UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

SOUTHERN DIVISION

PAUL SCHILF and CYNTHIA SCHILF, as special administrators for the ESTATE OF PETER RAYMOND SCHILF, Deceased, and PAUL SCHILF and CYNTHIA SCHILF, individually,	*	CIV 07-4015
Plaintiffs,	*	ORDER
vs.	*	
ELI LILLY AND COMPANY and QUINTILES TRANSNATIONAL CORPORATION,	*	
Defendants.	*	

Plaintiffs Paul and Cynthia Schilf ("Plaintiffs") allege that their son, Peter Schilf ("Peter"), committed suicide as a result of taking the antidepressant medication, Cymbalta, manufactured by Defendant Eli Lilly and Company ("Lilly").

Dr. Glenmullen is Plaintiffs' only expert witness on causation. On October 20, 2008, Defendants filed a Motion to Exclude the General Causation Opinion of Dr. Glenmullen, doc. 115, and briefing was completed on December 1, 2008. Defendants argue that they are entitled to summary judgment because Dr. Glenmullen's testimony on general causation is inadmissible under *Daubert* and therefore Plaintiffs cannot establish causation.[1] Defendants do no not challenge Dr. Glenmullen's qualifications. Plaintiffs submitted numerous documents in opposition to Defendants'

[1]Under South Dakota products liability law, the plaintiff must prove general causation through reliable scientific evidence, and expert testimony is required when the subject falls outside the common experience of a jury. *Burley v. Kytec Innovative Sports Equipment, Inc.*, 737 N.W.2d 397, 407-08 (S.D. 2007).

motion to exclude the general causation opinion of Dr. Glenmullen, but the Court found very little information in the documents on Cymbalta; most of the information submitted by Plaintiffs relates to Prozac.[2]

It appeared to the Court that Dr. Glenmullen relied in large part on the FDA's Public Health Advisory of October 15, 2004. Dr. Glenmullen admitted that the FDA did not review any Cymbalta data. The Court understood from the filings in this case that Dr. Glenmullen reviewed materials on antidepressants and suicide, but that he reviewed no study involving Cymbalta, referencing Cymbalta, or based on Cymbalta data, and that he was unaware of any data connecting Cymbalta to adolescent suicide. Plaintiffs did not dispute the fact that the 2004 FDA advisory was based on a study of 9 antidepressants that did not include Cymbalta. The FDA concluded that there was an increased risk of suicidality for the 9 drugs, and recommended for regulatory reasons that a warning be applied to all antidepressants. Defendants argue that the FDA's decision to place a warning on Cymbalta does not equate to a legal finding that Cymbalta causes suicide. Defendants cite *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986 (8th Cir. 2001) ("The FDA evaluates pharmaceutical drugs using a different standard than the causation standard at issue in the present case.").

Glastetter gives some support to Defendants' argument that Dr. Glenmullen's opinion that Cymbalta causes suicide in adolescents cannot be based on information that Prozac causes suicide. The Eighth Circuit in *Glastetter* affirmed the exclusion of plaintiff's expert's causation opinion that the drug Parlodel could cause strokes, in part because the opinion was based partially on studies of other drugs in the "class of medicinal substances called ergot alkaloids." Defendants contend and Plaintiffs do not dispute that Cymbalta and Prozac are made up of different compounds that work

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[2]A 19-year-old woman committed suicide during a Cymbalta clinical trial (for treatment of urinary stress incontinence, not for treatment of depression), but the FDA concluded that the suicide was not related to exposure to Cymbalta. The FDA memoranda are attached as Exhibit B to Defendant's Reply in Support of Motion for Summary Judgment on All Claims, doc. 158. Dr. Glenmullen did not rely on this information in support of his opinions that Cymbalta can cause suicide.

differently to treat depression. They were developed by Lilly and approved by the FDA at different times (Cymbalta years later), and are approved to treat different medical conditions in addition to depression.

On July 31, 2009, Defendants filed a notice of supplemental authority advising the Court of a recent *Daubert* opinion from the District of New Mexico. On August 26, 2009, Plaintiffs filed a supplemental report of Dr. Glenmullen. In that report, Dr. Glenmullen says he also relied for his opinion on the FDA's 2006 "updated analysis" which included Cymbalta data, and claims that Lilly knows this from his reports and depositions. This is the first time that Cymbalta data supporting Dr. Glenmullen's opinion was brought to the Court's attention, and it appears to the Court that adding this information may be enough to satisfy the *Daubert* criteria.

On September 8, 2009, Defendants moved to strike Dr. Glenmullen's supplemental report, arguing that it is untimely and that it contains new opinions. Plaintiffs have not yet responded to the motion to strike, and they have until September 25, 2009, to do so. The Court shall require Plaintiffs' response to include references to the record showing that Dr. Glenmullen relied on the FDA's updated analysis which included Cymbalta data, and also to explain in the alternative whether substantial justification exists for the untimely additional expert disclosure if, in fact, it is untimely as Defendants contend.

IT IS SO ORDERED.

Dated this 17th day of September, 2009.

BY THE COURT:

Lawrence L. Piersol
United States District Judge

ATTEST:
JOSEPH HAAS, CLERK

BY: _____
DEPUTY