UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation.

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

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ORDER

Defendant AstraZeneca ("AZ") has filed several motions *in limine* seeking to preclude introduction of certain types of evidence at the trials in individuals cases[1] within the Multidistrict Litigation *In re Seroquel*. The Court considers each Motion *in Limine* individually and rules as set forth below.

STANDARD FOR MOTIONS IN LIMINE

A motion *in limine* presents a pretrial issue of admissibility of evidence that is likely to arise at trial, and as such, the order, like any other interlocutory order, remains subject to reconsideration by the court throughout the trial. *Stewart v. Hooters of America, Inc.*, Civ. No. 8:04-cv-40-T-17-MAP, 2007 WL 1752843, *1 (M.D. Fla. 2007). "The real purpose of a motion *in limine* is to give the trial judge notice of the movant's position so as to avoid the introduction of damaging evidence which may irretrievably effect the fairness of the trial. A court has the power to exclude evidence in limine only when evidence is clearly inadmissible on all potential grounds." *Id*. (citing *Luce v. United States*, 469 U.S. 38, 41 (1984) (federal district courts have authority to make in limine rulings pursuant to their authority to manage trials).

[1]The individual cases are: *Linda Guinn v. AstraZeneca LP, et al*, Case No. 6:07-cv-10291-Orl-22DAB; and *David Haller v. AstraZeneca LP, et al.,* Case No. 6:07-cv-15733-Orl-22DAB.

Unless evidence meets this high standard, evidentiary rulings should be deferred until trial so that questions of foundation, relevancy, and potential prejudice may be resolved in proper context. *See generally* 21 Charles A. Wright & Kenneth W. Graham, Jr., FEDERAL PRACTICE AND PROCEDURE ¶ 5042 (1977 & Supp.1993). It is the better practice to wait until trial to rule on objections when admissibility substantially depends upon what facts may be developed there. *Bowden ex rel. Bowden v. Wal-Mart Stores, Inc.*, Case No. Civ. A 99-D-880-E, 2001 WL 617521, *1 (M.D. Ala. Feb. 20, 2001) (citing *Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir.1975)).

The movant has the burden of demonstrating that the evidence is inadmissible on any relevant ground. *Bowden*, 2001 WL 617521 at *1 (citing *Plair v. E.J. Brach & Sons, Inc.*, 864 F.Supp. 67, 69 (N.D. Ill.1994)). At trial, the court may alter its *limine* ruling based on developments at trial or on its sound judicial discretion. *Luce v. United States*, 469 U.S. 38, 41 (1984). "Denial of a motion *in limine* does not necessarily mean that all evidence contemplated by the motion will be admitted at trial." *Hawthorne Partners v. AT & T Tech.*, 831 F.Supp. 1398, 1401 (N.D. Ill. 1993). Instead, denial of the motion means the court cannot determine whether the evidence in question should be excluded outside the trial context. *United States v. Connelly*, 874 F.2d 412, 416 (7th Cir. 1989). The court will entertain objections on individual proffers as they arise at trial, even though the proffer falls within the scope of a denied motion *in limine*. *Id*. A ruling *in limine* does not "relieve a party from the responsibility of making objections, raising motions to strike or making formal offers of proof during the course of trial." *Thweatt v. Ontko*, 814 F.2d 1466, 1470 (10th Cir. 1987).

Evidence may be excluded when the probative value is outweighed by its prejudice. Under Rule 403, "[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. Rule 403 permits a district court to exclude relevant evidence only when "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." *United States v. Ross*, 33 F.3d 1507, 1524 (11th Cir.1994). Rule 403 is "an extraordinary remedy" whose "major function . . . is limited to excluding matter of scant or cumulative probative force, dragged in by the heels for the sake of its prejudicial effect." *United States v. Grant*, 256 F.3d 1146, 1155 (11th Cir. 2001).

MOTION: **DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT ALLEGED "GHOSTWRITING" (Doc. No. 1197)**

FILED: **January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED** in part and **DENIED** in part.

AZ moves to exclude evidence and argument about alleged "ghostwriting" or the "specter of plagiarism" of scientific articles, which may impugn the reputations of AZ or the physicians who wrote articles on its behalf. Doc. No. 1197 at 2. AZ employs Clinical Research Organizations such as Parexel Corporation to assist with medical communications concerning Seroquel. AZ does not dispute that Parexel assisted AZ in identified appropriate physicians to serve as authors of scientific papers regarding Seroquel and admittedly "often assisted in the preparation of those papers." AZ contends that "Parexel's authorial assistance is not improper, and thus "ghostwriting" allegations are irrelevant to Plaintiffs' claims. AZ contends the evidence is also irrelevant because there is no

evidence that any of Plaintiffs' prescribing physicians saw or relied upon any allegedly "ghostwritten" articles.

Plaintiffs respond that "ghostwriting is not a "common practice" in the industry as AZ argues, but a "spurious tool employed by AstraZeneca in its fraudulent manipulation of clinical trials' and studies' data through seemingly independent and credible articles." Doc. No. 1227 at 2. Plaintiffs allege that AstraZeneca misled the healthcare profession, including Plaintiffs' prescribing healthcare providers, about the risks associated with its prescription drug, Seroquel. Doc. No. 1227. Plaintiffs contend that "through ghostwriting, AstraZeneca was able to bury unfavorable trial data regarding Seroquel and, in turn, market Seroquel in an unduly (and dangerously) favorable light to the medical community at large" and "Seroquel prescribers were, therefore, improperly influenced in their prescribing decisions with respect to Seroquel." Doc. No. 1227 at 2. Plaintiffs point to the sales call notes pertaining to Plaintiffs' prescribing physicians as evidence of AstraZeneca's use of ghostwritten literature in the deliberate influence of Plaintiffs' physicians' prescribing habits; Plaintiffs contend that through its sales force, AstraZeneca meticulously detailed each Seroquel prescriber on the purported benefits and weight neutral profile of Seroquel with the aid of ghostwritten articles, other literature and related reprints.

Plaintiffs contend that evidence of AZ's exertion of control to influence the content of published articles or other literature relating to the safety or efficacy of Seroquel is relevant to their claims that AZ failed to warn of known safety risks related to Seroquel. Plaintiffs argue that evidence of ghostwriting is also relevant to Plaintiffs' claims that AstraZeneca knew of the dangerous side effects associated with Seroquel but nevertheless sought to suppress such negative data from clinical trials, as well as to Plaintiffs' claims that AstraZeneca's failure to warn. Doc. No. 1227 at 2.

Plaintiffs have agreed not to use the term "ghostwriting," but argue they should be permitted to explain to the jury the implications of AstraZeneca's misrepresentations in the creation and/or sponsorship of ghostwritten publications and other literature related to non-medically necessary uses of Seroquel and the safety and efficacy of Seroquel. The Court agrees. To the extent AZ seeks to preclude Plaintiffs use of the terms "ghostwriting" or "plagiarism" the Motion to Exclude is **GRANTED**. To the extent AZ seeks to preclude all evidence that third-party medical marketing firms, such as Parexel, prepared drafts or literature authored by physicians, the Motion is **DENIED**.

MOTION: **DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT THE ALLEGED RISKS OF SEROQUEL USE IN PEDIATRIC AND GERIATRIC POPULATIONS (Doc. No. 1198)**

FILED: **January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED** as to Trial Group One.

It is undisputed that none of the Plaintiffs in Trial Group One fall into either category of pediatric or geriatric populations (Doc. No. 1224), thus the evidence is not relevant to the Group One cases and will be excluded in these cases. To the extent Plaintiffs wish to use the evidence for any other purpose, such as an example of a stronger label warning, such evidence would lead to jury confusion.

MOTION: **DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT CLINICAL INVESTIGATORS' MISCONDUCT (Doc. No. 1199)**

FILED: **January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED**.

AZ seeks to exclude evidence and argument about alleged or actual misconduct of clinical investigator Dr. Richard Borison, or any other clinical investigator involved in clinical trials of Seroquel at Dr. Borison's research facility, arguing the evidence is irrelevant and any minimal relevance is substantially outweighed by the possibility of prejudice, confusion, misleading the jury and waste of time. Doc. No. 1199. AZ argues that "such evidence of criminality – where, if anything, AZ was the victim – has nothing to do with any of the plaintiffs in these cases and would be unfairly prejudicial and confusing." Doc. No. 1199 at 1.

AZ explains that Dr. Borison and a colleague Dr. Bruce Diamond were clinical investigators who conducted clinical trials for a number of pharmaceutical companies, including trials of Seroquel prior to its launch in 1997. Doc. No. 1199at 1-2. Dr. Borison was accused of improper conduct in connection with his research facility, failure to turn over payments for clinical studies to his employer the Medical College of Georgia; he pled guilty to RICO, theft, and false statement charges from his financial improprieties, and was incarcerated. Doc. No. 1199 at 2 and n 1. When AZ submitted to the FDA a New Drug Application ("NDA") for Seroquel, it included "all of the data from Dr. Borison's investigator sites," and "an analysis excluding that data" so the FDA had the "benefit of both analyses." Doc. No. 1199 at 2.

Plaintiffs contend the evidence is relevant to their claims because the clinical investigators' financial improprieties are directly related to Plaintiffs' claims and AstraZeneca's defenses. Doc. No. 1228. Plaintiffs contend "the fact that at least two of their hand-picked clinical researchers were routinely investigated and eventually incarcerated for acts related to their research goes directly to the credibility and competency of AstraZeneca's testing and scientific research." Plaintiffs also argue that they have a right to present evidence as to whether or not that "testing was properly performed

by qualified personnel." Doc. No. 1228 at 4. The Court does not agree that the researchers' financial improprieties "go directly to the credibility" of the AZ's testing; In fact, Plaintiffs have not shown how the financial improprieties relate to the actual testing. Moreover, Plaintiffs do not contradict AZ's representation that it submitted the Seroquel NDA to the FDA with the "controversial" data from Dr. Borison's investigator sites *excluded* as well as included; thus, the FDA's decision was not based exclusively on the Dr. Borison's information. Additionally, AZ's arguments that evidence of Dr. Borison's misconduct would inject a collateral issue and suggest to the jury AZ's "guilt by association" in violation of Rule 403, are arguments well-taken.

MOTION:	**DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT 1998, 1999, AND 2006 LETTERS FROM FDA'S DIVISION OF DRUG MARKETING, ADVERTISING, AND COMMUNICATIONS (Doc. No. 1200)**
FILED:	**January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED**.

AZ moves to exclude evidence of 1998, 1999 and 2006 Letters ("the Letters") from the FDA's Division of Drug Marketing, Advertising, and Communications[2] ("DDMAC"), arguing the Letters are not relevant because they are about products not at issue, modifications made as requested by the DDMAC, or concern a withdrawn promotional piece. Doc. 1200. AZ argues that the Letters are irrelevant because there is no evidence the promotional pieces were actually seen by Plaintiffs' prescribing physicians, and the Letters are unfairly prejudicial and will cause delay by necessitating testimony about the complex scheme governing prescription drug promotional pieces. AZ further

[2]Pursuant to 21 C.F.R. § 314.81(b)(3)(I), AZ is required to submit all promotional pieces to DDMAC for review.

argues that the Letters cannot be used to show it has a "propensity" for engaging in "misleading" advertising in violation of Rule 404(b) (evidence of other acts is not admissible to prove character).

Although Plaintiffs do not dispute that they have not tied the Letters to a particular prescribers' exposure, they argue that evidence of marketing activities "in general" is relevant to "show the extent to which AZ controlled and manipulated the content and dissemination of relevant Seroquel safety information to healthcare providers." Doc. No. 1229 at 2-3. Plaintiffs contend that evidence of "general 'marketing activities' tends to make the existence of facts of consequence more probable," *i.e.*, that AZ "failed to use reasonable care in promoting Seroquel and AZ's knowledge regarding the truth or falsity of its misrepresentations and omissions." Doc. No. 1229 at 3. Plaintiffs also argue the Letters may be introduced to rebut claims of good character and/or drug efficacy or safety; for impeachment purposes; for showing AstraZeneca's motive, intent, and/or state of mind; and for showing a pattern and practice of misconduct for purposes of punitive damages.

In the case of the 1998 Letter in particular, the promotional materials at issue did not involve Seroquel at all and the 1998 Letter is clearly irrelevant. As to the 1999 and 2006 Letters, which do concern promotional materials on Seroquel, Plaintiffs have not shown that their prescribing physicians were exposed to the promotional materials; thus, the evidence is excluded, except that it *may* be used in rebuttal if Plaintiffs establish facts that support their claim for punitive damages (that decision will be made by the trial judge).

MOTION:	**DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT FOREIGN SEROQUEL LABELS AND FOREIGN REGULATORY ACTIONS (Doc. No. 1201)**
FILED:	**January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED**.

AZ moves to exclude evidence about foreign labeling and regulatory action, including the regulation of Seroquel in Japan, France, and Holland. Doc. No. 1201. The Japanese regulatory authority required AZ to add a diabetes contraindication to the Japanese label in 2002 and required AZ to send "Dear Doctor" Letters informing Japanese physicians of the changes; the French regulatory authority in 2005 denied AZ permission to market Seroquel in France; and the Dutch regulatory authority asked Astra Zeneca to add language about hyperglycemia and diabetes to the Seroquel label in 2000-2001. Doc. No. 1201 at 2, 5 n. 3. AZ contends that the foreign label changes and French decision show "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." Doc. No. 1201 at 8.

Plaintiffs contend that the foreign labeling and regulatory actions in 2000-2002 and 2004 demonstrate AZ's notice and knowledge of serious hazards reasonably associated with Seroquel and are relevant to their allegations: that AstraZeneca failed to warn of risks of Seroquel that were known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time Plaintiffs ingested Seroquel; that AstraZeneca failed to exercise reasonable care in marketing and selling Seroquel without an adequate warning; that AstraZeneca knew or should have known that the representations it made were false, and that AZ acted in reckless

disregard of their truth or falsity and/or omitted information that made other statements misleading. Doc. No. 1225 at 1-2. Plaintiffs contend that they do not seek to introduce evidence of Japanese, French, or Dutch regulatory or legal standards, but plan to argue the "documents" are relevant and probative of AstraZeneca's notice and knowledge of information that its actions failed to meet the standard of care relative to warning about Seroquel's risks.

Plaintiffs contend that jury confusion, unfair prejudice and waste of time concerns can be alleviated by "an appropriate and simple limiting instruction" that the foreign warning standards are different from the legal standard applicable under Florida law. Plaintiff argues the jury can be told that the foreign regulatory evidence is not offered to determine whether a similar warning should have be given, and "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 should be instructed that the only controlling law on the failure to warn issue and all Plaintiffs' claims is Florida law. Doc. No. 1225.

The foreign Seroquel labels and the foreign regulatory actions have no relevance to Plaintiffs' main case. More importantly, whatever minimal relevance the foreign regulatory actions might have is clearly overwhelmed by the likelihood of jury confusion. *See Deviner v. Electrolux Motor, AB*, 844 F.2d 769, 771 n.2, 773 (11th Cir. 1988). In *Deviner*, the Eleventh Circuit concluded that evidence of foreign regulatory actions in the main case would confuse the jury and is thus irrelevant and unfairly prejudicial. *Id.* (holding that district court did not abuse its discretion in refusing to allow evidence of Swedish law and statistics regarding modification to chainsaws where the issues in the case arose under Alabama and federal law, and involved technical questions of fact regarding the logging business and the operation of chain saws). As in *Deviner*, evidence of prevailing foreign

regulations may be relevant in rebuttal on cross-examination of AZ employees as to their general knowledge of whether the foreign regulations/changes are linked to a "diminution in number and severity of injuries" in the foreign countries and the "various possible reasons to explain the phenomena experienced" in those countries. *Id*. at 774.

Plaintiffs cited cases are inapposite and do not hold that the evidence of foreign regulations or actions should be allowed in the case in chief; if anything, Plaintiffs' cited cases lean toward exclusion of such evidence or delay of the decision until trial where context and foundation were not disclosed. *See In re Rezulin Products Liability Litigation*, 309 F. Supp. 2d 531, 552 (S.D. N.Y. 2004) ("Assuming that evidence concerning foreign regulatory actions is relevant and admissible over Rule 403 objections, plaintiffs' experts are not the appropriate vehicles for its introduction."); *Blevins v. New Holland N.A., Inc*., 128 F. Supp. 2d 952, 959 (D. W.V. 2001) (refusing to rule on admissibility of foreign safety standards or testing where no context or foundation had been laid); *Sherry v. Massey Ferguson, Inc.*, No. 1:96-CV-76, 1997 WL 480893, at *1 (W.D. Mich. June 5, 1997) (holding that evidence of foreign designs – as opposed to foreign legal standards – was not inadmissible as matter of law, where evidence *might* be admissible on an issue such as feasibility or alternative designs).

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. *See, e.g.*, *id*. at 1997 WL 480893, at *1 ("I agree that evidence of European legal standards and requirements . . . will unnecessarily confuse the jury.").

MOTION: **DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT ZOLADEX SETTLEMENT (Doc. No. 1202)**

FILED: **January 8, 2009**

THEREON it is **ORDERED** that the Motion is **GRANTED**.

AZ moves to exclude evidence about AZ's 2003 settlement with the federal government relating to the pricing of Zoladex, an anti-cancer medication, or about the Corporate Integrity Agreement ("CIA") that was part of that settlement. Doc. No. 1202. AZ also argues that this evidence would unfairly prejudice AZ. In 2003, AZ settled a claim by the federal government that AZ had overcharged for Zoladex, a cancer medicine; AZ entered into a five-year Corporate Integrity Agreement, which required AZ to report the average sale price for Zoladex and seven other drugs. Doc. No. 11202 at 2; 202-2; 1202-3. AZ argues that the Zoladex Settlement evidence, which deals with a violation of reimbursement rules in the pricing of Zoladex, is irrelevant to the personal injury claims alleged in this case. AZ also argues that the evidence is unfairly prejudicial, misleading, and a waste of time.

Plaintiffs have stipulated that they will not introduce evidence of the Zoladex litigation or settlement except to rebut "any 'good corporate citizen' or similar testimony offered by Defendants at trial." Doc. No. 1223 at 2. However, Plaintiffs contend that evidence regarding the Zoladex CIA is relevant to determining and applying the standard of care for Plaintiffs' marketing, sales, and warning claims against Defendants. Plaintiffs explain that, as part of the CIA, AstraZeneca agreed to establish both a Code of Conduct and Policies and Procedures for its sales and marketing officers, employees, and agents, which they argue is akin to an industry custom, bearing on the standard of

care for determining negligence. Again, Plaintiffs contend that a cautionary jury instruction can be given to avoid jury confusion. Doc. No. 1223.

The Court finds that a party's agreement as to a particular standard of care for a completely different medication, used to treat a completely different condition – cancer – is irrelevant to Plaintiffs' claims in this case; its prejudice outweighs any potential probative value, wastes time, and will confuse the jury.

DONE and **ORDERED** on January 30, 2009.

David A. Baker

DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE

Copies furnished to:

Counsel of Record