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

This cause came on for consideration without oral argument on the following motion filed herein:

MOTION:	**DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND ARGUMENT ABOUT DOCTOR MACFADDEN'S PERSONAL RELATIONSHIPS (Doc. No. 1196)**
FILED:	**January 8, 2009**

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

AstraZeneca ("AZ") has filed this motion *in limine* seeking to preclude introduction of evidence and argument at the trials in individuals cases within the Multidistrict Litigation *In re Seroquel* concerning the sexual relationships of AZ's former director of clinical research and two women involved in independent clinical research studies associated with Seroquel.

STANDARD FOR MOTIONS IN LIMINE

Federal Rules of Evidence 401 and 402 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 alone, however; it must

be balanced with Rule 403, which dictates that 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.

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. June 18, 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).

Unless the objection 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; *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).

II. Analysis

A. Evidence of Doctor Macfadden's Personal Relationships

AZ moves *in limine* to exclude evidence and argument about two sexual relationships between Dr. Wayne Macfadden – AstraZeneca's former United States Medical Director for Seroquel and the Director of Clinical Research in the CNS Therapeutic Area – and two women who were directly involved in independent clinical research studies associated with the development and marketing of Seroquel.

AZ contends that this evidence is not relevant to the core issue before the jury, which it characterizes as whether Seroquel caused Plaintiffs' alleged diabetes, and if so, whether AZ adequately warned Plaintiffs' prescribing doctors; AZ argues that evidence of Dr. Macfadden's personal relationships "will only serve to inflame the jury and distract from the true issues." *See* Doc. No. 1196. AZ also argues that "the Macfadden relationships concern sensitive issues for persons not involved in this litigation," whose privacy should be protected. Doc. No. 1196 at 2.

Plaintiffs contend the evidence is relevant and probative of a "high level AstraZeneca employee" and his "exploitation of his sexual relationships with these women in order to elevate Seroquel's status in the prescribing medical community through supposedly 'independent' publications of Seroquel safety and efficacy data" and "the mere existence of these relationships calls into question the integrity of the scientific work product of those involved." Doc. No. 1226 at 2. Plaintiffs also argue the evidence is relevant in the context of AstraZeneca's efforts to "tout itself as a responsible, scientific company whose primary concern is promoting patient safety by providing complete and well-balanced information about Seroquel to the prescribing medical community." Doc. No. 1226 at 2.

1. Background on Macfadden's role in litigation and relationships[1]

Macfadden is a board certified psychiatrist with added qualifications in addiction psychiatry. Macfadden Dep. at 906-07. Macfadden served as AstraZeneca's U.S. Medical Director for Seroquel and the Director of Clinical Research in the Central Nervous System (CNS) Therapeutic Area beginning in 2001 until his termination in 2006. Macfadden Dep.[2] at 33-37, 939. At least 90% of his time at AstraZeneca was devoted to Seroquel-related matters. Macfadden Dep. at 34-35. Among his job responsibilities, Macfadden was responsible for Seroquel clinical trials in the United States. Macfadden Dep. at 604. He was the responsible clinical research physician and an author on the bipolar depression trials (BOLDER I and II), which were significant components of AZ's submissions to the FDA. Macfadden Dep. at 220, 342, 358-59, 990.

As United States Medical Director for Seroquel, Macfadden was consulted on strategy and decision-making concerning the monitoring of glucose in the Seroquel clinical trial plan. Macfadden Dep. at 273-75. In fact, after BOLDER I revealed "a lot of variance in" glucose levels in study participants, Macfadden changed the BOLDER II protocol to more accurately assess and monitor more closely blood glucose in study participants. Macfadden Dep. at 468-69. As the "physician at AstraZeneca with the most tenure on Seroquel," Macfadden signed the January 30, 2004 and April 22, 2004 "Dear Doctor" letters informing healthcare providers of the warning change to the label of Seroquel regarding hyperglycemia and diabetes. Macfadden Dep. at 141-42, 144, 148.

Macfadden was actively involved in the marketing and promotion of Seroquel and served on multiple commercial/marketing teams including the Seroquel Leadership Team, Brand Team,

[1]The background facts, to the extent they are supported by the deposition testimony and undisputed, are taken as stated in Plaintiff's Response. Doc. No. 1226.

[2]The depositions of Macfadden, Schwartz, and Piano, and certain research studies were filed under seal as exhibits to Plaintiffs' Response In Opposition to the Motion (Doc. No. 1226). Redacted versions were refiled in the public docket on March 11, 2009. *See* Doc. No. 1357.

Communications Team, and Bipolar Execution and Strategy Team ("BEST"). Macfadden Dep. at 94, 97-98. In an effort to expand Seroquel use, MacFadden was consulted on the decision to explore the opportunity among primary care physicians "focusing on dementia and treatment-resistant anxiety." Macfadden Dep. at 178-79, 181-82, 184-86. He also interacted with Key Opinion Leaders who were generally well-respected physicians chosen by AstraZeneca to promote Seroquel to their colleagues and the medical community at large. Macfadden Dep. at 154-56.

As Director of Clinical Research in the CNS Therapeutic Area, Macfadden engaged third parties in the United States and abroad to conduct clinical research involving Seroquel and its competitors, including the Institute of Psychiatry (IOP) in London, a postgraduate institute of the University of London and a school of King's College London. While collaborating with IOP, Macfadden became involved in a sexual relationship with an IOP researcher who, as well as being involved in other Seroquel-related projects, participated in the clinical research and abstract preparation relating to the effectiveness of Seroquel for use in the treatment of schizophrenia (hereinafter "IOP Researcher"). Macfadden Dep. at 870, 894-99, 911-12. Macfadden's affair with the IOP Researcher lasted for four years, from 2002 to 2006. Macfadden Dep. at 914, 944-45. During that time period, several research papers, relating to the effectiveness of atypical antipsychotics in general and Seroquel in particular, on which the IOP Researcher was a co-author, were published. Macfadden Dep. Ex. 54, 55, 56, 57 (Ex. 2, 3, 4, 5 of sealed submission). The results of at least some of this research were sent to United States physicians in response to Physician Information Requests (PIR). Macfadden Dep. at 882-83, 885-88.

As part of the communications and bipolar execution and strategy teams, Macfadden had a role in engaging third parties such as Parexel MMS (Medical Marketing Services) to draft manuscripts for AstraZeneca and authors (suggested by Parexel) which reported the results of

clinical studies; the reports were ultimately submitted for publication in various medical journals. Macfadden Dep. at 97-98, 306, 983. In addition to its publication responsibilities, Parexel organized advisory committees and prepared slide sets, posters and hand outs that were presented by AstraZeneca at medical conferences. Macfadden Dep. at 306-08; *see also* Piano Dep. at 26 (the term "publications" as used by Parexel included scientific literature in medical journals, posters, and abstracts presented at medical conferences and medical association meetings). As part of Plaintiffs' theory of the case, they argue that the Parexel Project Manager was responsible in part for communicating Seroquel efficacy and safety data to the medical community through multiple means. Doc. No. 1226.

Sometime during 2004, while collaborating with Parexel and while still involved in a sexual relationship with the IOP Researcher, Macfadden became involved in a sexual relationship with the Parexel Program Manager[3] responsible for AstraZeneca (hereinafter "PPM"). Macfadden Dep. at 944-45, 979-80, 983. Among her Seroquel-related responsibilities, the Parexel Project Manager was responsible for the "Seroquel global publications business," including the publication of the BOLDER I and II studies, on which Macfadden was listed as one author. Macfadden Dep. at 229, 234, 236-37, 999-1000. The BOLDER I and II studies supported AstraZeneca's FDA registration for a bipolar depression indication. Schwartz Dep. at 60-61.

2. Relevancy

Plaintiffs argue the Macfadden relationship evidence is relevant to their allegations that AstraZeneca misrepresented Seroquel's effectiveness and safety through "communications including letters to the medical community, and medical literature disseminated . . . to physicians and the

[3]Macfadden also admitted to offering to prescribe prescription drugs to the Parexel Program Manager. Macfadden Dep. at 997, 1027-28.

public . . . about the safety and efficacy of Seroquel." Doc. No. 42, Master Complaint, ¶ 62. Plaintiffs allege in conjunction with their misrepresentation claims that AstraZeneca controlled and manipulated efficacy and safety data in an effort to make that data appear more favorable to Seroquel, such as "[w]ith the assistance of researchers and medical marketing companies such as Parexel, AstraZeneca exercised vast control over medical publications and the materials presented at medical conferences which were passed off as independent and unbiased." Doc. No. 1226 at 7-8.

Plaintiffs contend that "Macfadden was charged, through his high-level job at AstraZeneca, with a position of public trust in that he was chiefly responsible for Seroquel-related research and development, and for communicating information generated from that work to doctors and the public. The women with whom Macfadden engaged in long-term sexual affairs were, at least in part, responsible for developing and publishing the very research that was ultimately used by Macfadden and AstraZeneca to promote Seroquel's safety and efficacy to physicians and patients." Doc. No. 1226 at 8.

Plaintiffs cite the communications between Macfadden and the two women as suggesting "a level of control and dependence between Macfadden and these women." The IOP Researcher recognized that Macfadden would not be pleased that she intended to look at studies that were favorable to Seroquel's competitors and suggested that she would "probably need to be punished" for looking at the studies. Macfadden Dep. at 948-51; Macfadden Dep. Ex. 63. Macfadden suggested to the IOP Researcher additional research for studies "which would be of interest to" AZ, also suggesting that the studies would be "great excuses to rondez-vous." Macfadden Dep. at 904-11. Macfadden also asked the IOP Researcher about information concerning one of AstraZeneca's competitors' development plans. Macfadden Dep. at 914-18; Ex. 60.

Plaintiffs argue that the admissibility of the Macfadden relationships is similar to the analysis in a *quid pro quo* sexual harassment lawsuit, or other cases in which such evidence is relevant to show the effect of inappropriate sexual conduct on the workplace and workplace decision-making. Plaintiffs also argue that the Macfadden relationships are relevant to the trustworthiness of the medical and marketing information AZ was disseminating to the medical community, *i.e.*, for those who prescribed Seroquel in part based on the safety and efficacy data published in the medical literature. Macfadden denied at his deposition that these relationships created a conflict of interest (Macfadden Dep. at 461), yet he teased the IOP Researcher in emails about the obvious conflict of interest as he reviewed drafts of her papers on Seroquel. Macfadden Dep at 928-931, 959-64, Ex. 13. Macfadden was given the "opportunity to resign" when AZ discovered his personal email correspondence regarding the relationship with the IOP Researcher. Macfadden Dep at 442-43, 447-49, 939-40. Plaintiffs additionally contend that the "precise nature of the relationships may be admissible to assess the credibility of Macfadden's testimony in deposition and at trial in terms of bias and prejudice because it may support claims of bias, and undermine Macfadden's credibility." Doc. No. 1226 at 11-12.

AZ devotes only a single paragraph to arguing that Macfadden's relationships are not relevant to the issues in Plaintiffs' cases, despite Chief Judge Conway's previous ruling that they are relevant. AZ contends that Plaintiffs "can point to no evidence suggesting the Macfadden Relationships affected any data or the "'integrity of clinical research and information disseminated,' 'influenced' AZ's promotion of Seroquel, or had any effect on plaintiffs or their prescribing physicians." Doc. No. 1196 at 3.

AZ ignores Judge Conway's ruling in a previous Order (Doc. No. 601) concerning the discoverability of this particular Macfadden-relationship evidence in which she held:

> The Macfadden Documents are relevant to Plaintiffs' claim that AstraZeneca misinformed the public regarding the potential health risks of Seroquel inasmuch as they convey the precise nature of the relationships between key players in the development and marketing of Seroquel. As such, Plaintiffs are entitled to the full context of the communications contained in the documents, not just the portions related to "business as usual." In the Court's view, Plaintiffs' request is much more than what Defendants imply is a mere "fishing expedition" which aims only to embarrass or harass; it is a focused inquiry into how certain events may have influenced Defendants' actions with regard to promoting the safety and efficacy of Seroquel.

Doc. No. 601 at 3. Considering its relevance, the evidence of Macfadden's relationships, is admissible.

C. Potential Prejudice

The remaining issue then is whether the probative value of the Macfadden relationship evidence is outweighed by its prejudice. AZ argues that the Court should exclude evidence of the Macfadden Relationships because it is unfairly prejudicial, inflammatory, and invites an emotional reaction from the jury, which Rule 403 is intended to prevent. Plaintiffs argue that the probative value of Macfadden's relationships far surpasses the potential for undue harm. Plaintiffs argue that the relationships affected the judgment of the persons involved which in turn compromised the information that was ultimately disseminated to physicians who are responsible for treating the mentally ill; they argue that any embarrassing effect felt by AZ or Dr. Macfadden, as former U.S. Medical Director for Seroquel, hardly reaches the level of "unfair" under these circumstances.

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 that should be used sparingly because it allows a court to exclude admittedly probative evidence." *Id.* "The 'major function' of Rule 403 'is limited to excluding matter of scant or cumulative probative force, dragged in by the heels for the sake of its prejudicial effect.'" *Id*. at 1048.

There is little dispute that generally inquiries into non-workplace, off-duty sexual contact have been held to be inappropriate and precluded. *See, e.g,, A.W. v. I.B. Corp*., 224 F.R.D. 20, 27 (D. Me. 2004) (declining to compel plaintiff to answer questions about "non-workplace, off-duty" sexual contact in hostile environment sexual harassment case); *Barta v. City and County of Honolulu*, 169 F.R.D. 132, 136 (D. Haw. 1996) (same). AZ cites three cases in support of its argument that even in sexual harassment cases where evidence of consensual sexual relations between an employee and a subordinate could have some relevance, courts exclude it as unfairly prejudicial. Doc. No. 1196 at 3. AZ cites three cases in which evidence of personal relationships was excluded, however, the facts in those cases are distinguishable from the evidence of Macfadden relationships.

In *Williams v. City of Kansas City, Mo.*, 223 F.3d 749 (8th Cir. 2000) cited by AZ, a former city employee brought claims against the city for hostile work environment and retaliation. The city appealed trial court rulings allowing evidence concerning relationships that plaintiff's supervisor had with a customer and with a coworker. First, *Williams* is distinguishable because the City challenged the evidence under a different evidence rule, Rule 404(b), barring prior act evidence which may not generally be admitted to prove conduct in conformity therewith. *Williams*, 223 F.3d at 755 (citing Fed. R. Evid. 404(b)). Second, the Eighth Circuit ruled that the inflammatory nature of the prior

affairs was outweighed by its minimal relevance since the affair with the customer was not in the workplace, and the affair with the coworker had taken place nineteen years before. *Id*. Macfadden's relationship are not so tangential or temporally remote, and are not offered to prove a propensity to engage in affairs.

The second case, *Stahl v. Sun Microsystems, Inc.*, 19 F.3d 533, 539 (10th Cir. 1994) is distinguishable where the Tenth Circuit affirmed the district court ruling excluding evidence of an affair between plaintiff's supervisor and his assistant in the trial of plaintiff's discrimination claim. The plaintiff argued that the evidence bore on the credibility of the supervisor and his assistant, both of whom testified at the trial. *Id*. The appellate court held that even assuming the evidence was relevant to the witnesses' credibility, the probative value of the affair evidence was "slight" and the potential for unfair prejudice was "obvious" and did not rise to an abuse of discretion by the trial judge. *Id.* The Tenth Circuit also held that the evidence which might have been relevant to a Title VII *quid pro quo* claim, *i.e.*, tending to show plaintiff's supervisor favored female employees who submitted to sexual advances over those who did not, plaintiff had not pled such a claim. *Id*.

The third case cited by AZ, *Monotype Corp. PLC v. International Typeface Corp*., 43 F.3d 443 (9th Cir. 1994), is not on point whatsoever. In *Monotype Corp*., the Ninth Circuit affirmed the trial court's exclusion of an email containing a derogatory term because of the prejudicial nature of the email from the "highly derogatory and offensive description" of one of plaintiff's employees, which outweighed any relevancy to plaintiff's claims of copying in breach of a typeface licensing agreement. The appellate court affirmed exclusion of the email – which defendant had argued should be admitted as a business record – based on the prejudicial nature of the derogatory remarks. None of the cases cited by AZ persuades the Court that the Macfadden relationship evidence must be excluded pretrial.

Plaintiffs argue the cases cited by AZ are inapposite, the Macfadden relationships "affected the judgment of the persons involved which in turn compromised the information that was ultimately disseminated to physicians who are responsible for treating the mentally ill." Doc. No. 1226 at 14. Evidence of romantic relationships and affairs has been admitted where the relationship is relevant to show that the relationship existed, and the existence of the relationship explains a bias or motive underlying certain conduct. *See, e.g., United States v. Potter*, 616 F.2d 384, 387-88 (9th Cir.1979) (finding that evidence of sexual conduct was relevant to show the physician's motive and intent in failing to comply with legitimate medical practices, and lack of good faith in prescribing drugs); *United States v. Hoffman*, Case No. 06-cr-66-P-S, 2006 WL 3691487, *5 (D. Me. Dec. 12, 2006) ("past romantic relationship" between doctor and patient was relevant to show that relationship existed and physician's potential motive in issuing prescriptions to patient).

There is no question that Mcfadden had a central and high-ranking position at AZ with direct and significant responsibility for important aspects of the science behind the approved uses and marketing of Seroquel. The evidence of Macfadden's relationship with the IOP Researcher is relevant to the content and validity of certain research studies on the safety and efficacy of Seroquel. The evidence of Macfadden's relationship with the Parexel MMS is relevant to the marketing and communications to physicians of the BOLDER I and II studies, dealing with the safety and efficacy of Seroquel. While it is not clear, at this stage, the amount of weight AZ intends to place on the studies acted upon by the two women, the reliability of those studies and Mcfadden's work generally is very much at issue. Depending on the emphasis AZ gives the studies, the evidence may be highly probative of the safety and efficacy of Seroquel, and its potential probative value is not substantially outweighed by the danger of unfair prejudice.

This conclusion, being *in limine*, is by its nature subject to review at trial, based on development of evidence and issues. Trial judges considering this evidence are free to entertain objections on individual proffers as they arise.

DONE and ORDERED at Orlando, Florida, July 2, 2009.

David A. Baker

DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE

Copies furnished to:

Counsel of Record