

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: YASMIN AND YAZ (DROSPIRENONE))
MARKETING, SALES PRACTICES AND) 3:09-md-2100-DRH-
PMF PRODUCTS LIABILITY LITIGATION)
) MDL 2100

This Document Relates to:

Kerry Sims v. Bayer HealthCare Pharmaceuticals, et al.,
Case No. 3:09-cv-10012-DRH-PMF

Patti Bradish v. Bayer HealthCare Pharmaceuticals, et al.,
Case No. 3:09-cv-20021-DRH-PMF¹

Tracy Laforet-Neer v. Bayer HealthCare Pharmaceuticals, et al.,
Case No. 3:10-cv-10223-DRH-PMF²

**ORDER REGARDING THE PARTIES'
MOTIONS *IN LIMINE***

I. Introduction

This matter is before the Court for case management. The parties have filed a total of 60 motions *in limine* (Bayer has filed 39 motions *in limine*, plaintiff has filed 21 motions *in limine* – one of which contains 36 sub-parts), all of which have been fully briefed. On December 19, 2011, the Court heard oral argument

¹ Bayer's motions *in limine* numbers 5 (Doc. 115); 14 (Doc. 122); 15 (Doc. 126); 16 (Doc. 127); 18 (Doc. 133); 19 (Doc. 139); and 36 (Doc. 129) relate only to the *Sims* case. All of plaintiff's motions *in limine* relate only to the *Sims* case.

² Bayer's motions *in limine* numbers 5 (Doc. 115); 14 (Doc. 122); 15 (Doc. 126); 16 (Doc. 127); 18 (Doc. 133); 19 (Doc. 139); and 36 (Doc. 129) relate only to the *Sims* case. All of plaintiff's motions *in limine* relate only to the *Sims* case.

on select motions *in limine*. With regard to the motions argued at the December 19, 2011 hearing, the Court announced his ruling at the time of the hearing in open court. As to the remaining motions *in limine*, the parties have informed the court that a portion of the motions have been resolved by agreement of the parties, concession, or withdrawn and a portion of the motions remain in dispute. With regard to the motions that remain in dispute, the parties have waived oral argument and are resting on their pleadings.

This Order identifies and summarily describes the Court's resolution of the motions *in limine* argued at the December 19th hearing. The Court's complete ruling on these motions will be memorialized in the transcript of the December 19th evidentiary hearing. This order also identifies the motions *in limine* that have been resolved by agreement of the parties, concession, or withdrawn. As to the motions *in limine* resolved by agreement, the parties have drafted a stipulation memorializing their agreement. That stipulation is attached hereto as Exhibit A. The Court acknowledges and adopts the parties' stipulation.

Finally, this Order identifies those motions that remain in dispute and, after fully considering the arguments of the parties, the Court renders its decision on each disputed motion accordingly.

II. Analysis

A. Defendants' Motions *In Limine*

11/18/2011	 99	SEALED MOTION <i>in Limine No. 1</i> to Exclude Evidence and Argument That Bayer Provided Inadequate or Incomplete Data to the Federal Food and Drug Administration by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, the Court DENIES Bayer's Motion <i>in Limine</i> No. 1.</p> <p>Bayer moves <i>in limine</i> to exclude evidence and argument (1) that Bayer allegedly failed to provide more timely or different information to FDA in connection with the marketing and sales of its prescription drugs Yasmin and YAZ or (2) speculating about what FDA might have done with such information. Bayer contends that such evidence and argument are irrelevant and inadmissible because FDA is solely responsible for policing whether it has received adequate information, and any state-law theory based on evidence of allegedly inadequate information provided to FDA is preempted by federal law.</p> <p>As support for its argument Bayer relies on <i>Buckman Co. v. Plaintiffs' Legal Committee</i>, 531 U.S. 341, 347-50 (2001), which holds that the cause of action of fraud-on-the-FDA is barred by principles of preemption. Bayer contends that in the instant case <i>Buckman</i> requires evidence of the actions or omissions of</p>		

Bayer in communicating information to the FDA be excluded. Plaintiffs contend that *Buckman* is inapplicable because this is not a fraud on the FDA claim and is clearly distinguishable.

The Court finds, as it has in the past, that *Buckman* is inapposite and Bayer's reliance thereon is misplaced (as it has been throughout this litigation). *Wyeth v. Levine*, 555 U.S. 555 129 S.Ct. 1187 (2009) is a far better guidepost for this Court and for this litigation. Bayer's knowledge and notice of the adverse effects of the subject drugs are of paramount relevance in this litigation. It will ultimately be an intertwined decision of the jury on the issue of proper warning whether Bayer complied with the FDA's policies. But, it is clear that the FDA is, for all practical purposes, wholly dependent upon the honesty of the pharmaceutical proponent of a drug when engaged in the approval process. In a case such as this, the jury must be fully informed of any information withheld from the FDA that could have effected decisions regarding the label.

It may well be prejudicial to the manufacturer but the probative value far outweighs that prejudice and the jury will decide if that prejudice is to be held against the pharmaceutical company (Bayer also argue that that the prejudice outweighs the probative value of such evidence under FEDERAL RULE OF EVIDENCE 403). Withholding information from the FDA which should have been considered by the agency in its labeling decisions or by the pharmaceutical company in future voluntary strengthening label changes constitutes sufficient evidence to allow the jury to consider the question of punitive damages.

11/18/2011	 104	SEALED MOTION <i>in Limine No. 2 to Exclude Evidence and Argument About Foreign Regulatory Actions or Labeling</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, the Court **DENIES** Bayer's Motion *in Limine No. 2*.

Bayer contends that foreign regulatory actions are irrelevant, would cause confusion, waste time, and would be unfairly prejudicial. Bayer also argues that foreign regulatory actions are not binding on U.S. foreign agencies and objects to proffered testimony by one of plaintiffs' experts, Dr. Parisian, regarding the duty of Bayer to react in the United States following action by European regulatory agencies. The Court addressed this issue to some extent in MDL 2100 Case Management Order Number 47 (MDL 2100 Doc. 2182). The Court concluded that the disputed testimony was admissible on the issue of assisting the jury in finding out what Bayer knew and when Bayer knew it. Defendant also contends that any probative value is outweighed by the risk of prejudice to Bayer and that the jury will likely be confused by such evidence.

The instant case involves a fairly unique oral contraceptive that was first tested in Europe and first introduced to a patient population in Europe. Bayer's book of knowledge on these contraceptives therefore did not begin with its United States experience. While the regulatory actions of European Medical regulators

are not binding on the FDA – a fact that should be made clear to the finders of fact in this case to avoid confusion – the full body of knowledge including the foreign regulatory process that came to bear on the drugs at issue and which were well within the notice and knowledge of Bayer is admissible as part of the fabric of how these drugs came to the United States market and whether all the information which should have been utilized in doing so was utilized. Such evidence is clearly probative and that value outweighs the prejudice to Bayer.

11/18/2011	 109	SEALED MOTION <i>in Limine No. 3</i> to Exclude Evidence and Argument Regarding Irrelevant Corporate History by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

This motion was argued and ruled on at the December 19th hearing. Bayer moved *in limine* to exclude incendiary historical evidence relating to Bayer's relationship with a Nazi war criminal. The motion was **GRANTED IN PART**. For the convenience of the parties, an overview of the Court's ruling is included below. The entirety of the Court's order on this motion will be memorialized in the transcript of the December 19th hearing.

At the December 19th evidentiary hearing, the Court ruled that there is clear evidence that the historical matters asserted by the plaintiffs are accurate. However, that evidence is likely irrelevant to the substantive issues at bar and the Court has precluded the plaintiff from introducing that evidence in her case in

chief except as otherwise provided. The Court further ruled that with the appropriate foundation, the disputed evidence might be admissible as impeachment. However, because of the incendiary nature of the disputed evidence, the Court strongly cautioned the parties and laid out explicit directives as to how the parties must proceed at trial in relation to introducing this evidence for impeachment purposes.

The Court also held that the plaintiff is also precluded from referencing Bayer's headquarters in Germany as a means of trying to persuade the jury that the location of Bayer's headquarters is a reason to find against Bayer. Plaintiff need not avoid the fact of Bayer's headquarter location in the natural course of discussing the facts of this case. However, the Court will not allow the plaintiff to emphasize it in such a way that it is clear that the plaintiff is playing to a pro-American sentiment and an anti-foreign mentality.

11/18/2011	 113	MOTION in Limine No. 4 to Exclude Evidence and Argument Related to Other Lawsuits by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>This motion was argued and ruled on at the December 19th hearing in conjunction with the Court's ruling on plaintiff's Motion <i>in Limine</i> No. 5. Bayer moved <i>in limine</i> to exclude evidence and argument related to other lawsuits. After considering all arguments, the Court GRANTED Bayer's motion. However, as noted in resolving plaintiff's motion <i>in limine</i> No. 5, such evidence may be admissible if Bayer "opens the door" to such evidence.</p>		

11/18/2011	 115	SEALED MOTION No. 5 to Exclude Evidence and Argument Not Appropriate to the Assessment of Punitive Damages by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion <i>in Limine</i> No. 5. Is GRANTED in part and DENIED in part.</p> <p>The Court has for the most part ruled on the relevant issues in MDL 2100 Case Management Order Number 52 (MDL 2100 Doc. 2187). The plaintiff will not be allowed to present evidence of other individual plaintiffs to support punitive damages. As for general misconduct that applies to others as well, such as failure to properly warn or the plaintiff's theory regarding the information provided to the</p>		

FDA and whether it was lacking in completeness, it does not violate any of Bayer's due process claims or other constitutional claims to have this plaintiff submit the issue of punitive damages to a jury in her trial even though those issues relate to others as well. Likewise, the net worth to the company as a whole is relevant on this issue, not just the sales of the drug in Illinois, as previously ruled.

11/18/2011	 117	SEALED MOTION <i>in Limine No. 6</i> to Exclude Evidence and Argument About its Corporate Integrity Agreements by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

This motion was argued and ruled on at the December 19th hearing. After considering the arguments of the parties and the pleadings, the Court **DENIED** the Bayer's Motion *in Limine* No. 6. The Court concluded that the Corporate Integrity Agreements are relevant. The Court also found that its ruling did not require a Rule 404(b) analysis and even if such an analysis were required, the Court found the disputed evidence admissible to show intent and lack of mistake.

11/18/2011	 121	SEALED MOTION <i>in Limine No. 7 to Exclude Evidence and Argument About Criminal Liability</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

This motion was argued and ruled on at the December 19th hearing. After considering the arguments of the parties and the pleadings, the Court **GRANTED** Bayer's Motion *in Limine* No. 7. The Court noted that a felony conviction goes to the credibility of a witness. In civil cases, the Court must be careful about allowing evidence that would only inflame the jury. Here, the disputed evidence would really just go to a theory of trying to inflame feelings or impassion feelings against Bayer as opposed to attacking the credibility of the witness. Further, the Court found probative value outweighed by the prejudice to Bayer.

11/18/2011	 125	SEALED MOTION <i>in Limine No. 8 to Exclude Evidence and Argument Regarding an Irrelevant, Third-Party Video Clip</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	--

This motion was argued and ruled on at the December 19th hearing. After considering the arguments of the parties and the pleadings, the Court **GRANTED** Bayer's Motion *in Limine* No. 8. The Court found that, without a showing that Bayer had some role in producing this film or in some way adopted the production, admitting the disputed advertisement would be unduly prejudicial to Bayer. Likewise, without such a showing the clip is irrelevant.

11/18/2011	  128	SEALED MOTION <i>in Limine No. 9</i> to Exclude Evidence and Argument Regarding Study Sponsorship Bias by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 9. Is **DENIED.**

Bayer contends that the Court should preclude anyone from arguing or testifying that if Bayer sponsored a study that sponsorship itself, without any other factor, can be the cause of an invalid result or a tainted study. Plaintiff contends that sponsorship bias is a valid challenge to the credibility of any pharmacological test.

Evidence which goes to bias is relevant and there is expert testimony in this case which opines on the issue of sponsorship bias of certain tests. This testimony has, in the court's determination, passed the Rule 702 scrutiny of admissibility.

11/18/2011	  130	MOTION <i>in Limine No. 10</i> to Exclude Evidence and Argument about Adverse Event Reports to Prove Causation or Comparative Risk by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's motion *in limine* No. 10 is **DENIED**.

The bulk of Bayer's argument is that Adverse Event Reports (AERs) are not restricted to events that are proven to be causally related to the drug at issue. Additionally, Bayer states that a drug manufacturer is not aware of the complete circumstances of the event or the identity of the original reporter, nor the integrity of the history for that matter. Plaintiff responds stating that she intends to use the disputed evidence for proving notice and that she intends to offer an expert, Dr. David Madigan, to show that Bayer received AERs containing data strongly indicating VTEs.

The FDA required the submission of Adverse Event Reports (AERs) for a reason. Bayer monitors AERs for a reason, The Court previously determined, under Rule 702, that Dr. David Madigan's methodology for mining data from AERs for valid information that can be gleaned from within was reliable. Dr. Madigan opines that such information provided ample notice to Bayer and others of VTE experiences apt to occur in YAZ and Yasmin users. It is up to the finders of fact in this litigation to determine if his methods are to be believed in whole, in part or not at all. On balance, the probative value of this evidence far outweighs any prejudice to Bayer.

11/18/2011	 101	SEALED MOTION <i>In Limine No.11</i> <i>To Exclude Evidence and Argument That Bayer Should Have Shown Doctors an Internal FDA Memorandum or Addressed Specific Suggestions in that Memorandum</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 11 is **DENIED**.

Bayer argues that it was not sent a copy of the disputed memo, no employee of Bayer has testified that he or she saw the memo and that therefore the memo is irrelevant. Defendant further argues the disputed memo's prejudicial effect upon Bayer outweighs any probative value the memo might have. Plaintiff counters that even if no employee saw the memo it was referenced in a letter to Bayer regarding another drosperinone (DRSP) drug four years prior to when plaintiff began taking YAZ. Moreover, plaintiff contends Charles Walsh, Bayer's safety officer at the time, received that letter and should have obtained the memo from the FDA in order to learn more of what the FDA was referencing. Finally, plaintiff contends, even without the letter, the memo was relevant because it shows information the government knew at the time about the comparative harm of DRSP-containing combined oral contraceptives (COCs) and what Bayer should have known.

The Court finds that plaintiff's argument is well reasoned. Bayer knew of the memo at a point in time well in advance of the plaintiff taking the subject OC

and was on notice of the general nature of its contents. Bayer cannot simply ignore the implications of such safety information given the nature of its business in relation to the health of people. It certainly is information which Bayer had an opportunity know, if it didn't already, and it should have availed itself of the information. The evidence is far more probative than prejudicial to Bayer.

11/18/2011	 112	Motion <i>In Limine No.12</i> to Exclude Evidence and Argument of Unrelated Injuries by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	--

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 12 is **DENIED**.

Bayer argues that plaintiff should not be allowed to discuss any injuries suffered by any other persons and particularly not any injuries other than those specifically alleged by the plaintiff. Plaintiff argues that during the course of its case in chief a great many studies will be referred to and not all are confined to the plaintiff's particular injury (pulmonary embolism). Likewise, plaintiff does not want to be confined if Bayer "opens the door" in discussing the evidence during its case in chief while discussing relevant studies.

While the court will not allow plaintiff to use the example of other plaintiffs or name specific people who allege to have been harmed by the drugs at issue in this case, it is inappropriate to discuss the scientific research in this case while

presenting only a part of that research for the jury. That research is intertwined and to redact portions because a study mentions some other malady would only serve to confuse the jury and leave them to speculate about the missing pieces. Bayer will not be unduly prejudiced. Moreover, the probative value of considering all the scientific evidence will better serve the interest of justice.

11/18/2011	 118	MOTION in Limine No.13 <i>To Exclude Evidence and Argument About Unrelated Drugs Withdrawn from the Market</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	--

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 13 is **GRANTED IN PART.**

Bayer argues that it expects plaintiff to introduce evidence of other drugs that have been withdrawn from the market, such as Vioxx. Bayer argues that such evidence is irrelevant. Plaintiff responds, arguing that Bayer's motion is overbroad, vague, and not specific as to which drugs it applies.

The Court concludes that evidence of drugs that have withdrawn from the market is irrelevant in the first instance. However, if Bayer presents evidence in suggesting that YAZ and/or Yasmin must be safe because the FDA has not caused them to be withdrawn from the market then plaintiff will be allowed to rebut that assertion by presenting evidence of drugs which have been withdrawn from the

market and the process surrounding that withdrawal.

11/18/2011	 122	MOTION in Limine No.14 to Exclude Improper Expert Medical Testimony Offered By Lay Witnesses by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	--

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 14 is

DENIED

Bayer argues that as lay persons neither plaintiff Kerry Sims nor her mother Diane Sims may testify about her medical conditions nor medical causation. Plaintiff counters that plaintiff herself is in the best position to testify about her physical condition, what she felt when, and why she feels the OC caused her injury. She can describe best why she changed her lifestyle and what she does now differently to accommodate her difference in physical condition. As for Plaintiff and her mother, they are both in a position to review the medical records, which are not hearsay and will be admitted already, because were present at the times memorialized in these records and testify about the matters discussed in the records

For the reasons stated by the plaintiff this motion is denied. There is nothing improper with plaintiff describing these matters herself because she is the best person to describe what she personally felt and to describe why she feels the

subject matter pills caused her pulmonary embolism. The same is true for the review of the medical records by her and her mother. The real issue at bar is the weight and credibility the fact finder wants to assign this testimony.

11/18/2011	 126	SEALED MOTION <i>In Limine No.15</i> to Exclude Evidence and Argument Regarding Irrelevant Marketing and Related Materials by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>Bayer has withdrawn this motion. Further information regarding the terms of that withdrawal were stated in open court at the December 19th hearing and will be memorialized in the transcript of that proceeding.</p>		

11/18/2011	 127	SEALED MOTION <i>No.16</i> to Exclude Evidence and Argument Relating to Irrelevant Direct-to-Consumer Marketing by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>Bayer has withdrawn this motion. Further information regarding the terms of that withdrawal were stated open court at the December 19th hearing and will be memorialized in the transcript of that proceeding.</p>		

11/18/2011	 131	SEALED MOTION <i>In limine No.17</i> to Exclude Evidence and Argument About Letters From FDA's Division of Drug Marketing, Advertising, and Communications by
------------	---	--

		Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
Bayer has withdrawn this motion as moot.		

11/18/2011	 133	SEALED MOTION <i>In limine No.18</i> to Exclude Evidence and Argument Related to Subsequent Remedial Measures to Prove Negligence or Culpable Conduct by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 18 is **DENIED**.

Bayer seeks to exclude evidence and argument relating to "subsequent remedial" measures taken by Bayer after plaintiff Kerry Sims stopped taking YAZ "to prove negligence, culpable conduct, a defect in [the] product, a defect in [the] product's design, or a need for a warning or instruction." FED. R. EVID. 407

In October 2008, after Kerry Sims stopped taking YAZ, FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") sent a letter to Bayer about two television advertisements for the prescription drug YAZ.³ In the letter, DDMAC asked Bayer to cease running these advertisements and to take corrective action. Bayer "voluntarily" agreed to take certain corrective action, and now takes the position that its "voluntary" conduct is a subsequent remedial

³ Letter from Thomas Abrams, Director, DDMAC, to Reinhard Franzen, President & CEO, Bayer HealthCare Pharmaceuticals Inc. ("BHCP") (Oct. 3, 2008) ("Oct. 2008 DDMAC letter") (Doc. 133-1).

measure subject to exclusion under FEDERAL RULE OF EVIDENCE 407 (Rule 407).

Bayer also agreed to a modification of a consent decree with several state attorneys general regarding marketing and to spend 20 million dollars for a 6 year corrective advertising campaign. Bayer anticipates plaintiff will introduce this evidence to establish that Bayer is culpable for her injuries. Bayer contends that this is also evidence of a subsequent remedial measure and that Rule 407 applies directly.

The Court disagrees. The FDA contemplates that when a company receives such a letter it will voluntarily comply with requests for corrective action without the FDA having to take further action. It is not a letter which makes an allegation of a violation but one, as was the situation with Bayer here, where the FDA states that a violation of law or regulation has occurred and wants the offender to correct the matter without causing the FDA to have to go through the more difficult task of an enforcement procedure. Therefore, while described as voluntary, it in reality is part and parcel to the enforcement mechanism of the FDA. It is no more voluntary that a party paying a judgment without the judgment creditor pursuing post-judgment relief such as a garnishment. This distinguishes the Rule 407 procedure where a party, of its own accord, seeks to eliminate a harmful situation, once it learns of its existence, in order to prevent further harm. As Bayer employee, Heidemarie Schnell, testified in this case, had it not been for the letter from the DDMAC, Bayer would not have taken action. Similar reasoning applies with regard to the consent decree modification.

11/18/2011	 139	SEALED MOTION <i>In Limine No.19</i> to Exclude Evidence and Argument Regarding Alleged Off-Label Marketing by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG
<p>Bayer has withdrawn this motion. Further information regarding the terms of that withdrawal were stated open court at the December 19th hearing and will be memorialized in the transcript of that proceeding.</p>		

11/18/2011	 140	SEALED MOTION <i>In limine No.20</i> to Exclude Evidence and Argument Implying That Internal Marketing Documents Are "Promotional Materials" by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>Bayer has withdrawn this motion. Further information regarding the terms of that withdrawal were stated open court at the December 19th hearing and will be memorialized in the transcript of that proceeding.</p>		

11/18/2011

 [98](#)

SEALED MOTION *in limine* **No. 21** to Exclude Evidence and Argument About Pejorative and Inaccurate References to Medical Literature by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 21 is **DENIED**.

Bayer moves *in limine* to exclude evidence and argument about so-called "ghostwriting" of medical literature concerning DRSP-containing COCs. Bayer contends that, under FEDERAL RULE OF EVIDENCE 403 (Rule 403), "Ghost-writing" is a misnomer calculated to inflame and mislead the jury and seeks to prevent use of that term. Further, Bayer claims that the practices to which this term refers are not relevant to any fact at issue in this litigation (citing to FEDERAL RULES OF EVIDENCE 401-02). Plaintiff argues that the practice of having articles or letters written by one person or a group of persons yet attributed to another is a purposeful attempt to deceive the target audience.

Bayer states that although it hired medical consultants to help physicians and academics with medical papers there is no evidence that the physicians and academics signed their names to anything they did not believe in or that the papers were not written with full input from the physicians and academics. Bayer suggests that people such as the President and federal judges utilize ghost writers and there is nothing wrong with the well accepted practice.

This argument is not well taken. Neither the President nor any federal judge to this judge's knowledge, to the extent speech writers or law clerks are used for drafts of speeches or orders, are trying to deceive the target audience for the purpose of influencing that audience's interpretation of the subject matter of the content of the speech or order. In this instance, it is just that which is occurring. Bayer wants the target audience to believe the words are those of a particular doctor or academic for the sake of influencing that audience with the name of the supposed author. Even though the supposed author may agree generally with the concepts and conclusions that is not the same as saying it exactly in the same tone and demeanor as the substitute writer. It would be more honest if the consultant wrote the article and the "name" doctor or academic wrote a forward or executive summary endorsing the concepts contained therein rather than trying to make the audience believe he or she actually wrote the entire article. In the context of this case and the issue of adequate warning, in particular, this kind of evidence is particularly relevant for the fact finder to consider with all the other evidence in the case.

11/18/2011	  100	MOTION in Limine No. 22 to <i>Exclude Evidence and Argument About General Sales Goals, Projections and Trends for YAZ and Yasmin</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 18 is **DENIED.**

Bayer seeks the entry of an Order barring evidence and argument related to general sales goals, projections, and trends for YAZ and Yasmin. Bayer, relying on FEDERAL RULES OF EVIDENCE 401-403, contends that such evidence and argument is irrelevant and raises the specter of juror confusion and delay. Plaintiffs contend that this evidence is clearly relevant. Plaintiffs' argument is easy to understand, given the many examples of comments by Bayer employees regarding the huge profit expectations for DRSP drugs and the expected financial benefits for employees. Plaintiffs contend the fact finder could infer, with such huge profits looming, Bayer might be inclined to overlook the trends suggested by the AERs. Plaintiff's argument carries over into issues relating to labeling.

The Court concludes that evidence about sales goals is certainly relevant particularly when it may impact decision making regarding labeling. There is an inherent tension between the desire for profit and scientific decisions that suggest warnings that may well shrink the customer base because of cautionary tone stricken by the warnings. The kind of evidence which has been uncovered by the plaintiffs in discovery and which the court adopts herein for this ruling are certainly relevant and far more probative than prejudicial to Bayer.

		<i>Providers Other Than the Plaintiffs' Prescribing Healthcare Providers</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>Bayer has withdrawn this motion. Further information regarding the terms of that withdrawal were stated open court at the December 19th hearing and will be memorialized in the transcript of that proceeding.</p>		

11/18/2011	 105	MOTION in Limine No. 24 to Exclude Evidence and Argument About Assertions of Attorney-Client Privilege by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.</p>		

11/18/2011	 107	MOTION in Limine No. 25 to Exclude Argument About Bayer's Lawyers at Trial by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>The parties have informed the Court that this motion has been resolved by</p>		

agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.

11/18/2011	 108	MOTION in Limine No. 26 to Exclude Evidence and Argument Regarding Defendants' Employees' Attendance or Non-Attendance at Trial by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	--	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 26 is **GRANTED IN PART.**

Bayer moves to preclude plaintiffs from referring to the attendance or non-attendance of Bayer's employees at trial. Bayer maintains that such references would allow the jury to draw irrelevant inferences. Plaintiff contends that it is perfectly appropriate to point out if certain persons are not present. For example, if no corporate representative is present at counsel table or if someone should be present to testify and the missing witness instruction is appropriate.

The Court concludes, if no corporate representative is present at counsel table, said absence is fodder for comment by plaintiff since it is customary for such a person to be present. Certainly, if plaintiff was never present in the court room Bayer would feel compelled to comment. There are circumstances when a missing witness instruction is appropriate and that will not be precluded prior to trial. On the other hand, assuming a missing witness instruction is not appropriate and the person is not the corporate representative, Bayer cannot be expected to have on hand every conceivable employee who had anything at all to do with DRSP COCs and the plaintiff is ordered not to comment.

11/18/2011	 111	MOTION in Limine No. 27 to Exclude Argument Regarding Witnesses Testifying by Deposition by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion <i>in Limine</i> No. 27 is GRANTED.</p> <p>Bayer seeks to preclude plaintiffs from suggesting that the jury should treat recorded testimony any differently from live testimony, or that the jury may draw any adverse inferences about witnesses who do not give live testimony. Plaintiffs contend that they should be able to argue to the jury that they can draw negative inferences from the fact that Bayer presented their employees by deposition rather than bringing them to testify live.</p> <p>Certainly, the jury will be instructed to give the deposition testimony the</p>		

same consideration as any other testimony. The motion presumes that the testimony of the employee is presented by deposition. Plaintiff is directed not to argue to the jury that it can take an adverse inference from the fact that Bayer did not bring the employee who appears by deposition to court to testify live. Many employees have jobs which are critical to the continued operation of the company. It is very time consuming and difficult to travel here from Indiana, New Jersey or Germany for either this trial or the one that is being tried nearly simultaneously in Philadelphia. Deposition testimony is, by rule, an acceptable substitute when a witness is otherwise unavailable.

11/18/2011	 114	MOTION in Limine No. 28 to Exclude Evidence and Argument About Unrelated Public Controversies by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion <i>in Limine</i> No. 28 is DENIED.</p> <p>Bayer asks that the Court prohibit any and all evidence regarding unrelated corporate controversies. Plaintiff counters, arguing that while most of the disputed controversies are likely irrelevant, the request is overbroad, vague, and not capable of enforcement.</p>		

The Court could just as easily grant this motion because the request incorporates the language “unrelated.” Thus, it would presume that the Court is only precluding that which is irrelevant. However, relevance is in the eye of the beholder. So while the Eli Lilly example provided by the plaintiff in her response is in her view relevant, Bayer undoubtedly would disagree. The Court finds that the request is too broad and will handle any individual objections at trial.

11/18/2011	 119	SEALED MOTION <i>in Limine No. 29 to Exclude Evidence and Argument Regarding Moral Duties or Business Ethics</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>This motion remains in dispute. After fully considering the parties’ arguments, and for the reasons stated herein, Bayer’s Motion <i>in Limine</i> No. 29 is GRANTED IN PART.</p> <p>Bayer argues that questions seeking opinions or evidence about ethical,</p>		

moral, industrial standards, decency are all subjective and therefore not the proper subject of inquiry. In addition, Bayer argues that such questions are irrelevant in a case based on legal standards. Finally, Bayer contends that the disputed material will confuse the jury and such inquiry will be more prejudicial, depending on the witness, than probative. Plaintiffs argue that the motion is over broad. Further, Plaintiffs contend that custom and practice in the industry is not a subjective inquiry. Plaintiffs also contend that Bayer has not met its burden in its position on issues of morality and decency relative to FEDERAL RULE OF EVIDENCE 403.

The court has already ruled on expert witness testimony. As far as asking individual Bayer witnesses if they believe Bayer has acted morally or with decency or in an ethical manner the motion is **GRANTED**. Plaintiffs may ask a witness, who has familiarity with other pharmaceutical companies, if that witness is familiar with custom and practice in the industry. Asking that witness whether Bayer's action comported with that industry standard is also a permissible line of inquiry. The inquiry allowed is far more probative than prejudicial to defendant.

11/18/2011	  124	SEALED MOTION <i>in Limine No. 30</i> to Exclude Argument That Bayer Exerted Improper Influence Over the FDA Because It Retained a Former FDA Employee as a Consultant by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion <i>in Limine</i> No. 30 is</p>		

DENIED.

Bayer moves to exclude argument that Bayer exerted improper influence over the FDA because it retained Dr. Daniel Shames, a former FDA employee, as a consultant on issues relating to YAZ and YAsmin. Bayer contends that such hiring is common place in the industry and any suggestion of impropriety is unfair. Bayer states that any such argument is baseless speculation unsupported by evidence and that it would be unduly prejudicial under FEDERAL RULE OF EVIDENCE 403. Plaintiffs contend that there is evidence Bayer began speaking with Dr. Shames about a consulting relationship before he retired and that any evidence pertaining to that relationship is relevant. Plaintiffs also note that evidence is not necessarily unfairly prejudicial simply because it is damaging.

The Court agrees with plaintiffs. This clearly is evidence the fact finder should be allowed to consider and draw what inferences are to be reasonably drawn from it. Bayer does not like the potential inferences and this may be business as usual in this industry but it is highly probative of the facts surrounding the issues in this case. Any prejudice to Bayer is far outweighed by the probative value of this evidence.

11/18/2011	 106	SEALED MOTION <i>in Limine No. 31</i> to Exclude Evidence and Argument of Inappropriate Personal Conduct by a Former Bayer Employee by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
The parties have informed the Court that this motion has been resolved by		

agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.

11/18/2011	 110	MOTION in Limine [No. 32] to Exclude Evidence and Argument Regarding a Medical Malpractice Suit Against a Bayer Employee by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion <i>in Limine</i> No. 32 is DENIED.</p> <p>Bayer seeks to exclude evidence and argument regarding a medical malpractice lawsuit filed many years ago against Dr. Leo Plouffe, Jr. Bayer contends that such evidence and argument is irrelevant and unduly prejudicial to Bayer. Dr. Plouffe is Vice President of Women's Healthcare at Bayer HealthCare Pharmaceuticals. Before joining Bayer, Dr. Plouffe was a physician practicing in OB/GYN and reproductive endrocrinology. Based on a series of questions put to Dr. Plouffe at deposition, Bayer anticipates that plaintiffs will attempt to introduce evidence and argument regarding an unrelated medical malpractice lawsuit filed against Dr. Plouffe.</p> <p>Plaintiff contends that because Dr. Plouffe has been designated as an expert by Bayer, the prior malpractice action is probative of Dr. Plouffe's credibility, bias, and truthfulness. Plaintiffs also argue that the unique facts of Dr. Plouffe's</p>		

litigation are particularly probative of his credibility and bias. Plaintiffs state that because an expert witness' credibility is always a relevant area of inquiry, the Court should deny the Motion.

The plaintiff has clearly demonstrated that credibility and bias are appropriate areas of inquiry on the subject of Dr Plouffe's medical malpractice case and his activities directly related to it thereafter. Considering plaintiffs' argument, the court finds that an *in limine* order to prevent that inquiry would be inappropriate. The probative value of this inquiry outweighs any potential prejudice to Bayer which in this instance actually lies with its witness.

11/18/2011	 116	SEALED MOTION <i>in Limine No. 33</i> to Exclude Media Reports About YAZ or Yasmin by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion <i>in Limine</i> No. 33 is DENIED.</p> <p>Bayer moves to exclude media reports about YAZ or Yasmin. Bayer</p>		

contends these media reports are hearsay, irrelevant, and prejudicial. Specifically, Bayer states that the disputed material constitutes hearsay not subject to any hearsay exceptions (FED. R. EVID. 801-804 or the residual exception FED. R. EVID. 807) and is irrelevant and unduly prejudicial under FEDERAL RULES OF EVIDENCE 401-403. Plaintiffs argue that the motion is overbroad and that there are reported uses of media that are not hearsay such as introduction of media reports not to prove the truth of the matter asserted, for example in this case the way the contraceptives were marketed to doctors. Plaintiffs note that Bayer was not specific as to any particular media report of which it was concerned. Finally, plaintiffs assert rulings should be made on an exhibit by exhibit basis.

The court agrees with plaintiffs. This motion is too overbroad. Some media reports are admissible without the hearsay hurdle and the court will have to examine them with an eye toward the purpose of the exhibit.

11/18/2011	 120	MOTION in Limine No. 34 to Exclude Evidence and Argument Regarding Settlements of and Refusal to Settle YAZ/Yasmin Related Claims by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
<p>The parties have informed the Court that this motion has been resolved by agreement. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation. The stipulation provides that the parties are not</p>		

opposed to this motion. Accordingly, pursuant to the parties' stipulation, the motion is **GRANTED**.

11/18/2011	 123	SEALED MOTION <i>in Limine No. 35 to Exclude Evidence and Argument Relating to Isolated Manufacturing and Quality control Issues at Bayer's Bergkamen Facility</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 35 is **DENIED**.

Bayer seeks to exclude plaintiffs from introducing evidence and argument about the FDA's August 5, 2009 warning letter regarding Bayer's Bergkamen facility, including the events leading up to the FDA's issuance of the letter and Bayer's response. Bayer contends that this evidence and argument is irrelevant and would be unduly prejudicial to Bayer pursuant to FEDERAL RULES OF CIVIL PROCEDURE 401-403.

Specifically, Bayer contends that there is no allegation that plaintiffs ingested any YAZ or Ocella that was manufactured at that facility. Accordingly, Bayer argues the incident is irrelevant to the case and would lead to speculation that would be unduly prejudicial under FEDERAL RULE OF EVIDENCE 403. Plaintiffs contend that the Bergkamen facility is the sole Bayer facility responsible for producing DRSP and ethinyl-estradiol and therefore the DRSP and ethinyl-

estradiol ingested by Plaintiffs was produced at the Bergkamen facility.

The court finds that in light of the fact that the Bergkamen facility is the sole Bayer facility responsible for producing DRSP and ethinyl-estradiol the evidence which Bayer seeks to preclude is relevant. Whether it is relevant for plaintiff's case in chief or just for issues of credibility and impeachment remains to be seen. The court cannot preclude it pretrial, however. Moreover, its probative value certainly outweighs its prejudicial harm to defendant.

11/18/2011	 129	SEALED MOTION <i>in Limine No. 36 to Exclude Evidence and Argument Regarding Future Damages Not Reasonably Certain to Accrue</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, Bayer's Motion *in Limine* No. 36 is **DENIED**.

Bayer challenges plaintiffs' expert witness testimony regarding future damages. This matter has already been addressed by the Court in motions addressing the exclusion of expert testimony (*See e.g.*, MDL 2100 Doc. 2186 pp. 43-46; 3:09-cv-20021 Doc. 257 pp. 9-24).

11/18/2011	 132	SEALED MOTION <i>in Limine No. 37 to Exclude Argument That Compensatory Damages Should be Used to Punish Defendants or for Any Purpose Other than to Reimburse Actual Losses</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	--

The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.

11/18/2011	 134	MOTION in Limine No. 38 to <i>Exclude Evidence and Argument Regarding Promises to give Damages Awarded to Charity</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.

11/18/2011	 136	MOTION in Limine No. 39 to <i>Exclude Evidence and Argument Regarding the Availability of Liability Insurance</i> by Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare, LLC, Bayer Schering Pharma AG.
------------	---	---

The parties have informed the Court that this motion has been resolved by agreement. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation. The stipulation provides that the parties are not opposed to this motion. Accordingly, pursuant to the parties' stipulation, the motion is **GRANTED**.

B. Plaintiffs' Motions *in Limine*

11/18/2011	 135	MOTION in Limine [No. 1] <i>to Exclude Certain Subjects from Evidence at Trial</i> by Kerry Sims. (Denton, Roger) (Entered: 11/18/2011)
------------	---	--

This motion contains 36 subparts. Plaintiffs seek to preclude Bayer from offering evidence, argument, inference or eliciting testimony concerning or regarding the subjects set forth below on the ground that such topics are irrelevant, highly prejudicial and/or calculated to sway the sympathies or emotions of the jury. Some of the subparts have been resolved by agreement of the parties. The remaining disputes are decided by the Court accordingly below.

<p>(1) Any comment, evidence, testimony, inference or document that a verdict for the Plaintiff will adversely impact pharmaceutical companies' incentive/ability to develop new medications. Such argument is irrelevant, highly prejudicial and calculated to sway the sympathies of the jury.</p>	<p>GRANTED for the compensatory damages phase. During the compensatory damages phase there will be no discussion regarding net worth of the company; the impact on the company will have no relevance whatsoever. However, in the punitive damage phase, where the plaintiff will be allowed to discuss the evidence of the company's net worth and argue for a verdict that will have an impact on the defendant, Bayer will be allowed to defend that discussion by arguing what impact a punitive damage verdict will have on the defendant.</p>
<p>(2) Any comment or inference, or submitting any evidence, testimony or documents or tending to suggest in any way that any award of damages in this case will adversely affect the ability of any member of the jury to purchase or have available medications in the future, or affect the cost thereof, or have any adverse effect on the medical or health products available to individuals or industries in the United States or worldwide. Such argument is irrelevant, unfairly prejudicial and calculated to sway the sympathies of the jury.</p>	<p>GRANTED in both phases, including the punitive damages phase. This is too speculative regarding the specific availability of medication and it personalizes the issue by suggesting that members of the jury would not be able to obtain medication</p>

<p>(3) Any comment, evidence, testimony, inference or document or making reference that this case or other Yaz/Yasmin product liability litigation cases may have a negative impact on the stock value of Defendants or any other publicly traded pharmaceutical manufacturer. Such argument is irrelevant, unfairly prejudicial and calculated to sway the sympathies of the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation. The stipulation provides that the parties are not opposed to this motion. Accordingly, pursuant to the parties' stipulation, the motion is GRANTED.</p>
<p>(4) Any comment, evidence, testimony, or inference that a verdict for the Plaintiff will or could result in people losing their job or lead to lay-offs. Such argument is irrelevant, unfairly prejudicial and calculated to sway the sympathies of the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation. The stipulation provides that the parties are not opposed to this motion. Accordingly, pursuant to the parties' stipulation, the motion is GRANTED.</p>
<p>(5) Any comment, evidence, testimony, inference or document that this case or any other Yaz/Yasmin products liability case may cause an increase in the cost of purchasing or maintaining insurance. Such argument is irrelevant, unfairly prejudicial and calculated to sway the sympathies of the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation. The stipulation provides that the parties are not opposed to this motion. Accordingly, pursuant to the parties' stipulation, the motion is GRANTED.</p>

<p>(6) Any comment, evidence, testimony, inference or document that this case or any other Yaz/Yasmin product liability case may cause an increase in the cost of purchasing medications for the public. Such argument is irrelevant, unfairly prejudicial and calculated to sway the sympathies of the jury.</p>	<p>GRANTED - Once again this calls for speculation regarding the cost of medication increasing and personalizes the issue, suggesting to the jury that their cost will go up.</p>
<p>(7) Any comment, evidence, testimony, inference or document mentioning medical conditions of the Plaintiff's family that are unrelated to the injuries at issue in this lawsuit. Such arguments are irrelevant.</p>	<p>GRANTED – Such arguments are irrelevant.</p>
<p>(8) Any comment, evidence, testimony, or inference about how, when, or under what circumstances Plaintiff chose or employed any of her attorneys. Such comments would be irrelevant, unfairly prejudicial, and designed solely to embarrass Plaintiff or the attorneys involved in the case.</p>	<p>GRANTED – This is no more relevant than how Bayer came to hire each of its lawyers. Whether a commercial played a role in it is likewise irrelevant.</p>
<p>(9) Any comment, evidence, testimony, or inference about the date or circumstances under which Plaintiff employed her attorneys, the name of any other lawyer retained or consulted by the Plaintiff, whether or not such lawyers were the original attorneys of record and whether such lawyer or any other lawyer referred her to the undersigned attorneys. Such argument is irrelevant, and calculated to mislead and confuse the jury.</p>	<p>GRANTED – Such arguments are irrelevant.</p>

<p>(10) Any comment, inference, testimony, or evidence about current or former ownership interest by Plaintiff's counsel, their experts, Plaintiff, or her family, in the Defendants. Such argument is irrelevant, unfairly prejudicial, and calculated to mislead and confuse the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation. The stipulation provides that the parties are not opposed to this motion. Accordingly, pursuant to the parties' stipulation, the motion is GRANTED.</p>
<p>(11) Any comment, inference, evidence, testimony, or document tending to suggest or in any way reflect the financial status or resources of any of Plaintiff's attorneys or their law firms, or any of those attorneys' other business or cases. Such argument is irrelevant, unfairly prejudicial and calculated to inflame the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.</p>
<p>(12) Any comment, inference, evidence, testimony, or document relating to travel by private jet for any of the lawyers or witnesses involved in this case. Such argument is irrelevant, unfairly prejudicial and calculated to inflame the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation. The stipulation provides that the parties are not opposed to this motion. Accordingly, pursuant to the parties' stipulation, the motion is GRANTED.</p>

<p>(13) Any comment, inference, evidence, testimony or document mentioning any noncriminal conduct of the Plaintiff. Misdemeanors and human frailties should not become “fair game” during trial. Federal and state rules of evidence prohibit such character assassination, and such argument is irrelevant, unfairly prejudicial and calculated to sway the sympathies of the jury.</p>	<p>GRANTED – The Court will enforce the FEDERAL RULES OF EVIDENCE (in particular Rules 608 and 609) on such matters.</p>
<p>(14) Any comment, inference, evidence, testimony, or document regarding any settlement negotiations offered or demanded by the parties to this lawsuit that have occurred or may occur prior to or during trial. Such argument is unfairly prejudicial.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties’ stipulation. The stipulation provides that the parties are not opposed to this motion. Accordingly, pursuant to the parties’ stipulation, the motion is GRANTED.</p>
<p>(15) Any mention or disclosure, whether directly or indirectly, in any manner, that Plaintiff is covered by some form of insurance for the incident in question or some other collateral source. Such fact is entirely immaterial to any issue in this case and any mentioning or inference thereof, directly or indirectly, in any manner, will be harmful or unjustly prejudicial to Plaintiff.</p>	<p>GRANTED – evidence pertaining to plaintiff’s insurance is irrelevant.</p>
<p>(16) Any indication that Defendants may have to pay a judgment entered in this case, that Defendants may have limited policy limits or cash, or the effect or results of such judgment upon the insurance rates, premiums, finances, or ability of Defendants to compete in the marketplace. Such evidence is irrelevant and calculated to sway the sympathies of the jury.</p>	<p>GRANTED IN PART – Bayer may argue that they may have to pay a judgment entered in this case but may not argue about coverage. As previously ruled, in the punitive damages phase, Bayer can argue about the impact of punitive damages on the company.</p>

<p>(17) Any suggestion that any recovery the Plaintiff may receive in this case in the way of damages awarded by a jury verdict, may be subject to prejudgment interest or judgment interest. Such argument is irrelevant and unfairly prejudicial to the Plaintiff.</p>	<p>GRANTED – Any decision on prejudgment interest is left to the Court. No such decision has been issued and it cannot be argued.</p>
<p>(18) Any mention that Plaintiff's recovery will be increased or enhanced by operation of law. Such argument is irrelevant and is unfairly prejudicial to the Plaintiff.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation. The stipulation provides that the parties are not opposed to this motion. Accordingly, pursuant to the parties' stipulation, the motion is GRANTED.</p>
<p>(19) Any comment, inference, evidence, testimony, or document tending to suggest in any way that an award of punitive damages in this case is unconstitutional, illegal, or not supported by the current state of the law. See generally <i>TXO Prod. Corp. v. Alliance Res. Corp.</i>, 509 U.S. 443, 462 (1993). Such argument is irrelevant, unfairly prejudicial and calculated to invoke the emotions of the jury.</p>	<p>GRANTED – Bayer can argue the content of the jury instruction and explain it to the jury. Bayer should avoid any suggestion that it disagrees with the Court's ruling on the subject and save that argument for the appellate court. Bayer can, however, argue that it believes this is a case where no punitive damages are in order at all and the jury should award nothing in that area.</p>

<p>(20) Any mention of the purported “litigation crisis,” “lawsuit crisis,” “lawsuit abuse,” “lawyer driven litigation,” or similar terms or phrases. Such argument would be irrelevant, highly prejudicial, and calculated solely to inflame the jury.</p>	<p>GRANTED IN PART– Bayer is prohibited from using terms such as "lawsuit abuse" "litigation crisis" "lawsuit crisis" in order to attempt to persuade the jury that this litigation is somehow "a symptom of what is wrong with our legal system today, a system that allows plaintiffs to overrun the courts with frivolous lawsuits" or some argument to that effect. However, Bayer will be allowed to develop, if the evidence supports it, its theory put forth in its response that advertisements for clients drove up the number of adverse events reported regarding these contraceptives</p>
<p>(21) Any comment, evidence, testimony, or inference about Mass Torts Made Perfect or any other seminars for plaintiffs’ attorneys. Such argument would be irrelevant, unfairly prejudicial, and calculated solely to inflame the jury.</p>	<p>DENIED - this request is very broad as indicated in Bayer’s response, it is appropriate to cross examine an expert about presentations to a plaintiff’s only seminar (or a defendant’s only seminar) and that title may come up in that regard</p>
<p>(22) Any comment, evidence, testimony, or inference about the Plaintiff’s fee agreement and who is paying expenses or who is responsible for expenses in connection with this litigation. Such argument would be irrelevant, unfairly prejudicial, and calculated to solely inflame the jury.</p>	<p>GRANTED - Litigation expense payment in this case is irrelevant.</p>

<p>(23) Any comment, evidence, testimony, inference or document mentioning, suggesting or inferring that if Defendants are made to pay a judgment that it may negatively affect the Illinois economy or the economy of any state. Such argument is irrelevant, unfairly prejudicial and calculated to sway the sympathies of the jury.</p>	<p>GRANTED - It is entirely speculative what impact a judgment in this case, whether compensatory or punitive, would have on Illinois' economy even in cases where the defendant is the state of Illinois, the jury would not be allowed to have argued before it by the attorney general's office the impact on the state economy</p>
<p>(24) Any comment, evidence, testimony, inference, or document that bolsters the unchallenged character (<i>e.g.</i>, honest) or traits (<i>e.g.</i>, generous) of the Defendants' current or former employees, managers, consultants, experts, agents or fiduciaries preemptively. Such arguments are irrelevant and calculated to sway the sympathies of the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.</p>
<p>(25) Any comment, evidence, testimony, inference, or document concerning societal good the Defendants perform by manufacturing other drugs, such as aspirin or cancer treatment drugs. Such arguments are irrelevant and calculated to sway the sympathies of the jury</p>	<p>GRANTED IN PART - Bayer is not allowed to argue to the jury, even in the punitive damages phase, that it is the company that introduced a drug or drugs that greatly benefited society in an effort to have the jury overlook any wrong the jury might otherwise find with the contraceptive at issue here.</p> <p>On the other hand Bayer and plaintiff (without opening any doors) must be allowed, during voir dire, to explore the venire's familiarity with Bayer and its products, their favorability feelings relative to those drugs or not and overall disposition with Bayer</p>

<p>(26) Any comment, evidence, testimony, inference, or document that any of Plaintiff's family, friends, or acquaintances has taken Yasmin or Yaz. Such argument is irrelevant, unfairly prejudicial, and calculated to confuse and mislead the jury.</p>	<p>GRANTED IN PART - Whether any of plaintiff's relatives took YAZ or Yasmin is irrelevant unless that played a role in plaintiff's decision to ask for the contraceptive or accept the doctor's recommendation for the drug (neither of which is the court's understanding of the facts). Therefore, unless a family member's use of either drug played such a role the motion is granted</p>
<p>(27) Any comment, evidence, testimony, inference, or document mentioning that state warning defect or failure-to-warn laws pressure drug manufacturers to add unsubstantiated, false, or invalid warnings in order to avoid lawsuits. Such arguments are irrelevant, unfairly prejudicial to Plaintiff and designed to inflame the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.</p>
<p>(28) Any comment, evidence, testimony, inference, or document mentioning that state tort law undercuts the FDA's mission to provide only scientifically valid warnings. Such arguments are irrelevant, unfairly prejudicial to Plaintiff and designed to inflame the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.</p>
<p>(29) Any comment, evidence, testimony, inference, or document mentioning that too many warnings of serious injuries will dilute the effectiveness of warnings generally. Such arguments are irrelevant, unfairly prejudicial to Plaintiff and designed to inflame the jury.</p>	<p>DENIED - This is a matter for the fact finder to determine and the subject of fair argument.</p>

<p>(30) Any comment, evidence, testimony, inference, or document mentioning that state products liability law frustrates the FDA's protective regime. Such arguments are irrelevant, unfairly prejudicial to Plaintiff and designed to inflame the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.</p>
<p>(31) Any comment, evidence, testimony, inference, or document mentioning that Defendants should not be exposed to fifty-one separate tort-law regimes. Such arguments are irrelevant, unfairly prejudicial to Plaintiff and designed to inflame the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.</p>
<p>(32) Any comment, evidence, testimony, inference, or document mentioning that state law must be preempted to protect the public from recklessly warning of unsubstantiated associations between the drugs and health risks. Such arguments are irrelevant, unfairly prejudicial to Plaintiff and calculated to sway the sympathies of the jury.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.</p>

<p>(33) Any comment, testimony, inference that the Court has any particular view of the evidence in this case. Such arguments are irrelevant and unfairly prejudicial.</p>	<p>The parties have informed the Court that this motion has been resolved by agreement and a ruling from the Court is no longer being sought. The parties have drafted a stipulation memorializing that agreement, which is attached hereto as Exhibit A. The Court hereby acknowledges and adopts the parties' stipulation.</p>
<p>(34) Any comment, evidence, testimony, inference or document mentioning that a verdict for the Plaintiff will or could take a prescription choice away from doctors. Such argument would be irrelevant, highly prejudicial, and calculated solely to inflame the jury or have the jury base its decision on emotion.</p>	<p>GRANTED – This is too speculative and irrelevant to the jury's consideration in this case.</p>
<p>(35) Any comment, evidence, testimony, inference or document concerning the fact that certain of Plaintiff's experts have agreed to give expert testimony or issued reports in other YAZ/Yasmin bellwether cases, including bellwether gallbladder cases. Such information is irrelevant, highly prejudicial, and calculated solely to inflame the jury.</p>	<p>DENIED - This is a fair area of cross examination of an expert that a fact finder may view as an issue on credibility and bias.</p>
<p>(36) Any comment, evidence, testimony, inference or document mentioning that Mary Sita, the Bayer sales representative who called on Dr. Shores, has multiple sclerosis and is out on disability leave. Such argument would be irrelevant, highly prejudicial, and calculated solely to have the jury base its decision on emotion.</p>	<p>DENIED - There is substantiation for this assertion, the fact finder should be allowed to consider it when assessing her testimony but Bayer will not be allowed to argue the point to invoke sympathy for her or to cast plaintiff in a bad light for requiring her testimony</p>

11/18/2011

 [137](#)

MOTION in Limine [No. 2] *To Exclude Reference to Any Communications Between Any Lawyer to Any Expert Who Will Not Testify in the Sims Case* by Kerry Sims. (Denton, Roger) (Entered: 11/18/2011)

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, plaintiff's Motion in Limine No. 2 is **GRANTED.**

Plaintiff seeks to exclude all evidence, references, inferences, testimony, documents, or argument referencing any communication between any lawyer (or their staff) to any expert who will not testify in the Sims case on the grounds that such evidence is irrelevant and/or the probative value of the evidence and/or testimony is greatly outweighed by the danger of unfair prejudice, confusion of issues, and/or will cause undue delay and waste of time. Additionally, plaintiff contends that such communications constitute hearsay without a legally recognized exception.

The Court agrees with the plaintiff. Such communications are not relevant and are hearsay. Likewise, such testimony is likely to be misleading and confusing. Finally, the prejudice to the plaintiff far outweighs the probative value.

11/18/2011

 [138](#)

MOTION in Limine [No. 3] *To Exclude Evidence That Bayer Could Not Have Been Negligent or Are not Liable to Plaintiff Because Yaz and Yasmin Were Approved by the FDA* by Kerry Sims.

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, plaintiff's Motion in Limine No. 3 is **GRANTED IN PART.**

Plaintiff seeks to exclude all evidence, references, inferences, testimony, documents, or argument claiming that Defendants could not have been negligent or are not liable to Plaintiff because YAZ and Yasmin were approved by the FDA, on the grounds that such evidence is irrelevant and/or the probative value of the evidence and/or testimony is greatly outweighed by the danger of unfair prejudice, confusion of issues, and/or will cause undue delay and waste of time. Additionally, plaintiff contends that such argument is contrary to the relevant case-law.

As the Supreme Court said in *Wyeth v. Levine*, 555 U.S. 555; 129 S.Ct. 1187 (2009), approval by the FDA does not provide a complete defense to plaintiff's tort claims, so it would follow that Bayer cannot argue that it is not liable to plaintiff because YAZ and Yasmin were approved by the FDA.

Bayer argues that it should be able to present evidence of the FDA's approval of the contraceptives and that certainly is true. Bayer also concedes that FDA approval is not dispositive on the issue of liability insofar as the plaintiff here is concerned. However, the Court also notes that FDA approval is not dispositive

of the issue of adequacy of warning or strict liability on product defectiveness.

Thus, the Court finds that Bayer may not argue that it is not liable to plaintiff because YAZ and Yasmin were approved by the FDA. However, Bayer may present evidence of the FDA's "approval" for them to begin marketing the drugs but may not argue that said approval absolves them of liability or means they did nothing wrong.

11/18/2011	 141	MOTION in Limine No. 4 <i>To Exclude Any Evidence, Argument or Inference Pertaining to Plaintiff Kerry Sims' Sexual Activity or Sexual History</i> by Kerry Sims.
------------	---	--

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, plaintiff's Motion in Limine No. 4 is **GRANTED IN PART.**

Plaintiff seeks to exclude all evidence, references, testimony or argument relating to the sexual activity or sexual history of Plaintiff, including, but not limited to, oral testimony on this topic and any mention thereof in Plaintiff's medical records. Plaintiff contends that evidence pertaining to the sexual activity and sexual history of plaintiff has no relevance to any of the facts at issue in this case. Further, plaintiff contends such evidence would serve no purpose but to play upon potential prejudices the jury may hold regarding the sexual activity of an unmarried 28-year-old.

Bayer argues that the motion should be denied because plaintiff has put her sexual activity directly at issue. Bayer contends evidence of her sexual history is

central to why she took YAZ, to the jury's assessment of the risks and benefits of YAZ, and to her claims of injury.

Bayer confuses contraceptive history with sexual history. Clearly the plaintiff's history with contraceptives is relevant and any in particular any problems she has experienced with them. However, her sexual history beyond her use of contraceptives and experience with them is not an issue in this case and any probative value of it is far outweighed by the prejudice to the plaintiff by creating an image of a sexually promiscuous woman.

11/18/2011	 142	MOTION in Limine No. 5 <i>To Exclude Evidence of Compensation of Expert Witnesses for Work Not Specific to the Sims Case</i> by Kerry Sims.
------------	---	--

This motion was argued and ruled on at the December 19th hearing. Plaintiff moved *in Limine* to exclude evidence of compensation of expert witnesses for work not specific to the *Sims* case. The motion was **DENIED**. For the convenience of the parties, an overview of the Court's ruling is included below. The entirety of the Court's order on this motion will be memorialized in the transcript of the December 19th hearing.

At the December 19th hearing, the Court ruled that each party has the right to pursue the question of bias; if an expert only testifies for a living Bayer is entitled to explore that. Accordingly, each party may pursue the issue of compensation of expert witnesses, including compensation not related to the *Sims*

case. This issue may be explored in terms of dollar amounts or percentage of income. If Bayer chooses to pursue this line of questioning, the “door will be open” to informing the jury that there are thousands of cases pending. However, the Court will not tolerate mini-trials discussing the specifics of the thousands of other pending cases. Finally, counsel for Bayer suggested, with respect to case specific experts, Bayer will limit its compensation questioning to the compensation relating to the *Sims* case. The Court adopts that case specific restriction.

11/18/2011	 143	MOTION in Limine No. 6 <i>To Exclude the Presentation of Defendants' Deposition Counter-Designations During Plaintiff's Case-In-Chief</i> by Kerry Sims.
------------	---	---

This motion was argued and ruled on at the December 19th hearing. Plaintiff moved *in Limine* to exclude the presentation of Bayer’s deposition counter-designations during plaintiff’s case-in-chief. The motion was **DENIED IN PART**. For the convenience of the parties, an overview of the Court’s ruling is included below. The entirety of the Court’s order on this motion will be memorialized in the transcript of the December 19th hearing.

FEDERAL RULE OF CIVIL PROCEDURE 32(a)(6) governs this matter. Pursuant to Rule 32(a)(6), when a party offers in evidence only part of a deposition, an adverse party is permitted to introduce other parts of the deposition that in fairness should be considered with the part introduced. The rule contemplates that the

adverse party be able to do so at the time the designated testimony is introduced. This matter will be handled on an individual basis, considering the specific designations. In so deciding, the Court will follow Rule 32(a)(6), however, as the rule reads **only** so much counter designation will be read as is necessary to allow for a **fair** reading of the testimony.

11/18/2011	 144	SEALED MOTION in Limine No. 7 to Exclude Evidence of a Statement Contained in a July 16, 2008 X-Ray Report from St. John's Mercy Medical Center by Kerry Sims.
<p>This motion was argued and ruled on at the December 19th hearing. Plaintiff moved <i>in Limine</i> to exclude evidence of a statement contained in a July 16, 2008 X-Ray report from St. John's Mercy Medical Center. The motion was GRANTED. For the convenience of the parties, an overview of the Court's ruling is included below. The entirety of the Court's order on this motion will be memorialized in the transcript of the December 19th hearing.</p> <p>The Court concluded that the disputed document lacked sufficient trustworthiness and that it would be speculation to conclude that the plaintiff was the source of the disputed statement.</p>		

11/18/2011

 [145](#)

MOTION in Limine [No. 8] *To Preclude Bayer from Certain Pretrial Advertising or Otherwise Engaging in Pretrial Publicity* by Kerry Sims.

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, plaintiff's Motion in Limine No. 8 is **DENIED.**

Plaintiff seeks an order directing Bayer Corporation, Bayer AG, Bayer Healthcare LLC, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Pharma AG f/k/a Bayer Schering Pharma AG, to avoid initiating new advertising and marketing campaigns related to it being a good company that makes life-saving medicines or its birth control products in the greater St. Louis/Southern Illinois market or generating pretrial publicity before jury selection and during the trial in this case.

The Court finds that Bayer denies any intent to engage in such pretrial publicity and plaintiff cannot direct the Court to any specific examples of offending advertising. Further, prior restraint of First Amendment rights is very serious. The Court would have to view the content of specific advertising prior to granting an order prohibiting it.

11/18/2011	 147	MOTION in Limine [No. 9] <i>To Exclude Evidence That Bayer Was Not Permitted to Change the Label of Yaz/Yasmin Without Prior FDA Approval</i> by Kerry Sims.
------------	---	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, plaintiff's Motion in Limine No. 9 is **GRANTED.**

Plaintiff seeks to exclude any evidence, testimony, comment, inference or document that Bayer was not permitted to change the label for YAZ/Yasmin without prior FDA approval. Plaintiff contends that any such evidence must be excluded as irrelevant, unduly prejudicial, and confusing to the jury because FDA regulations and clear Supreme Court precedent establish that such evidence is false. Bayer responds, arguing that, under the circumstances of this case, whether Bayer could have changed the YAZ or Yasmin labeling without prior FDA approval – is a question of fact that is properly decided by the jury based on the evidence at trial.

The Court agrees with plaintiff. The contention that a drug manufacturer cannot change its label to reflect stronger warnings is clearly not the law. Thus, the Court will not permit Bayer to suggest that it cannot change its label to reflect

stronger warnings without prior FDA approval.

11/18/2011	 148	MOTION in Limine [No. 10] <i>To Exclude Evidence Relating to the Amount of Money Bayer Specifically and the Drug Industry Generally Spent on Research and Development</i> by Kerry Sims.
------------	---	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, plaintiff's Motion in Limine No. 10 is **GRANTED**.

Plaintiff seeks to exclude any evidence, testimony, comment, inference or document mentioning the amount of money Bayer specifically and the pharmaceutical industry in general spend on research and development of drugs that do not reach the market, or about the amount spent for research and development for any drug, including YAZ and Yasmin. Plaintiff argues that research and development evidence, even that not specifically related to YAZ/Yasmin, should be excluded because the evidence is irrelevant and its probative value, if any, is substantially outweighed by its prejudicial effect. Further, plaintiff contends, if such evidence were to be admitted, a series of mini trials would result. Bayer responds, arguing that if it is not permitted to present this evidence plaintiff will be able to argue that Bayer did not do enough to

research on the medicine before putting it in the hands of the public.

The Court concludes that Bayer can present evidence to the jury regarding what it did to research the subject drug without translating that into money. The issue is not how much money was spent but what actions were taken to insure that the drug was reasonably safe for human consumption. If Bayer had a monetary cutoff for halting research and development (*i.e.* when research costs reach a certain amount the company stops research regardless of whether the company has obtained sufficient information regarding the drug's safety) then it would be an issue of safety and it would be the plaintiff wanting to talk about it.

In conclusion, Bayer is precluded from presenting the amount of money Bayer specifically and the pharmaceutical industry in general spend on research and development of drugs that do not reach the market, or about the amount spent for research and development for any drug, including YAZ and Yasmin. Bayer's concerns can be adequately addressed by presenting evidence relating to the steps that were taken to insure safety.

11/18/2011	 149	SEALED MOTION <i>Plaintiff's</i> Motion In Limine [No. 11] to Preclude Evidence or Testimony That Plaintiff Kerry Sims Suffered a Pulmonary Embolism On Or Before June 17, 2008 by Kerry Sims.
<p>This motion was argued and ruled on at the December 19th hearing.</p> <p>Plaintiff moved <i>in Limine</i> to exclude evidence or testimony that plaintiff suffered a pulmonary embolism on or before June 17, 2008. The motion was DENIED.</p>		

For the convenience of the parties, an overview of the Court's ruling is included below. The entirety of the Court's order on this motion will be memorialized in the transcript of the December 19th hearing.

The Court disagreed with plaintiff's contention that the testimony of Bayer's experts was contradictory with regard to this issue. The Court concluded, upon considering the testimony of the experts at issue, it is clear that the pertinent testimony in issue comes down to a decision of the fact finder based on the weight and credibility the jury wants to place on these experts opinions.

11/18/2011	 150	SEALED MOTION <i>Plaintiff's Motion In Limine [No. 12] To Exclude Any Specific Causation Opinions By Defense Expert Witness Hematologists</i> by Kerry Sims.
<p>After reviewing Bayer's response to plaintiff's motion <i>in limine</i> No. 12, the Court determined that this issue was not in dispute. Accordingly, the Court entered an order GRANTING plaintiff's motion <i>in limine</i> No. 12 (3:09-10012 Doc. 245).</p>		

11/18/2011	 151	SEALED MOTION <i>Plaintiff's Motion In Limine [No. 13] To Preclude Evidence Or Testimony That Plaintiff's Pulmonary Emboli Were Caused By Prior Use of Oral Contraceptives</i> by Kerry Sims.
<p>This motion was argued and ruled on at the December 19th evidentiary hearing. Plaintiff moved <i>in limine</i> to exclude evidence or testimony that plaintiff's pulmonary emboli were caused by prior use of oral contraceptives. The motion</p>		

was **DENIED**. For the convenience of the parties, an overview of the Court's ruling is included below. The entirety of the Court's order on this motion will be memorialized in the transcript of the December 19th hearing.

The Court concluded that this issue is a matter of weight and credibility. It is clear that this evidence makes plaintiff uncomfortable, however, plaintiff's arguments do not warrant exclusion. The objections asserted by plaintiff can be addressed at trial during cross examination, via the presentation of contrary evidence and/or competing experts, and during closing argument.

11/18/2011	 152	SEALED MOTION <i>Plaintiff's Motion In Limine [No. 14] To Exclude Misleading References That The Plaintiffs' Steering Committee Retained or "Paid" Ojvind Lidegaard, M.D.</i> by Kerry Sims.
------------	---	---

This motion was argued and ruled on at the December 19th evidentiary hearing. Plaintiff moved *in limine* to exclude references that the plaintiffs' steering committee retained or "paid" Ojvind Lidegaard, M.D. The motion was **GRANTED**. For the convenience of the parties, an overview of the Court's ruling is included below. The entirety of the Court's order on this motion will be memorialized in the transcript of the December 19th hearing.

The Court concluded that Dr. Lidegaard's scientific work, analysis, written report, article and conclusions were clearly completed prior to any contact with the plaintiffs. The peer review process was underway when Dr. Lidegaard was

contacted by plaintiff's counsel. Accordingly, allowing Bayer to argue and/or reference Dr. Lidegaard as being on the payroll of the plaintiffs (or similar contentions) would be fundamentally unfair. Further, asserting similar arguments regarding Dr. Lidegaard's work on his reanalysis would also be fundamentally unfair. Thus, Bayer is precluded from presenting anything which would give the jury the impression that there was any relationship between Dr. Lidegaard being retained as an expert witness and his work on the reanalysis. There is no evidence of any quid pro quo agreement. Thus, any innuendo to that effect would be inappropriate and improper. Further, the highlighted portion of the document discussed in open court will be redacted to eliminate any further confusion on the issue.

11/18/2011	 153	MOTION in Limine [No. 15] <i>To Exclude Evidence Relating To The Personal Use Of Yaz/Yasmin By Any Bayer Employees Or Their Family Members</i> by Kerry Sims.
<p>This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, plaintiff's Motion in Limine No. 15 is GRANTED.</p> <p>Plaintiff seeks to exclude any evidence, testimony, comment, inference or document related to personal use of YAZ/Yasmin by Bayer employees or the family members of Bayer employees. Bayer argues that unless evidence is inadmissible on <i>all</i> grounds the motion <i>in limine</i> must be denied. Accordingly,</p>		

Bayer contends, the Court is obligated to wait and see the context in which such evidence is offered before ruling on the motion.

The Court disagrees with Bayer's argument. Bayer could parade employees or non-employees through the courtroom to testify in a manner that is consistent with its theory of the case. The plaintiff could then parade an equal or greater number of other plaintiffs in rebuttal to testify in a manner that is consistent with her theory of the case. This type of anecdotal evidence is either not relevant or is marginally relevant at best depending on one's point of view. The disputed evidence is not probative of the issues at hand. That employees are loyal to the brand label is neither surprising nor probative of the issues at bar. Such evidence is at the very least unduly prejudicial to the plaintiff who is certainly precluded from bringing in an equal or greater number of similarly situated plaintiffs who are not quite as enamored with the product.

The jury will hear about scientific studies and will hear from the plaintiff in this particular case. That will be relevant testimony. What this trial cannot achieve is another scientific study on the realm that was achieved in any of the studies to be discussed by the parties' experts. This case will be difficult enough for a jury without a battle of such advocates and detractors.

11/18/2011	 154	MOTION in Limine [No. 16] <i>To Preclude The Admission Of The Euras Study Into Evidence At Trial</i> by Kerry Sims.
This motion remains in dispute. After fully considering the parties'		

arguments, and for the reasons stated herein, plaintiff's Motion in Limine No. 16 is **DENIED**.

This motion *in limine* relates to Bayer's second motion *in limne* which sought exclusion of evidence and argument about foreign regulatory actions or labeling (Doc. 104).

Plaintiff's motion *in limine* No. 16 seeks an order prohibiting Bayer from introducing evidence, eliciting testimony, making argument, or making any reference to the EURAS study⁴ in the event that Bayer seeks to preclude any evidence relating to actions taken by foreign regulatory agencies with regard to drospirenone-containing oral contraceptives Yasmin and YAZ.

Bayer responds, arguing that actions and decisions by foreign regulatory bodies regarding YAZ and Yasmin are inadmissible, whereas scientific studies, even if conducted overseas, that address the safety and/or efficacy of YAZ or Yasmin are relevant and admissible. Bayer also contends that plaintiff has conceded to the relevance of the EURAS study.

First, the Court has denied Bayer's motion *in limine* No. 2. Thus, evidence relating to actions taken by foreign regulatory agencies with regard to the subject drugs is not precluded. Second, the EURAS study is clearly relevant to matters in issue in this case. Accordingly, plaintiff's motion is denied.

⁴ EURAS stands for European Active Surveillance study. The EURAS study is a published epidemiology study evaluating the safety and/or efficacy of the subject drugs.

11/18/2011	 155	SEALED MOTION <i>in Limine</i> [No. 17] To Limit The Introduction Of Evidence And Testimony Concerning Speculation As To Whether Plaintiff Would Have Had A Pulmonary Embolism Had She Been Using A Different Oral Contraceptive by Kerry Sims.
------------	---	---

This motion remains in dispute. After fully considering the parties' arguments, and for the reasons stated herein, plaintiff's Motion *in Limine* No. 17 is **GRANTED IN PART AND DENIED IN PART.**

Plaintiff seeks to exclude any evidence, testimony, comment, inference or document mentioning certain vague, hypothetical lines of questioning to physician experts. Specifically, plaintiff contends that Bayer should not be allowed to present evidence or elicit testimony from experts regarding whether plaintiff Kerry Sims would still have had a pulmonary embolism on July 18, 2008 had she been using a combination oral contraceptive other than YAZ. Plaintiff argues that any such evidence would be inadmissible due to its speculative nature and lack of relevance to the underlying claims

Plaintiff characterizes this line of inquiry as speculation and protests that it

is beyond the scope of what she is required to prove, *i.e.* that her pulmonary embolism was not caused by some other oral contraceptive or some other factor. Bayer characterizes plaintiff's motion as a *Daubert* motion and therefore untimely. Beyond that, Bayer argues that this line of inquiry is not speculation but a primary element of its defense, *i.e.* that its product was not the precipitating cause of the plaintiff's pulmonary embolism but that another product was.

The Court finds that Bayer is clearly allowed to pursue its theory, but to do so it must not simply ask the expert witnesses to speculate. The jury's verdict in this case must not be based on speculation, guess, or conjecture. Bayer may, however, ask experts question based on hypotheticals.

Therefore, Bayer is **BARRED** from asking its expert witnesses to *speculate* as to whether another oral contraceptive caused plaintiff's pulmonary embolism. However, Bayer's expert witnesses may offer testimony regarding whether another product was the cause of the plaintiff's pulmonary embolism, so long as that testimony is not based on speculation, guess, or conjecture. Bayer may also ask experts questions based on hypotheticals.

11/18/2011	 156	SEALED MOTION <i>In Limine</i> [No. 18] To Exclude Expert Epidemiology Testimony Offered By Unqualified Bayer Employees by Kerry Sims.
<p>The Court will provide a separate written order addressing this motion that will be filed contemporaneously herewith.</p>		

11/18/2011

 [157](#)

SEALED MOTION ***In Limine*** [No. 19] *To Exclude The Statement Contained In A Family And Medical Leave Act Report Signed By Dr. Irwin* by Kerry Sims.

This motion was argued and ruled on at the December 19th hearing. The motion was **GRANTED**. For the convenience of the parties, an overview of the Court's ruling is included below. The entirety of the Court's order on this motion will be memorialized in the transcript of the December 19th hearing.

Plaintiff seeks to exclude any evidence, testimony, comment, inference or document mentioning the statement "June 16, 2008" as the approximate date Plaintiff's condition commenced (hereinafter the "Statement") found in a Family and Medical Leave Act form report signed by Dr. Irwin ("the Report"). Plaintiff contends that the Statement constitutes hearsay without a recognized exception to permit it to be received into evidence. Plaintiff further contends that the FMLA forms do not qualify for the business record exception because they contain a mistake and therefore by operation of the Rule 803 lack trustworthiness and therefore are inadmissible. Dr. Irwin has submitted two affidavits indicating that the Statement is a mistake.

Bayer argues that the FMLA forms meet the test of the business record exception and that the Statement is proper for use of impeachment of Dr. Irwin, noting that Dr. Irwin was not just plaintiff's treating physician but is also a family friend and his credibility is subject to being tested on the matters at issue.

To be admissible as a business record, neither the source nor the method of circumstance of preparation must indicate a lack of trustworthiness. With the affidavit from Dr. Irwin indicating that both forms are a mistake, it is clear there is a lack of trustworthiness. The Court concludes that the Statement is hearsay and the business record exception does not apply to make it otherwise admissible because of the inability to meet the trustworthiness test in light of Dr. Irwin's affidavits. The motion is **GRANTED** unless and until Bayer has a witness in court to inquire of and can get around the hearsay issue.

11/18/2011	 158	SEALED MOTION <i>In Limine</i> [No. 20] To Exclude Argument Regarding The "Age" Of Plaintiff's Pulmonary Embolus by Kerry Sims.
Plaintiff has conceded and withdrawn motion <i>in limine</i> No. 20.		

11/18/2011	 159	SEALED MOTION <i>In Limine</i> [No. 21] To Preclude Defendants From Limiting Evidence Of Punitive Damages To Sales Of Yaz Within The State by Kerry Sims.
<p>In accord with the Court's ruling on Bayer's motion to exclude the testimony of Robert Johnson (Case Management Order No. 52 MDL 2100 Doc. 2187) and with the Court's ruling on the motion for summary judgment filed in the <i>Sims</i> case (3:09-10012 Doc. 257), plaintiff's motion <i>in limine</i> No. 21 is GRANTED. Accordingly, Bayer is BARRED from limiting evidence of punitive damages to sales of YAZ within the state.</p>		

IT IS SO ORDERED.



 David R. Herndon
 2011.12.22
 12:56:06 -06'00'

**Chief Judge
United States District**

Date: December 22, 2011