IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DISTRICT

THE ESTATE OF JAMES MOFFETT;
TAMMY MOFFETT, Individually and
On behalf of the Wrongful Death
Beneficiaries of JAMES MOFFETT — PLAINTIFFS

VS. — CIVIL ACTION NO.: 1:03CV532GRo

SMITHKLINE BEECHAM CORPORATION
d/b/a GLAXO SMITHKLINE CORPORATION
and JOHN DOES 1 through 50 — DEFENDANTS

PLAINTIFF'S REPLY TO DEFENDANT GLAXO SMITHKLINE'S OPPOSITION TO MOTION FOR RECONSIDERATION OF JUNE 9, 2005 MEMORANDUM OPINION AND FINAL JUDGMENT

I. Introduction

Plaintiff's reply herein responds to defendant Glaxo SmithKline's ("GSK") opposition to plaintiff's motion for reconsideration of the June 9, 2005 memorandum opinion and final judgment.

II. Argument in Reply

In its opposition to plaintiff's motion for reconsideration, GSK continues to erroneously argue "specific causation" rather than the Court ordered standard of causation, that being "evidence that Paxil caused or contributed to Moffett's death." The distinction is significant. It goes to the issue of GSK's withholding Dr. Breggin's "Attachment 6" from summary judgment consideration. GSK skirts over that point in its Opposition, merely stating those 28 pages "could have been presented in response to GSK's Motion for Summary Judgment." *(GSK Response Page 6*).

Plaintiff "could have" submitted any number of evidentiary items. As pointed out in the moving papers, plaintiff responded to the "specific causation" allegation that GSK raised in its summary judgment moving papers.

GSK's rigid alternatives of "specific causation" and "general causation" do not coincide with Mississippi law. This observation is one the Court agreed with in its Memorandum Opinion. But more than labels or legal terminology, GSK's withholding of Dr. Breggin's Attachment 6 denied the Court 28 pages of background consideration Plaintiff's expert weighed in rendering his opinion on factors which he concluded "contributed to Moffett's death."

A. GSK had no response to Plaintiff's argument that GSK's omission of Dr. Breggin's report excluded 4 factors satisfying Mississippi causation law.

No rebuttal was made to plaintiff's argument that GSK's withholding of Dr. Breggin's Attachment 6 addressed symptoms that Dr. Breggin later attributed to Mr. Moffett. *(Plaintiff's Motion for Reconsideration, page 5*). GSK cannot be allowed to exclude 28 pages of Breggin reporting merely by calling them "general causation" data, and then shifting to a "specific causation" argument by leaving the evidence behind. In those pages Dr. Breggin identified 4 symptoms he later applied to James Moffett.[1] To effectively cut off the 28 pages of explanatory symptoms and data used by Dr. Breggin to explain Paxil generally, and then leave isolated the expert's subsequent commentary on Mr. Moffett's identical symptoms would be a manifest injustice. Nothing in GSK's opposition can explain why the Court would otherwise conclude: "Breggin's report clearly fails to set forth the basis and reasons for his opinions." (*Page 6 from the Memorandum Opinion*)

B. GSK's Causation Argument Against Dr. Breggin Is Inconsistent

GSK attempts to impose upon Dr. Breggin a higher standard than it imposes upon itself. In its Opposition, GSK criticized Dr. Breggin's report:

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[1]As Plaintiff's Motion for Reconsideration stated on page 5, "Anxiety, insomnia, irritability, and depression" were symptoms noted by Dr. Breggin in the omitted portion of his report, and attributed to Mr. Moffett by Dr. Breggin's review of the medical and therapy notes that were cited by date.

> "Dr. Breggin's multiple theories as to how SSRIs in general, or Paxil in particular, allegedly can induce suicidality in some patients, as expressed in his Lacuzong report, shed no light on which one of those mechanisms may have been operative in Mr. Moffett's case." *(GSK Opposition page 5*)

While plaintiff rightfully bears the burden of proof, plaintiff bears no burden beyond that of presenting "evidence that Paxil caused or contributed to Moffett's death." GSK contention that plaintiff owes more detail, such as specific theories or sub-theories of "mechanisms" causing suicidality, has no legal basis.[2] Certainly GSK cites no authority for such a high standard. The contention illustrates GSK's disingenuousness, one might say hypocrisy, in holding that Dr. Breggin is responsible in an expert's report for answers that GSK has refused for the past 20 years to itself investigate. This discrepancy is directly in play as the Court assumes the gatekeeper role in weighing and controlling scientific evidence under *Daubert v Merrill Dow Pharmaceuticals, Inc.* (1993) 509 U.S. 579). On all such scientific questions, the Court must weigh the relative merits of plaintiff's scientific experts versus defendant's in critical arenas. The fact that Dr. Breggin (and Dr. Healy) have been a decade ahead of GSK and the pharmaceutical lobby in identifying and warning about the antidepressant suicide risk–Paxil included–is a strong factor militating for the Court's favorable view of Dr. Breggin's evidence–as opposed to GSK's evidence.[3] Dr. Breggin in essence presents

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[2]No thanks to GSK and other antidepressant manufacturers, independent researchers have identified, among others, three (3) possible conditions caused by antidepressants that could cause suicide: a "stimulant continuum," combined state of stimulation and depression–an agitated depression, obsessive preoccupations with aggression against self or others, akathisia, mania. (*E.g. Breggin declaration 6/22/05 Appendix B*). Further,theories of: akathisia, (b) emotional blunting, and (c) psychotic decompensation. (*E.g. Healy expert report, GSK Summary Judgment moving papers, pages 27 and 28*).

[3]From September 20, 1991, when the FDA initially insisted there was no scientific evidence linking antidepressants to suicide, until March 22, 2004, when the federal agency ordered GSK to warn of suicide for Paxil, nearly 13 years elapsed. Dr. Breggin spoke out on the suicide risk early, pubishing (continued...)

a "but for" causation argument that but for Paxil, Mr. Moffett would not have committed suicide. Causation opinion evidence is as much relevant to this issue as other factors in the antidepressant suicide controversy. Dr. Breggin has not come around to the FDA and GSK's thinking on the subject. They have come around to his. This is not inconsequential where the Court is asked to evaluate Dr. Breggin's background information in coming to the conclusion he did on Mr. Moffett's suicide. GSK has no credibility in pointing out flaws against the expert who exposed an entire industry on the antidepressant front. On the contrary, GSK should be made to explain at trial why "they" have been to last to come to the grips with the reality of antidepressant induced suicide.[4]

There is another large issue. More than the mere questionable evidentiary positions, GSK has adopted, a strategy to ensure Paxil's suicide traits are not uncovered. There is a void of scientific data on the subject of antidepressants and suicide, because GSK has refused to test the suicide hypothesis over all these years.

There is no debate on this. GSK psychiatrist and Vice President for Regulatory Affairs David Wheadon, had to, and did, answer "no' to all the questions put to him on the subject. Dr. Wheadon testified in 2001 in a U.S. district court action that GSK has never done a prospective study "to specifically measure the potential relationship between...(Paxil)...and suicidal ideation as a

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[3](...continued)
"Prozac, Suicide and Violence (et al)" in 1992 and "Talking Back to Prozac" in 1994, and continuing overall with 19 books on the subject. (e.g. "Bigography" under Breggin Expert Report). (Note: Plaintiff's other suicide expert, Dr. Healy likewise spoke out against industry's position throughout the 1990's that antidepressants were totally safe, writing in 1997 "*The Antidepressant Era" and in 2000 "*Antidepressant Induced Suicidality". (e.g. pages 25 and 28, D. Healy Expert Report submitted by defendant in Summary Judgment moving papers).

[4]GSK did not voluntarily add the suicide warning to Paxil. The FDA issued its March 22, 2004, suicide warning for Paxil (and other antidepressants). It took GSK a month before it acquiesced to what amounted to an FDA ultimatum, and agreed to the label change in April, 2004.

primary outcome" or "ever done a large-scale epidemiological study focusing on that." (See Exhibit B, *Farber Declaration, Appendix C attached thereto, page 1954*). In the most noteworthy regulatory meeting of its kind since 1991 on antidepressants, the FDA, on February 2, 2004, authorized its own consultant, Dr. David Shaffer of Columbia University, to instruct the public that "There have been no direct studies–with frequent and careful measurements–examining whether SSRI's increase, decrease or have no effect on suicidal ideation and behavior." (*Ibid Appendix B*).

When asked in this action in discovery why it had failed to do such testing, GSK responded

> "GSK believes that it is neither ethically nor methodologically possible to design and conduct a scientifically reliable clinical study that would yield a greater scientific understanding between Paxil and suicide than now exists." *(Ibid Appendix A, page "9" under "Response to Interrogatory 40.")*

This is not a trivial matter. Lives are at stake, perhaps thousands. In this motion the Court is not asked to choose between competing scientific theories. The Court is asked to render a judgment on whether Dr. Breggin's initial expert's report is sufficient to overcome GSK's charge–essentially–that the Breggin report is insufficient to place Mr. Moffett's suicide in issue as to whether Paxil caused "or contributed" to that death. Dr. Breggin's track record, and GSK's own policy of forestalling scientific research on the subject should weigh heavily in the Court's decision to respect Dr. Breggin's status and his contentions on what he medically asserted. This commentary, obviously, is in addition to those specific passages Plaintiff referred to when noting Dr. Breggin's specific references to Mr. Moffett's medical and therapy entries leading to his conclusion on causality.

C. GSK's Causation Position Is Further Undercut by New Evidence Available on June 30, 2005 from the Food & Drug Administration.

In addition to the manifest injustice standard Plaintiff argued in her moving papers for reconsideration, on June 30, 2005 the Food & Drug Administration ("FDA") issued a new public advisory on Paxil's association with adult suicide. The FDA advisory, attached as Appendix D to the accompanying declaration of Donald J. Farber, and for which judicial notice is requested, highlights GSK's misleading position regarding causation and antidepressant suicides.

The FDA states that adults being treated with antidepressant medications, particularly those being treated for depression, should be watched closely for worsening of depression and for increased suicidal thinking or behavior. Close watching may be especially important early in treatment. (*Farber Declaration, Appendix D*). Paxil was specifically tabbed by the FDA as one of the suspect antidepressants. (*Ibid, Appendix F*).

It could not be clearer that this new evidence and regulatory finding applies to Dr. Breggin's finding on Mr. Moffett. The Breggin report emphasized Mr. Moffett's increasing anger and irritability after three (3) days on Paxil, along with "poor appetite, trouble sleeping, and depressed mood along with the anger." (*Breggin Expert Report, page 1*). Dr. Breggin further reported Mr. Moffett's diagnosis by Dr. Barrett as "depression and anxiety" on the last visit to his physician, eighteen (18) days after starting Paxil. (Ibid) Mr. Moffett killed himself only 58 days after starting Paxil. This FDA public health advisory issued while this Motion for Reconsideration was pending is thus highly relevant evidence that adds considerably weight to Dr. Breggin's observations contained in his report.

D. GSK's Opposition to Plaintiff's 'Motion to Compel" Argument Lacks a Critical Component.

GSK's argument that it was not required to compel an "essential element" missing from Plaintiff's expert report is a valid point were causation the only issue the defendant raised in Summary Judgment. But that was not the case. From the outset, GSK bootstrapped the Rule 26 requirement onto the causation issue. As plaintiff pointed out in this motion, those are two distinct issues, not one. This is an important distinction because GSK, refusing to confront the sentence that plaintiff contended was Dr. Breggin's statement on "specific causation," diverted to the argument that Dr. Breggin's expert report was incomplete and inadequate. GSK's lead in reply to Plaintiff's Opposition to Summary Judgment was stated as "Dr. Breggin's Sentence Is Not a 'Detailed and Complete' Expert Report." *(GSK Reply dated 11/29/04 to Plaintiff's Opposition to Summary Judgment, page 4*). Notwithstanding that Plaintiff takes issue with the finding on the legal significance of the "sentence," it nonetheless is apparent on its face that GSK expanded the motion into the overall adequacy of Dr. Breggin's report. As Plaintiff pointed out elsewhere, and is a point we will not repeat, a large segment for Dr. Breggin's background of that "sentence" was omitted both from GSK's moving papers and the Court's Memorandum Opinion.

Now GSK, in effect, has totally reversed itself. The defendant is saying in its Opposition by quoting from the "Advisory Committee" that the Rule 37 provision in question concerns only sanctions for a party trying to admit at trial what it did not disclose in the expert's report. (*GSK Opposition to Motion for Reconsideration page 8*, e.g. "self executing sanction for failure to make a disclosure" etc.) It is clear GSK has merged two distinct and dissimilar concepts into one argument. That is, somehow in combination, these two concepts show that Dr. Breggin is

disqualified from testifying at trial that but for Paxil, Mr. Moffett would be alive today. GSK ends its defense on that point by again reverting to the "specific causation" reference. Plaintiff, again, requests the Court to consider Dr. Breggin's evidence in the total context of "evidence that Paxil caused or contributed to Moffett's death."

E. Plaintiffs Are Not Prohibited from Offering "New" Evidence in Support of a Motion to Reconsider.

The Defendant insists that all of the evidence offered in support of the Plaintiffs' Motion to Reconsider should be disregarded or even struck, because it was available to them at the time GSK filed its Motion for Summary Judgment. That is true for some exhibits. Other evidence, including the June 30, 2005 FDA Notice referenced above certainly was not available.

However, regardless of whether any evidence was or was not available in November 2004, the Fifth Circuit permits consideration of such evidence without any showing of excusable neglect or even inadvertence. Ford v. Elsbury, 32 F.3d 931, 937 (5th Cir. 1994), citing, Lavespere v. Niagra Mach. & Tool Works, Inc., 910 F.2d 167, 174 (5th Cir. 1990). "Because Rule 59(e) is not subject to the limitations of Rule 60(b), the district court has considerable discretion in deciding whether to reopen a case in response to a motion for reconsideration arising under the former rule." Lavespere at 174. In exercising this broad discretion and striking the proper balance when presented with new evidence, the court should consider, among other things, "(1) the reasons for the plaintiffs' default, (2) the importance of the evidence to the plaintiffs' case, (3) whether the evidence was available to plaintiffs [prior to the entry of judgment], and (4) the likelihood that the defendants will suffer unfair prejudice if the case is reopened." Texas A&M Research Foundation, v. Magna Transportation, Inc.,338 F.3d 394, 400-401, *quoting*, Ford at 937-38.

As to the first factor, primary responsibility must be borne by GSK. GSK failed to attach all of Dr. Breggin's report, as represented in their Motion. The Plaintiffs reasonably relied upon the Defendant's representation that the entire report had been provided to the Court. At the same time, GSK offered a flawed legal argument ("general" vs. "specific" causation), which focused the plaintiff more on arguing the law, than offering any particular facts to support "specific" causation.

Regarding the second factor, the Plaintiffs' evidence is crucial to the case, if for no other reason to clarify and reinforce Dr. Breggin's opinions but for GSK's conduct regarding Paxil, Mr. Moffett would be alive today. As indicated in their Motion, the Plaintiffs respectfully would show the Court that sufficient evidence has been proffered regarding proximate cause, thereby creating a genuine issue of material fact.

Addressing the third factor, some of the evidence offered by the Plaintiffs was available before this Court entered its judgment. However, the Fifth Circuit has held that when deciding a Motion to Reconsider, the Court must consider the record as it exists at the time the Motion is filed, and not as the record existed at the time of the initial ruling. Zerox Corp. v. Genmoora Corp., 888 F.2d 345, 349 (5th Cir. 1989). All of the evidence offered by the Plaintiffs, with the exception of Dr. Breggin's and Mr. Farber's declarations filed in support of this Motion, have been in the possession of the Defendant for some time.

Regarding the final factor, there can be no unfair prejudice to the Defendants if this Court were to consider this "new evidence" and set aside its Judgment. Prior to the entry of summary judgment, the parties had been engaged in vigorous discovery efforts. The Defendants had only recently noticed a number of persons for deposition (by the way, without any discussion beforehand with Plaintiffs' counsel). Finally there can be no prejudice to a Defendant who pressed faulty legal arguments in their Motion for Summary Judgment, while offering only parts of the Plaintiff's expert

report, and all the while bypassing this Court's Local Rules and the Federal Rules of Civil Procedure requirements that parties "meet and confer," exchange "good-faith" certificates, and file motions to compel, when expert reports are deemed insufficient.

F. The Absence of Oral Argument is a Factor Plaintiff Requests the Court To Consider.

As this Motion for Reconsideration is considered, plaintiff requests the Court consider that the matters in antidepressant suicide are so complicated–that even the FDA has not been able to grasp the significance of the technical issues of causation the last 14 years. (supra). Moreover, the science is evolving as we speak, as evidenced by the FDA health advisory on June 30, 2005. For the harsh result of a Summary Judgment on such a complex technical matter, the Court is asked to reconsider the ruling in light of the lack of opportunity for the Court to have heard an oral argument on the subject.

III. Conclusion

The Court should grant the Motion for Reconsideration based on the manifest injustice that would result from the harsh Summary Judgment ruling following Defendant's withholding of Dr. Breggin's 28 pages of justification in Attachment 6 to his report. Contrary to GSK's main theme, it is not "specific causation" that is the sole issue, but rather under Mississippi law evidence showing Paxil "contributed to" the decedent's death has equal status for finding causation. Additionally, the FDA's June 30, 2005 public health advisory is "new evidence" coming to light since the original Summary Judgment ruling that adds considerable weight to Dr. Breggin's opinions that Paxil was responsible for the adult suicide in question.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, JOE R. COLINGO, do hereby certify that I electronically filed the foregoing with the Clerk of the Court using the ECF system which also electronically served same upon:

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SO CERTIFIED, this the 14th day of July 2005.

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