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

**IN RE: Seroquel Products Liability Litigation**

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

**This document relates to:**

**JANICE BURNS v. ASTRAZENECA PHARMS. LP, ET AL.**
**MDL Case No. 6:07-cv-15959-Orl-22DAB**

**RICHARD UNGER v. ASTRAZENECA PHARMS. LP, ET AL.**
**MDL Case No. 6:07-cv-15812-Orl-22DAB**

**CONNIE M. CURLEY v. ASTRAZENECA PHARMS. LP, ET AL.**
**MDL Case No. 6:07-cv-15701-Orl-22DAB**

**LINDA WHITTINGTON v. ASTRAZENECA PHARMS. LP, ET AL.**
**MDL Case No. 6:07-cv-10475-Orl-22DAB**

**EILEEN MCALEXANDER v. ASTRAZENECA PHARMS. LP, ET AL.**
**MDL Case No. 6:07-cv-10360-Orl-22DAB**

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# ORDER

## I. INTRODUCTION

This cause comes before the Court for consideration of Plaintiffs' Appeal From, Objections To, and Motion to Vacate Magistrate Judge's Order Excluding Evidence and Argument About Foreign Seroquel Labels and Foreign Regulatory Actions (Doc. No. 1288), filed on February 13, 2009. Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively, "AstraZeneca") have filed a legal memorandum in response. (Doc. No. 1308.) Upon carefully

considering the parties' submissions, the Court determines that Magistrate Judge David A. Baker's January 30, 2009 Order (Doc. No. 1253) should be affirmed.

## II. BACKGROUND

The January 30th Order addressed several motions in limine filed by AstraZeneca. The only aspect of the Order being appealed is Judge Baker's ruling granting AstraZeneca's Motion In Limine to Exclude Evidence and Argument About Foreign Seroquel Labels and Foreign Regulatory Actions (Doc. No. 1201). That motion addressed regulatory actions in Japan, France and Holland. In particular, as stated in Judge Baker's Order,

> [t]he Japanese regulatory authority required [AstraZeneca] to add a diabetes contraindication to the Japanese label in 2002 and required [AstraZeneca] to send "Dear Doctor" Letters informing Japanese physicians of the changes; the French regulatory authority in 2005 denied [AstraZeneca] permission to market Seroquel in France; and the Dutch regulatory authority asked AstraZeneca to add language about hyperglycemia and diabetes to the Seroquel label in 2000-2001.

(Doc. No. 1253 at 9.)

AstraZeneca sought exclusion of such evidence on the asserted basis that it would confuse the jury, is irrelevant, and would be unfairly prejudicial. In its motion, AstraZeneca conceded that "[i]n certain circumstances, the adverse events leading to the foreign regulatory action might be relevant to show whether AstraZeneca was on notice of the risk of diabetes[,]" and that "[t]he AstraZeneca scientists' analysis of those adverse events may be relevant to show what AstraZeneca scientists believed at the time." (Doc. No. 1201 at 2.) Nevertheless, AstraZeneca argued,

> The jury would not benefit . . . from learning that an agency in Japan, Holland, or France, applying different regulatory standards to the same adverse event data that the FDA had, reached conclusions regarding diabetes warnings that were at odds with the conclusion reached by the FDA with respect to warnings in the United States.

> Rather, evidence of these foreign regulatory decisions would only confuse and mislead the jury, waste time, and unfairly prejudice AstraZeneca. Introduction of this evidence would supplant the FDA's role as the only relevant regulatory authority in this case. It would import confusing foreign labeling standards at odds with the FDA's domestic regulatory scheme. It would invite the jury to render a verdict based on those inapplicable foreign regulatory standards, rather than on the relevant domestic standards at issue in this case. Finally, admission of this evidence would require litigation of multiple satellite issues regarding the unique criteria employed by foreign agencies in making regulatory decisions - a result at odds with this Court's desire for streamlined trials. *See* Dec. 9, 2008 Order (Doc. No. 1181).

(*Id*. at 2-3.)

Regarding the label change ordered by the Japanese regulators, AstraZeneca repeated its position that it was not challenging "the potential relevance of the 13 adverse events themselves"; however, the company argued "that does not mean the Japanese agency's decision in reaction to those 13 adverse events is also relevant." (*Id.* at 5.) "To the contrary," AstraZeneca maintained, "the agency's decision adds nothing to the question of notice." (*Id.*) Continuing, AstraZeneca argued:

> If the Court were to allow plaintiffs to present evidence and argue about Japanese regulatory events, AstraZeneca would have the right to respond in kind. For example, AstraZeneca would be entitled to present evidence on the difference between the social, political and medical landscapes in the United States and Japan, on how and why Japan's regulatory system differs greatly from the American system, on how and why the MHLW[1] imposes different requirements and employs different labeling and evidentiary standards than the FDA, and on why the Japanese regulatory system reflects a more prophylactic approach than the approach taken in the U.S. (and for that matter, in every other country), as evidenced by the MHLW's

[1]AstraZeneca represented that MHLW is the Japanese regulatory authority. (Doc. No. 1201 at 2.)

> decision to require a diabetes contraindication when no other country has done so. AstraZeneca would also be entitled to present evidence about the 80-plus other foreign countries that to this day do not require a contraindication in Seroquel's label. This mini-trial focused on the Japanese regulatory regime, and possibly the regimes of 80-plus other foreign countries, would confuse the jury, distract from the core issues in this case and pointlessly lengthen the trial. Moreover, it might give rise to the highly prejudicial and improper suggestion that the FDA does not care as much about its citizens as the MHLW. Hence, the Court should exclude evidence of the Japanese label change.

(*Id.* at 6-7) (footnote added.)

As for the French regulatory action, AstraZeneca asserted that France's decision in 2005 not to allow Seroquel to be sold in that country (and the French regulatory authority's associated comments regarding the safety of the drug vis-a-vis metabolism disorders) came after "the FDA had already determined in 2004 exactly the diabetes warning that should be included in the U.S. Seroquel label[.]" (*Id.* at 7.) Accordingly, maintained AstraZeneca, "[a] **2005** decision by the French regulatory authority . . . plainly has no possible bearing on what AstraZeneca should have known in **2004**." (*Id.*) AstraZeneca stated Plaintiffs had conceded that evidence of foreign regulatory actions is relevant only to the issue of AstraZeneca's notice regarding the problems associated with Seroquel prior to the company's revision of the drug's label in 2004. (*Id.* at 7-8.) On that basis, the company sought exclusion of evidence of the French agency's decision.

Regarding the Dutch regulatory action, AstraZeneca argued:

> As with the Japanese label change and the French decision, the Dutch label change shows only that a different regulatory authority, applying different standards in a different social and medical landscape, reached a conclusion different than the conclusion reached by the FDA under the U.S. system. If the Court were to allow plaintiffs to inject the Dutch issue at trial, AstraZeneca would be entitled to present its own evidence and arguments on the Dutch

> decision, thereby preventing the streamlined trials envisioned by the Court. Hence, the Court should exclude evidence of the Dutch label change pursuant to Rules 402 and 403.

(*Id.* at 8.)

In their response to the motion, Plaintiffs argued that evidence of the foreign regulatory actions and label changes is relevant concerning knowledge and scienter, i.e., to "demonstrate AstraZeneca's notice and knowledge of serious hazards reasonably associated with Seroquel" and "AstraZeneca's reaction to that notice and knowledge[.]" (Doc. No. 1225 at 2.) Plaintiffs clarified that they were not seeking "to introduce evidence of Japanese, French, or Dutch regulatory or legal standards." (*Id.* at 7.) Nevertheless, Plaintiffs asserted that the foreign regulatory documents "are plainly relevant and probative of AstraZeneca's notice and knowledge of information that may lead a reasonable juror to believe that AstraZeneca misrepresented, or omitted, that information or failed to meet the standard of care relative to warning about Seroquel's risks at times material to Plaintiffs' cases." (*Id.* at 7-8.) Further, Plaintiffs argued that the Court could "alleviate" concerns regarding jury confusion, waste of time, and unfair prejudice "through an appropriate and simple limiting instruction that the Japanese, French, and Dutch 'warning' standards are different from the legal standard applicable to this case under Florida law." (*Id.* at 2; *see also id.* at 9.) Finally, Plaintiffs characterized AstraZeneca's other claims of unfair prejudice as "meritless"on the ground that they were simply based on the fact that the evidence sought to be excluded was unfavorable to the company. (*Id.* at 9.)

Judge Baker articulated three grounds for granting AstraZeneca's motion in limine: (1) "[t]he foreign Seroquel labels and the foreign regulatory actions have no relevance to Plaintiffs' main case"; (2) "[m]ore importantly, whatever minimal relevance the foreign regulatory actions might

have is clearly overwhelmed by the likelihood of jury confusion" (citing *Deviner v. Electrolux Motor, AB*, 844 F.2d 769, 771 n.2, 773 (11th Cir. 1988)); and (3) "Plaintiffs' approach of allowing the evidence of foreign regulations and dispositions as to Seroquel - which the Court views as akin to evidence of foreign legal standards - even with Plaintiffs' proposed limiting instruction, will not alleviate the risk of jury confusion." (Doc. No. 1253 at 10-11.) However, relying on language from *Deviner*, 844 F.2d at 774, Judge Baker did suggest that evidence of foreign regulations might be relevant in rebuttal on cross-examination of AstraZeneca's employees concerning their knowledge about whether the foreign regulations were linked to a reduction in the number or severity of injuries in the foreign countries, as well as the possible reasons for the phenomena experienced in those other countries. (*Id.* at 10-11.)

## III. PLAINTIFFS' POSITION ON APPEAL

Plaintiffs challenge Judge Baker's exclusion of evidence and arguments about foreign Seroquel labels and foreign regulatory actions on three principal grounds. First, they argue that such evidence is very relevant. In that regard, Plaintiffs contend the evidence is "highly probative of AstraZeneca's notice and knowledge of a causal connection between Seroquel and glucose dysregulation, hyperglycemia, and/or diabetes during the period at issue."[2] (Doc. No. 1288 at 2.) Plaintiffs contend this evidence is likewise "highly probative of AstraZeneca's reaction to that notice and knowledge, especially in view of the company's communications with the United States Food and Drug Administration ('FDA') during the same time periods and its continuing position that there

[2]In their response to the motion in limine and in their appeal memorandum, Plaintiffs do not address AstraZeneca's argument that the French regulatory document is irrelevant for temporal reasons.

exists *no* evidence of a causal association between Seroquel and glucose dysregulation, hyperglycemia, and/or diabetes." (*Id.*) Second, Plaintiffs assert that admitting this evidence presents only a "minimal risk of unfair prejudice, jury confusion, or wasted time[.]" (*Id.* at 3.) Third, Plaintiffs maintain that this "minimal risk" can be alleviated by means of an appropriate limiting instruction. (*Id.* at 10.) Elaborating on that point, Plaintiffs state:

> The jury may be instructed that the cited evidence and argument are not offered as a standard for the jury to use to determine that a similar (or different) warning should have been given, and that the laws and regulations of those respective foreign countries is irrelevant to the jurors[']' determination as to whether AstraZeneca provided physicians an adequate warning. The jury may also be instructed that the only controlling law on the failure to warn issue and all Plaintiffs' claims is Florida law, over which the Court shall further instruct the jurors.

(*Id.* at 11.)

Alternatively, Plaintiffs argue that a final ruling regarding the admissibility of the foreign regulatory documents should be deferred to the time of trial, "when Plaintiffs will have the opportunity to establish their foundation and context." (*Id.* at 3.) Finally, Plaintiffs contend Judge Baker erred in limiting their use of the foreign regulatory evidence to "a very narrow rebuttal purpose that is extremely unlikely [to] arise at trial." (*Id.* at 2.)

## IV. ASTRAZENECA'S RESPONSE

AstraZeneca urges the Court to affirm Judge Baker's ruling regarding foreign labeling and regulatory actions. In the company's view, Plaintiffs' arguments on appeal are merely a rehash of the points Plaintiffs raised in their legal memorandum opposing the original motion in limine. AstraZeneca also contends Judge Baker's ruling is consistent with the decisions of other courts.

Finally, AstraZeneca claims that broadening the use of such evidence for rebuttal purposes, as Plaintiffs request, would "eviscerate" Judge Baker's exclusionary ruling. (Doc. No. 1308 at 9.)

## V. STANDARD OF REVIEW

Rule 72(a) of the Federal Rules of Civil Procedure allows a party to serve and file objections to a magistrate judge's non-dispositive ruling within ten days after being served with a copy of the magistrate's order. On review, the district judge "must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law." Fed. R. Civ. P. 72(a); *see also* 28 U.S.C. § 636(b)(1)(A) (providing that a judge may reconsider any non-dispositive pretrial matter determined by a magistrate judge "where it has been shown that the magistrate judge's order is clearly erroneous or contrary to law").

## VI. ANALYSIS

The undersigned judge concludes that Judge Baker did not err in ruling that Plaintiffs may not present evidence of foreign regulatory actions and foreign label changes during their main case. Accepting for argument's sake that such evidence is relevant regarding notice and scienter, the fact remains that its probative value is greatly overmatched by the jury confusion, waste of time, and unfair prejudice that would result if the Court were to allow Plaintiffs to introduce this evidence during their main case. To admit evidence about the foreign regulators' actions regarding Seroquel without providing context concerning the regulatory schemes and decision-making processes involved would strip the jury of any framework within which to evaluate the meaning of that evidence. Absent such background and context, a jury might be more inclined to abdicate its responsibilities and defer to the negative decisions of three foreign regulators regarding Seroquel's safety. Hence, precluding AstraZeneca from offering such contextual evidence would unfairly

prejudice the company. On the other hand, allowing AstraZeneca to introduce this evidence would result in a series of "mini-trials" regarding the grounds for the decisions and the regulatory schemes of the three foreign countries involved. This would confuse the jury and waste everyone's time. For these reasons, the Court concurs in Judge Baker's determination that the prejudicial effect of this evidence substantially outweighs its probative value. Finally, the undersigned judge agrees entirely with Judge Baker's conclusion that a limiting instruction would not suffice in this case; it would neither alleviate the significant risk of jury confusion and waste of time, nor would it cure the substantial prejudice AstraZeneca would suffer if evidence of regulatory actions were admitted at trial.

The Court also rejects Plaintiffs' objections regarding the potential rebuttal uses for foreign regulatory evidence identified in the January 30th Order. In the Court's view, the categories Judge Baker listed were merely exemplary, not exclusive or exhaustive. The Court recognizes the possibility that there may be other permissible rebuttal uses for this evidence. However, the Court cannot render a final decision about these other potential uses in the present context. Accordingly, a final ruling will have to await trial.

Before concluding, it is important to appreciate the actual scope of Judge Baker's exclusionary ruling. His 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.[3] AstraZeneca at least partially conceded as much in its motion in limine. (*See* Doc. No. 1201 at 2 ("In certain circumstances, the adverse events leading to the foreign regulatory action might be relevant to show whether AstraZeneca was on notice of the risk of diabetes. The AstraZeneca scientists' analysis of those adverse events may be relevant to show what AstraZeneca scientists believed at the time.") and 5 ("This motion does not challenge the potential relevance of the 13 adverse events themselves, but that does not mean the Japanese agency's decision in reaction to those 13 adverse events is also relevant.").)[4] After all, what AstraZeneca was being *told* by foreign regulators about the safety of Seroquel is more probative of issues of notice, knowledge and scienter than what the foreign agencies decided to do - or required AstraZeneca to do - in the face of that information. Additionally, it appears more likely that the former evidence can be presented without creating jury confusion and wasting time. In other words, if Plaintiffs present evidence of what foreign regulators were telling AstraZeneca about the safety of Seroquel without disclosing what the foreign agencies did - or compelled AstraZeneca to do - in response to those concerns, there is no need to stray into the nettlesome area of the foreign standards and regulatory schemes. However,

[3]Even though information the foreign regulators communicated to AstraZeneca regarding the dangers of Seroquel may be admissible in AstraZeneca's main case, the regulatory documents themselves are not. The Court has examined the three documents and sees no practical way to redact them so as to alleviate the significant potential for jury confusion and unfair prejudice to AstraZeneca.

[4]Similarly, in its legal memorandum opposing Plaintiffs' appeal, AstraZeneca conceded: "In certain circumstances, the adverse events leading to the foreign regulatory action might be relevant to show whether AstraZeneca was on notice of the alleged risk of diabetes. The AstraZeneca scientists' analysis of those adverse events may be relevant to show what AstraZeneca scientists believed at the time." (Doc. No. 1308 at 4-5.)

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.

## VII. CONCLUSION

Based on the foregoing, it is ORDERED as follows:

1. Plaintiffs' Appeal From, Objections To, and Motion to Vacate Magistrate Judge's Order Excluding Evidence and Argument About Foreign Seroquel Labels and Foreign Regulatory Actions (Doc. No. 1288), filed on February 13, 2009, is OVERRULED AND DENIED.

2. Magistrate Judge Baker's January 30, 2009 Order (Doc. No. 1253) is AFFIRMED.

3. Plaintiffs' Motion to Reconsider Order (Doc. No. 1287), filed on February 13, 2009, is MOOT.

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

ANNE C. CONWAY
United States District Judge

Copies furnished to:

Counsel of Record
Magistrate Judge Baker