assistance of Dr. Arnett's testimony. (*Id.* at 25.)

In response, Plaintiffs clarify that Dr. Arnett will not testify as to the format of the NDA, nor will she opine on whether AstraZeneca defrauded the FDA. (Doc. No. 1332 at 23.) However, Plaintiffs state she "will opine on whether a significant scientific basis exists, based on clinical data generated from [AstraZeneca's] trials, to conclude that there is an association between Seroquel treatment and diabetes." (*Id.*) Accordingly, Plaintiffs assert, Dr. Arnett will offer her opinion about the overall design of the clinical studies conducted by AstraZeneca in support of its NDA, and will testify as to the inclusion or exclusion of data generated by those studies. (*Id.*) In Plaintiffs' view, Dr. Arnett is more than qualified to testify about the "design and execution of epidemiological studies, including clinical trial, cohort and case-control studies" because she has "devoted her career" to such work. (*Id.* at 25.) For these reasons, Plaintiffs state, Dr. Arnett's "expert evaluation" of the design of AstraZeneca's clinical trials and the data gleaned from those trials will assist the jury. (*Id.*)

As Plaintiffs concede, Drs. Plunkett and Arnett may not properly testify that AstraZeneca

defrauded the FDA in connection with the Seroquel NDA, nor may they testify as to whether the format or contents of the NDA comply with FDA regulations. However, they may use the contents of the NDA to support their opinions that Seroquel can cause diabetes, and they may analyze and criticize the clinical studies conducted by AstraZeneca. These subjects are within the witnesses' qualifications and testimony on these points may assist the jury.

E. Expert Testimony Regarding How Doctors Understood Pharmaceutical Labeling or Marketing Materials/Inappropriate Marketing

AstraZeneca seeks to exclude the testimony of Drs. Plunkett and Arnett to the extent the experts "wish to substitute their own opinions for those of plaintiffs' doctors on their understanding of Seroquel's FDA-approved labeling or how those doctors' prescribing practices were affected by AstraZeneca's marketing,"on the ground that such testimony is speculative and is not the proper subject of expert testimony. (Doc. No.1121 at 10.) AstraZeneca voices a similar objection regarding Dr. Wirshing. (*Id.* at 19-21.)

Specifically, AstraZeneca contends that Dr. Plunkett's intended testimony as to whether physicians are able to "understand the implications of the adverse events section of drug labeling" or whether "doctors need to see basic medical information such as the metabolic complications of weight gain in pharmaceutical labeling," should be excluded because Dr. Plunkett admittedly "has not undertaken any study or research to verify these claims." (*Id.* at 13.) In response, Plaintiffs make clear that Dr. Plunkett will not offer any opinions as to these matters. (Doc. No. 1332 at 12 & 16.) Accordingly, these arguments appear to be moot regarding Dr. Plunkett.

AstraZeneca additionally maintains that Dr. Wirshing should be barred from testifying about whether physicians generally comprehend information contained within the adverse events section

of a label because such an opinion is speculative and he "lacks relevant experience to address the formatting of a pharmaceutical label." (Doc. No. 1121 at 19.) AstraZeneca also seeks to exclude Dr. Wirshing's analysis and criticisms of the company's marketing materials. (*Id.* at 20.)

Plaintiffs respond that Dr. Wirshing's "knowledge, experience, training and education, including decades of prescribing antipsychotic drugs and instruction of medical students on their respective characteristics, more than qualify him to discuss the clinical psychiatrist's perception of scientific information in Seroquel's labeling." (Doc. No. 1332 at 18.) Plaintiffs also note that drug marketing materials are scientific in nature and are therefore beyond the ken of lay jurors; they assert that Dr. Wirshing's qualifications enable him to "explain scientific information in Seroquel marketing pieces and compare that information to both the evidence upon which it is based and other information known only to [AstraZeneca]." (*Id.* at 19.) Further, Plaintiffs maintain that Dr. Wirshing "will offer no opinion that doctors do not pay attention to labeling" and "has no opinion on whether prescribers in general are attentive." (*Id.* at 18.) Instead, say Plaintiffs, "Dr. Wirshing will testify that the presentation of information in Seroquel's labeling over time is at odds with evidence available to [AstraZeneca.]" (*Id.*)

AstraZeneca also seeks exclusion of Dr. Arnett's testimony regarding the company's marketing of Seroquel. Specifically, AstraZeneca challenges Dr. Arnett's qualifications to render any opinion that AstraZeneca "undertook a concerted effort to promote Seroquel as safe and metabolically neutral." (Doc. No. 1121 at 27.) AstraZeneca points to Dr. Arnett's lack of expertise and experience regarding the marketing of prescription drugs. (*Id.*) Moreover, AstraZeneca argues that a jury is capable of evaluating the marketing materials without the assistance of an epidemiologist. (*Id.*)

In response, Plaintiffs reiterate that drug marketing materials aimed at physicians are different from ordinary advertising capable of being understood by lay persons. (Doc. No. 1332 at 27.) Building on that point, Plaintiffs argue that "Dr. Arnett's experience as an epidemiologist, specializing in study design, generally, and particular experience as a clinical researcher, qualify her to explain scientific information in Seroquel marketing prices [sic] and compare that information to the evidence upon which it is based and other information known only to [AstraZeneca]." (*Id.*)

The Court concludes that none of Plaintiffs' experts may properly testify regarding whether physicians generally read and comprehend drug labels, or whether doctors generally understand the contents of the Seroquel label. Such opinions are impermissibly speculative. However, the witnesses the Court is allowing to testify regarding labeling (Drs. Plunkett and Wirshing; *see* section IV.H. *infra*) may express opinions regarding the accuracy and adequacy of the Seroquel label without reference to the asserted perceptions of other doctors.

Further, the Court accepts that drug marketing materials aimed at physicians may be technical in nature and, for that reason, expert testimony may be necessary to explain those materials. However, it is one thing for an expert to testify as Plaintiffs suggest Dr. Arnett will—to explain and compare information in Seroquel marketing materials to other evidence—and quite another matter for an expert witness to render an opinion concerning what a drug company intended or sought to achieve through the use of those marketing materials. The latter are proper subjects for closing argument, not expert testimony.

The Court hastens to caution that any testimony about marketing materials must remain within the proper bounds of the witnesses' expert opinions. In other words, Plaintiffs' witnesses are not necessarily precluded from referring to Seroquel marketing materials, provided they do so in the

course of rendering otherwise permissible expert testimony.

F. Expert Opinion Regarding AstraZeneca's Alleged Failure to Fund Studies

AstraZeneca seeks to exclude Dr. Arnett's opinion that AstraZeneca "withheld support for studies that she believes would have shown metabolic risks associated with Seroquel." (Doc. No. 1121 at 28.) AstraZeneca contends that Dr. Arnett offers no methodology underlying her opinion and bases her opinion on only "a handful of AstraZeneca documents." (*Id.*) As such, says AstraZeneca, this type of testimony is unreliable.

In response, Plaintiffs clarify that Dr. Arnett "will offer no opinion regarding Defendant's funding of particular studies." (Doc. No. 1332 at 28.) Instead, they say, she "will offer testimony regarding the design of [AstraZeneca's] studies and resulting manipulation of data presented." *Id.* Based on this concession, this aspect of AstraZeneca's motion appears to be moot.

G. Risk-Benefit Testimony

AstraZeneca contends that Dr. Plunkett should not be permitted to testify as to whether safer alternatives to Seroquel exist. (Doc. No. 1121 at 15-17) In AstraZeneca's view, Dr. Plunkett, as a pharmacologist, lacks the requisite medical training to opine as to whether certain medications provide a safer alternative to Seroquel for all patients, for a subgroup of a patients, or for any particular patient. (*Id.* at 16.) Furthermore, AstraZeneca notes that Dr. Plunkett only reviewed "a small fraction" of the efficacy data for Seroquel and other antipsychotic medications, and accordingly asserts that she does not follow a reliable methodology in framing her risk-benefit opinion. (*Id.* at 17.)

AstraZeneca also seeks to exclude Dr. Arnett's testimony that Seroquel is "unsafe," an opinion that AstraZeneca characterizes as a "risk-benefit view[]." (Doc. No. 1121 at 23.) In support

of this contention, AstraZeneca maintains that Dr. Arnett has not reviewed any of the efficacy data for Seroquel and, in any event, lacks the requisite medical training to make a judgment as to whether the benefits of Seroquel outweigh its risks. (*Id.* at 23-24.)

In response, Plaintiffs state that Drs. Plunkett and Arnett will offer no opinions regarding "whether another drug may have been safer than Seroquel for any individual patient." (Doc. No. 1332 at 16 & 23.) Additionally, in their opposition memorandum, Plaintiffs list the opinions Dr. Arnett has rendered in this case. Conspicuously absent from that list is the following opinion that was listed in Dr. Arnett's expert report: "(4) the metabolic risks associated with Seroquel outweigh the benefits of treatment." (*Id.* at 22.)

It is unclear whether these concessions by Plaintiffs moot AstraZeneca's arguments entirely. Potentially problematic is the language "for any individual patient." Does this mean Drs. Plunkett and Arnett will still seek to testify that, in general and without regard to any particular patient, Seroquel is unsafe or the drug's risks outweigh its benefits? If so, the Court concludes that such testimony is inadmissible. Dr. Plunkett is a pharmacologist and a toxicologist. Dr. Arnett is an epidemiologist. Neither is a medical doctor. Whether Seroquel is "unsafe" or whether safer alternatives to the drug exist are subjects beyond their expertise. Allowing these witnesses to testify on these subjects would permit them to venture into the realm of speculation and conjecture. Accordingly, the Court will grant AstraZeneca's motion on this point.

H. Adequacy of Labeling

Finally, AstraZeneca challenges Dr. Plunkett's proposed testimony regarding the adequacy of the Seroquel label. AstraZeneca maintains that Dr. Plunkett is neither qualified to give such an opinion (she is not a medical doctor) nor does she have any experience "using a label to weigh risk

and benefit information for individual patients." (Doc. No. 1121 at 12.) AstraZeneca furthermore contests Dr. Plunkett's labeling opinion on the ground that it reflects nothing more than her personal view about how the metabolic information should be conveyed in the label and how physicians read and understand such information. (*Id.* at 13.) AstraZeneca points out that other courts have barred her from providing such testimony. (*Id.*) Finally, AstraZeneca argues, Dr. Plunkett did not look at "key documents" related to Seroquel's safety. (*Id.* at 14.)

In response, Plaintiffs assert that Dr. Plunkett has not offered an opinion about what Seroquel product labeling means to physicians. (Doc. No. 1332 at 12.) They also state that Dr. Plunkett has "explicitly disclaimed any qualifications that address the use of Seroquel labeling to 'weigh risk and benefit information for individual patients,'" and she will not seek to testify concerning "how doctors use labels 'to weigh risk and benefit information for individual patients.'" (*Id.* at 12 & 16). Nor, Plaintiffs say, will Dr. Plunkett seek to testify about "whether physicians 'understand the implications' of the adverse events section of drug labeling,'" or whether "doctors needs to see basic medical information such as the 'metabolic complications' of weight gain in pharmaceutical labeling." (*Id.* at 16.) Plaintiffs further state that Dr. Plunkett's opinions regarding the Seroquel labeling are as follows: (1) "Prior to 2004, the risk of diabetes-related adverse events was not disclosed in Seroquel's labeling in a manner that was commensurate [with] the severity of the known risk or with the information available to [AstraZeneca];" and (2) "After 2004, Seroquel's labeling inadequately warned of its association with diabetes by, among other things, characterizing the risk as a 'class effect.'" (*Id.* at 11.) In Plaintiffs' view, Dr. Plunkett's opinions will help the jury understand "why Seroquel's chemical structure made [AstraZeneca's] placement of information about diabetes[-]related side effects in its label inappropriate." (*Id.* at 15.) Furthermore, Plaintiffs

suggest that Dr. Plunkett's lack of a medical license does not disqualify her from forming a reliable opinion about the label, as her background in pharmacology and work with clients on issues related to statements in product labeling regarding efficacy and warnings constitute sufficient qualifications.

Plaintiffs' response resolves some of the objections raised by AstraZeneca, i.e., testimony concerning how physicians understood the drug label and made risk-benefit determinations. The Court is unimpressed with the remainder of AstraZeneca's arguments. AstraZeneca has not established that Dr. Plunkett is unqualified to render labeling opinions simply because she is a pharmacologist and not a medical doctor. The case upon which AstraZeneca principally relies, *Upjohn Co. v. MacMurdo*, 562 So.2d 680 (Fla. 1990), is both legally and factually distinguishable. First, the opinion does not state that only the opinion of a *physician* is admissible to establish inadequate labeling; rather, it speaks in terms of "medical expert[s]." 562 So.2d at 683. Second, the pharmacologist in *MacMurdo* testified about the meaning of certain terms to physicians, and the Florida Supreme Court did not consider that testimony "probative on [that] issue." *Id.* n.3. Here, in contrast, Dr. Plunkett has expressly disclaimed any such opinions. Hence, *MacMurdo* is inapposite.

Further, it appears Dr. Plunkett's background and education qualify her to render opinions regarding the adequacy of the Seroquel label. Contrary to AstraZeneca's suggestion, it does not appear that Dr. Plunkett is merely stating her personal views in the guise of an expert opinion. AstraZeneca's objection regarding the selection of documents that Dr. Plunkett examined goes to the weight of her testimony, not its admissibility. Finally, as for AstraZeneca's argument that other courts have refused to allow Dr. Plunkett to testify regarding drug labeling, the two trial court opinions AstraZeneca has filed contain no reasoning for the exclusion of Dr. Plunkett's testimony. Accordingly, they shed little light on the issue of whether her labeling opinion is admissible in the

present case.

AstraZeneca also seeks to exclude Dr. Wirshing's testimony about the placement of the metabolic risk information in the Seroquel label and about the adequacy of the class warning added to the label in 2004. According to AstraZeneca, Dr. Wirshing lacks "relevant experience to address the formatting of a pharmaceutical label" and "has never been involved with preparing a drug's label." (Doc. No. 1121 at 19.) Thus, in AstraZeneca's view, Dr. Wirshing's labeling opinion is "speculative and inadmissible." (*Id.*) Plaintiffs respond that "Dr. Wirshing's knowledge, experience, training and education, including decades of prescribing antipsychotic drugs and instructing medical students on their respective characteristics, more than qualify him to discuss the clinical psychiatrist's perception of scientific information in Seroquel's labeling." (Doc. No. 1332 at 18.) Plaintiffs additionally point to Dr. Wirshing's experience "leading interactive lectures with actual treating physicians" on manufacturers' communication of diabetes-related risk information, which, in Plaintiffs' view, "renders him uniquely qualified to assist the jury in understanding the adequacy of Seroquel's label." (*Id.* at 17.) Once again, Plaintiffs also make clear that Dr. Wirshing will not be testifying about "how doctors read labels or make prescribing decisions in general." (*Id.* at 19.)

As with Dr. Plunkett, the Court is unpersuaded by AstraZeneca's arguments that Dr. Wirshing is unqualified to testify concerning the adequacy of Seroquel's labeling. Dr. Wirshing's extensive clinical psychiatric work, medical school teaching, participation in clinical trials regarding atypical antipsychotic drugs, publication of peer-reviewed articles in the field, and interactive lectures to doctors concerning the marketing of atypicals qualify him to render the opinions challenged by AstraZeneca.

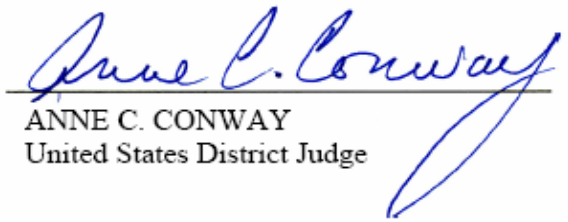
V. CONCLUSION

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

1. Defendants' Motion and Supporting Memorandum of Law to Exclude Non-Causation Expert Testimony Under Federal Rules of Evidence 702, 401 and 403 (Doc. No. 1121), as it relates to the "non-causation" testimony of Drs. Plunkett, Arnett and Wirshing, is **GRANTED IN PART, DENIED IN PART, AND MOOT IN PART**, as more fully specified herein.

2. The Court reserves ruling on the admissibility of the "non-causation" testimony of Drs. Abramson, Perry, Tulloch and Young pending resolution of the appeal in *Guinn v. AstraZeneca Pharmaceuticals LP, et al.*, Case No. 6:07-cv-10291-Orl-22DAB.

DONE and **ORDERED** in Chambers, in Orlando, Florida on July 17, 2009.



Copies furnished to:

Counsel of Record