IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

In re: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	MDL No. 1871
THIS DOCUMENT RELATES TO:	:	Case No. 2:07-cv-05360-CMR
DEBORAH A. BURFORD, et al., Plaintiffs, v. SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, Defendant.	:	

PRETRIAL MEMORANDUM OF DEFENDANT GLAXOSMITHKLINE LLC

Defendant GlaxoSmithKline LLC ("GSK")[1] submits this pretrial memorandum pursuant to Pretrial Order No. 124 and Local Rule of Civil Procedure 16.1(c).

I. STATEMENT OF THE CASE

A. Failure to Warn Claim

This is a failure to warn case involving Avandia, a prescription diabetes medication manufactured by GSK. Plaintiffs claim that James Burford, a Type 2 diabetic with long-standing, serious health problems, suffered a fatal heart attack because he ingested Avandia. The proofs at trial will show that plaintiffs' claim fails because they cannot establish proximate cause under North Carolina law and because the Avandia warning met the state of art at the

[1] On October 27, 2009, SmithKline Beecham Corporation re-domiciled from Pennsylvania to Delaware, converted into a limited liability company and changed its name to GlaxoSmithKline LLC.

relevant time.[2]

North Carolina General Statute 99B-5, which governs failure to warn claims, provides that plaintiffs must demonstrate that GSK acted unreasonably in failing to provide an adequate warning to Mr. Burford's prescribing physician concerning Avandia and that the failure to provide an adequate warning was a "but for" cause of Mr. Burford's death.[3] Plaintiffs must also show that without an adequate warning or instruction, Avandia created an unreasonably dangerous condition that GSK knew or should have known posed a substantial risk of harm to the plaintiff.[4]

As this Court recognized, North Carolina uses the "but for" standard for proximate causation.[5] The North Carolina Supreme Court defines proximate cause as "[t]he cause producing the injurious result [which] must be in a continuous sequence, without which the injury would not have occurred, and one from which any person of ordinary prudence would have foreseen the likelihood of the result under the circumstances as they existed."[6] There are two prongs to the causation analysis under North Carolina law. First, plaintiffs must establish that Avandia was a "but for" cause of Mr. Burford's heart attack (causation in fact).[7] Second,

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[2] The parties agree that North Carolina law applies to plaintiffs' claims.

[3] N.C. Gen. Stat. § 99B-5 (2010).

[4] *Id.*

[5] 1/14/2011 Opinion (Doc. No. 947) at 3, fn. 5. Plaintiffs may continue to argue that North Carolina employs a "substantial factor" test for proximate causation, but this is clearly not the standard.

[6] *Goodman v. Wenco Foods, Inc.*, 423 S.E.2d 444, 333 N.C. 1, 18 (1992); *Gibson v. Ussery*, 675 S.E.2d 666, 668 (N.C. Ct. App. 2009).

[7] *Carroll v. Litton Sys.*, No. B-C-88-253, 1990 U.S. Dist. LEXIS 16833, at *132-133 (W.D.N.C. Oct. 29, 1990), *aff'd in part, rev'd in part on other grounds*, No. 94-cv-3036, 1995 U.S. App. LEXIS 2015 (4th Cir. Feb. 1, 1995) (holding that under North Carolina law, "plaintiff bears the burden of proving that a defendant actually caused his injuries" and that plaintiffs had to prove that "but for their alleged exposures, they would not have developed their specific illnesses or complaints") (citing North Carolina cases).

plaintiffs must prove that a different warning would have altered the prescribing doctor's conduct and produced a different result.[8] Plaintiffs cannot satisfy either proximate cause element.

Specific causation, as addressed at the hearing on January 4, 2011, is at the heart of the cause-in-fact element of plaintiffs' burden in this case. GSK has requested that the Court reconsider its motion to exclude the testimony of Dr. Nicholas DePace, or in the alternative, that the Court hold a hearing pursuant to Federal Rule of Evidence 104(a) with an advisory jury regarding the admissibility of Dr. DePace's testimony.

B. Plaintiffs' Other Claims

This is a failure to warn case, and that is the cause of action that should be tried. Plaintiffs have asserted a "design defect" claim under North Carolina law, but they have no expert or other proofs that Avandia, as a chemical entity, was improperly "designed" or "formulated." This claim is subject to a pending motion for summary judgment.[9]

Plaintiffs also pled various warranty causes of action. These claims are the subject of a pending motion for summary judgment,[10] but it should be noted that they all fail because, among other things, (a) GSK never made any representations of fact to Mr. Burford, much less any that became the basis of a purchase transaction and (b) having received no such representations, Mr. Burford could not have relied upon them.

Plaintiffs also allege claims of intentional and negligent infliction of emotional

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[8] *See Wehling v. Sandoz Pharms. Corp.*, No. 97-2212, 1998 U.S. App. LEXIS 38866, at *12 (4th Cir. Aug. 20, 1998) (applying North Carolina law) (stating that the evidence must show "at least some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug" and the plaintiffs would not have been injured).

[9] *See* GSK's Reply in Supp. of Mot. for Summ. J. at 8-9 (Doc. No. 27).

[10] *See* GSK's Mem. in Supp. of Mot. for Summ. J. at 13 (Doc. No. 18).

distress. With respect to the intentional infliction of emotional distress claim, because GSK had no direct contact with the Burfords, nor even knew of them, there can never be a showing that GSK acted towards them in an "intentional" manner.[11] Further, plaintiffs did not witness Mr. Burford's alleged heart attack, thus foreclosing their negligent infliction of emotional distress claim. GSK moved for summary judgment on these claims.[12]

Plaintiffs also bring a claim under the North Carolina Unfair and Deceptive Trade Practices Act ("UDTPA"). Assuming this cause of action is available in a case premised on a failure to warn,[13] the disposition of this claim should be reserved for the punitive damages phase, if any, because the determination of whether an act violates the statute is a matter for the judge, not the jury, to decide.[14] To the extent that plaintiffs suggest the UDTPA claim permits introduction of proof of GSK's communications with and conduct involving physicians other than Dr. Spencer, plaintiffs are misreading the law. The UDTPA requires that the plaintiff suffer actual injury as a proximate result of the defendant's conduct.[15] GSK's conduct not directed to Mr. Burford's prescribing physician could not have played a role in his heart attack. Further, plaintiffs must elect their remedy – they cannot obtain both treble damages under the Act and

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[11] It is for the Court, not the jury, to decide in the first instance whether GSK engaged in extreme and outrageous conduct. *Lenins v. K-Mart Corporation*, 391 S.E.2d 843, 848 (N.C. Ct. App. 1990); *Murray v. Justice*, 385 S.E.2d 195 (N.C. Ct. App. 1989); *Johnson v. Bollinger*, 356 S.E.2d 378 (N.C. Ct. App. 1987).

[12] *See* GSK's Mem. in Supp. of Mot. for Summ. J. at 8-13 (Doc. No. 18).

[13] *See Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643, 645 (W.D.N.C. 2010) (holding that "[w]hile the plaintiff's claims [including UDTPA claim] are masked in various legal theories, they are premised on a single claim of product liability" and should be brought under the North Carolina Products Liability Act).

[14] *S. Atl. P'Ship of Tenn. v. Reise*, 284 F.3d 518, 534 (4th Cir. 2004) (citing, *inter alia*, *Gray v. N.C. Ins. Underwriting Ass'n*, 539 S.E.2d 676, 681 (N.C. 2000)).

[15] *Ellis v. Northern Star Co.*, 388 S.E.2d 127, 131 (N.C. 1990).

punitive damages.[16] Finally, the Court – not the jury – must determine whether GSK engaged in unfair or deceptive acts.[17] For these reasons, consideration of plaintiffs' UDTPA claim, if any, should be presented in a separate phase.

II. COUNTERSTATEMENT OF FACTS

On November 21, 2006, Mr. Burford suffered a fatal cardiac injury. Plaintiffs claim that this injury was caused by Avandia, a diabetes medication Mr. Burford took for 15 months starting in August 2005. Dr. James Spencer, Mr. Burford's primary care physician, diagnosed him with Type 2 diabetes on June 21, 2004 at the age of 47. Mr. Burford was first prescribed metformin in an attempt to control his rising blood glucose levels. Despite increasing the dosage of metformin, Dr. Spencer was unable to adequately control Mr. Burford's blood sugar levels prompting him to add Avandia 4 mg to Mr. Burford's treatment regimen on August 22, 2005. This dosage was increased to 8 mg by December 2005. Mr. Burford continued to struggle with his blood glucose levels, and was prescribed Amaryl, a sulfonylurea, on October 12, 2006. Mr. Burford took these three diabetes medications until his death on November 21, 2006.

The proofs will show that Mr. Burford died of conditions unrelated to Avandia. Mr. Burford's autopsy revealed that his cause of death was hypertensive atherosclerotic disease. Plaintiffs' experts all agree that Avandia does not cause hypertension or atherosclerosis, and further agree that it had no impact on Mr. Burford's cholesterol levels. Despite this, plaintiffs contend that Mr. Burford's heart attack was caused by Avandia.

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[16] *See United Labs. v. Kuykendall*, 437 S.E.2d 374, 379 (N.C. 1993) ("[A] party may not recover punitive damages for tortious conduct and treble damages for a violation of [UDPTA] based on that same conduct.") (internal citations omitted).

[17] *S. Atl. P'Ship of Tenn. v. Reise*, 284 F.3d 518, 534 (4th Cir. 2004) (citing, *inter alia*, *Gray v. N.C. Ins. Underwriting Ass'n*, 539 S.E.2d 676, 681 (N.C. 2000).

Prior to taking Avandia, Mr. Burford had multiple medical conditions that were directly linked to his death. First, Mr. Burford had Type 2 diabetes, which itself is a cardiovascular risk factor that places patients at increased risk for a number of micro- and macrovascular complications. Dr. Spencer testified that "[i]t's been estimated that 65 percent of the [diabetic] patients will eventually die of cardiovascular disease."[18]

Second, Mr. Burford suffered from high cholesterol, a condition diagnosed as early as May 1994 in connection with his application for a life insurance policy. Mr. Burford was refused a "preferred status" policy as a result of being diagnosed with high cholesterol and triglycerides. In November 1999, Mr. Burford participated in a study involving a nutrient-supplemented medical food - "Heartbars" - designed to improve endothelial function in individuals with high cholesterol. The informed consent form Mr. Burford received and signed upon enrollment in this study advised: "You have been told that your cholesterol levels are too high. Research studies show that when arteries are stiff or clogged with cholesterol deposits, they will not function properly. This increases your chance of having a heart attack or stroke. This situation is particularly dangerous if your cholesterol is already high." At the time he entered the study, Mr. Burford's LDL cholesterol (so-called "bad cholesterol") and total cholesterol levels were above normal. He was prescribed a statin (Lipitor) to control his cholesterol levels in 2000, which he took until the time of his death. Despite use of this medication, Mr. Burford's cholesterol levels were elevated prior to and during the time he took Avandia.

Third, Mr. Burford suffered from obesity and struggled with his weight since at least 1991, when he weighed 226 pounds (at 6'0" tall, this yields a BMI of 30.6, which is

[18] J. Spencer Dep. 63:23-24, Sept. 23, 2009.

clinically obese). Although Dr. Spencer made repeated efforts to encourage Mr. Burford to lose weight and better manage his diet, Mr. Burford continued to disregard Dr. Spencer's advice.

Fourth, Mr. Burford also suffered vascular problems evidenced by erectile dysfunction for which he took several medications.

Fifth, Mr. Burford had hypertension. All of these conditions contributed to Mr. Burford's heart attack.

No one witnessed Mr. Burford's fatal cardiac injury on November 21, 2006. He was alone in his house. Plaintiff Deborah Burford testified that she found her husband nonresponsive on the sofa with his eyes partially open and lips blue. The emergency medical service ("EMS") arrived minutes later and observed that Mr. Burford was without a pulse and not breathing.[19] After Mr. Burford was pronounced dead and his body was covered with a sheet, his son, Michael Burford, arrived home from school and was told that his father had died. An autopsy was performed, which reported that Mr. Burford suffered a heart attack as a result of hypertensive atherosclerotic cardiovascular disease.

III. GSK'S WITNESS LIST

A copy of GSK's list of witnesses to be presented at trial is attached hereto as Exhibit A. GSK requests a directive from the Court that each side provide 48 hours notice prior to calling any witness at trial, whether live or by deposition designation.

The parties were directed to use best efforts to meet and confer about objections to witnesses prior to the Court's final Pretrial Conference on January 18, 2011. But despite GSK's multiple requests that plaintiffs identify which witnesses they intend to call live at trial or

[19] There is no proof that Mr. Burford suffered any conscious pain and suffering from the time of his heart attack until his death. Accordingly, no claim for Mr. Burford's pain and suffering should go to the jury.

through deposition designation, plaintiffs failed to do so. GSK was therefore forced to seek a ruling from Special Master Shestack to obtain this information, which was issued on January 12, 2011. Plaintiffs provided GSK with this information this evening and, in many instances, indicated that they intended to call the witness "live/tape." Thus, plaintiffs have failed to comply with the Special Master's order and it is still unclear whether plaintiffs intend to call these witnesses live or by deposition designation.[20] Plaintiffs' delay in providing this information has hampered GSK's ability to evaluate plaintiffs' witness list and confer with plaintiffs regarding objections.

IV. GSK'S EXHIBIT LIST

A copy of GSK's exhibit list is attached hereto as Exhibit B. Plaintiffs provided an exhibit list on January 7, 2011, but – without permission from the Court or agreement with GSK - served a supplemental list today. GSK objects to plaintiffs' supplemental exhibit list, and submits that this will further impede GSK's ability to meet and confer concerning authentication and admissibility of exhibits prior to the final Pretrial Conference on January 18, 2011. Additionally, GSK requested copies of plaintiffs' exhibits, but only received a set that appears to be incomplete this afternoon.[21] This will further delay the parties meet and confer efforts.

V. GSK'S DEPOSITION DESIGNATIONS

The parties were directed to use best efforts to meet and confer about objections

[20] In addition, as an express condition of obtaining the depositions of Professors Philip Home and Stuart Pocock in the United Kingdom, plaintiffs' counsel (Mr. Zonies) represented to the English court that plaintiffs in this case would submit these depositions, in their entirety, in their case in chief. Because the testimony ultimately obtained directly contradicts their position in this case, they have reversed their position, and have not included these individuals on their witness list or designated any of their testimony. Because plaintiffs used the auspices of this Court to obtain this testimony, plaintiffs should be required to honor their representations.

[21] As of the date of this submission, despite repeated requests and assurances from plaintiffs, GSK still has not received all of plaintiffs' exhibits.

to deposition designations prior to the Court's final Pretrial Conference on January 18, 2011. Although plaintiffs represented to the Court in a letter dated December 15, 2010 that they would provide deposition designations on January 7, 2011, they failed to do so. Thus, GSK was forced to seek a ruling from Special Master Shestack, which was issued on January 12, 2011. Pursuant to the Special Master's ruling, plaintiffs were to provide GSK with this information by 5:00 pm yesterday, Thursday, January 13, 2011. But plaintiffs failed to comply with the Special Master's ruling, as they are still sending their deposition designations as of the date of this submission. This delay has hampered GSK's ability to provide its own deposition designations and to discuss any objections with the plaintiffs. Further, based on GSK's preliminary review, many of the plaintiffs' deposition designations relate to extraneous and irrelevant information that have nothing to do with Mr. Burford and fail to comply with the Court's directive that this trial be very precise and focus on issues relevant to this case.[22]

VI. TIME REQUIRED FOR TRIAL

Pursuant to Pretrial Order 124, the Court has allotted two weeks for this trial. Despite this directive, plaintiffs have indicated that they need six trial days. Given plaintiffs' lengthy witness list and voluminous deposition designations, and their stated intention of calling many witnesses live and by deposition designation (to testify about irrelevant issues), it is inconceivable that plaintiffs could complete their case in six days. GSK requests that the court divide the trial time equally between the parties for opening statements, examination and cross-examination of witnesses, and closing statements.

VII. STATEMENT OF DAMAGES

GSK is seeking no damages in this action. GSK will be prepared to challenge

[22] Jan. 4, 2011 Hrg. Tr. at 218:13-14.

plaintiffs' damages computation at trial.

VIII. PROPOSED JURY INSTRUCTIONS

GSK's proposed jury instructions are attached hereto as Exhibit C. Given the Court's ruling on bifurcation of this trial, instructions related to punitive damages are not included in the attached proposed jury instructions. Additionally, instructions related to plaintiffs' claim brought under the UDTPA are not included in the attached proposed jury instructions. Under North Carolina law, the Court must make a ruling that would dictate the language of this charge. Thus, GSK respectfully requests that these instructions be submitted at such time, if any, as they become relevant.

IX. PROPOSED VOIR DIRE AND JURY QUESTIONNAIRE

GSK's proposed voir dire is attached hereto as Exhibit D. GSK also requests that the Court present the jury with a jury questionnaire, which GSK will provide the Court at the final Pretrial Conference. A jury questionnaire is warranted here because the parties will seek personal medical information from prospective jurors, which they should not have to disclose in open court. A questionnaire will also facilitate a more efficient voir dire process. Further, GSK and Avandia have been the subject of recent, widespread media coverage and lawyer advertising. Asking prospective jurors to respond to questions in open court regarding their awareness of or exposure to such coverage presents the risk of tainting the entire panel.

Accordingly, because of this publicity, GSK will request that the Court provide preliminary instructions to the jury to refrain from doing any type of internet or other research about the parties and issues, and to advise the Court if they have seen or read any television, newspaper, or other media regarding GSK or Avandia.

In addition, because this is the first bellwether trial, and involves complex factual issues that will likely necessitate a lengthy trial and deliberations period, GSK will ask the Court,

by separate motion, to impanel a twelve-person jury pursuant to Local Rule 48.1.

X. PROPOSED JURY INTERROGATORIES

GSK's proposed jury interrogatories are attached hereto as Exhibit E. A supplemental set of jury interrogatories is attached hereto as Exhibit F, and contains interrogatories addressing several additional causes of action brought by plaintiffs. GSK asserts that these additional claims should not be before a jury, but includes supplemental interrogatories should the Court hold otherwise.

XI. STIPULATIONS OF COUNSEL

The parties have agreed that North Carolina law applies to this action, as plaintiffs reside in North Carolina, and decedent purchased and consumed Avandia within North Carolina. The parties will discuss proposed stipulations prior to the January 18, 2011 final Pretrial Conference, and anticipate being able to stipulate as to authenticity of certain exhibits.

XII. EVIDENTIARY OBJECTIONS AND PENDING MOTIONS

On January 4, 2011, the Court held a hearing on several pending *Daubert* motions and motions *in limine* pertaining to the *Burford* case. As of the date of this submission, the following motions have not been ruled on.

- Motion for Reconsideration of GSK's Motion to Exclude the Testimony of Plaintiffs' Specific Causation Expert Nicholas L. DePace, M.D. or in the Alternative, to Hold a Hearing Pursuant to Fed. R. Evid. 104(a) with an Advisory Jury
- Motion to Exclude Proffered Opinions of Suzanne Parisian, M.D.
- Omnibus Motion for Summary Judgment with Respect to Plaintiffs who Developed Congestive Heart Failure and Used Avandia after February 2001[23]

[23] Plaintiffs' response to GSK's motion is due February 28, 2011, but GSK requests that the Court accelerate plaintiffs' response date should they contend that Mr. Burford developed congestive heart failure as a result of taking Avandia.

- Motion *in Limine* to Exclude Evidence of Avandia's Claimed Effect on LDL, ApoB, or Lp-PLA2 or Regarding the Experimental Drug Darapladib
- Motion *in Limine* to Exclude References to, and Evidence of, Conduct by GlaxoSmithKline Occurring After November 21, 2006
- Motion *in Limine* to Exclude References to, and Evidence of, Regulatory Developments After November 21, 2006
- Motion *in Limine* To Exclude Evidence of or Reference to Congressional Committee Reports and Related Materials
- Motion *in Limine* to Exclude Evidence of "Untitled Letters" and Warning Letters Received from the FDA's Division of Drug Marketing, Advertising and Communications
- Motion *in Limine* to Exclude References to, and Evidence of, Foreign Regulatory Action
- Motion *in Limine* to Exclude Evidence of or References to "Ghostwriting"
- Motion *in Limine* to Exclude Evidence of Marketing and Promotional Materials Not Identified as Having Been Seen by James Burford's Prescribing Physician
- Motion *in Limine* to Exclude References to, and Evidence of, Media Reports and Related Evidence
- Motion *in Limine* to Exclude Evidence Relating to Injuries Not Sustained by Plaintiff Decedent
- Motion *in Limine* to Exclude Evidence Relating to Other Claims, Litigation and Investigations
- Motion to Exclude Mayer-Davis, Gavin, Gotto and any opinions based upon "tertile" charts for ADOPT and ICT-42
- Motion to Exclude witnesses from relying on the "RECORD" study
- Motion to Exclude Proffered Opinions of John L. Gueriguian, M.D.[24]
- Motion to Exclude Proffered Opinions of Peter Rost, M.D.[25]

[24] As Dr. Gueriguian is not included on plaintiffs' witness list, this motion can be deferred.

[25] As Dr. Rost is not included on plaintiffs' witness list, this motion can be deferred.

XIII. ANTICIPATED LEGAL ISSUES

Many of the legal issues in this case were presented in the parties' motions *in limine* and GSK's motion for partial summary judgment or have been addressed elsewhere in this pretrial memorandum. The pending motions, which GSK anticipates will be decided prior to trial, are listed in Section XII. Some anticipated legal issues are addressed below.

A. Evidence Unrelated to Mr. Burford's Experience with Avandia and Specific Injuries Alleged is Inadmissible

In an effort to introduce evidence unrelated to this case, plaintiffs claim that this lawsuit is "not limited to Jim Burford and/or his physician," or the specific injuries he suffered. (Pl.'s Pretrial Memo at 9). Indeed, based on the plaintiffs' pretrial memorandum, the majority of plaintiffs' evidence has nothing to do with whether Avandia caused Mr. Burford's heart attack. Rather, plaintiffs assert that this case is about what GSK should have told the public generally about any potential risks associated with Avandia that GSK knew or should have known about. This approach is fundamentally flawed and inconsistent with North Carolina law. This case is not about a hypothetical plaintiff having hypothetical injuries. This case must be based on what injuries Mr. Burford suffered and what information GSK did or did not disclose to his prescribing physician, Dr. Spencer. To bring a failure to warn claim under North Carolina law, plaintiffs must demonstrate that GSK acted unreasonably in failing to provide an adequate warning to Mr. Burford's prescribing physician concerning Avandia and that the failure to provide an adequate warning was a proximate cause of Mr. Burford's death.[26] By statute, plaintiffs must prove that any allegedly inadequate warning proximately caused the "harm for

[26] N.C. Gen. Stat. § 99B-5.

which damages are sought:" here, Mr. Burford's death.[27] In addition, plaintiffs must show that without an adequate warning or instruction, Avandia created an unreasonably dangerous condition that GSK knew (or should have known), would pose a substantial risk of harm.[28] There is no requirement that plaintiffs must show that GSK knew of and failed to inform the public about any and all risks associated with Avandia. Rather, plaintiffs must show that GSK failed to warn Dr. Spencer, and that Mr. Burford's death was caused by this failure.[29]

The clearest examples of plaintiffs' efforts to introduce improper evidence is evidence of Avandia's effect on LDL cholesterol, ApoB and Lp-PLA2. Evidence on these issues is not relevant here as there is no evidence Mr. Burford's heart attack was caused by Avandia's effect on any of these factors. Plaintiffs' own experts admit this.[30] This evidence fails to meet the threshold for relevancy under Federal Rules of Evidence 401 and 402, as such evidence will not have a tendency to make the existence of any fact of consequence to the determination of the action more probable or less probable than it would be without that evidence. Further, if introduced, this evidence would only confuse the issues in this case and cause undue delay and waste of time and should be excluded pursuant to Rule 403.

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[27] *Id.* at § 99B-5(a).

[28] *Id.*

[29] Plaintiffs claim that *Fussman v. Novartis Pharmaceuticals Corporation*, No. 1:06-cv-149, 2010 U.S. Dist. LEXIS 110721, at *8-10 (M.D.N.C. Oct. 18, 2010) stands for the proposition that North Carolina courts have found proximate cause can be established by evidence of a defendant's failure to warn "foreseeable treating medical professionals." *Id.* This case does not stand for this proposition. This case does not hold that plaintiffs can base their failure to warn claims on evidence of what GSK told physicians generally. The issue in *Fussman* is whether the duty to warn extends to plaintiff's treating physicians, not all physicians regardless of their contact with the plaintiff. *Id.* at *8 (discussing *Holley v. Burroughs Wellcome Co.*, 348 S.E.2d 772, 776-77 (N.C. 1986)). Thus, *Fussman* does not support plaintiffs' claim that evidence unrelated to Mr. Burford or his injuries is relevant here.

[30] 1/14/2011 Opinion (Doc. No. 947) at 7-8.

B. The Doctrine of Preemption Bars Plaintiffs' Failure to Warn Claims

Plaintiffs' claim that GSK should have provided a different warning regarding Avandia's association with heart attacks is preempted by operation of federal law. As will be more fully developed at trial, GSK's efforts to change the Avandia labeling regarding potential heart attack risks were rejected by the FDA during the relevant time. Consistent with *Wyeth v. Levine*, when a manufacturer is prevented by FDA from changing a prescription drug's label, state tort law claims may be preempted. This is an issue of law for the Court. GSK will present the Court with a motion based upon the record developed at trial.

Respectfully submitted,

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Dated: January 14, 2011

CERTIFICATE OF SERVICE

I, Yvonne M. McKenzie, hereby certify that on January 14, 2011 a true and correct copy of the foregoing Pretrial Memorandum of Defendant GlaxoSmithKline LLC was served via the ECF system upon the following:

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