

**IN THE UNITED STATES DISTRICT COURT FOR THE  
WESTERN DISTRICT OF MISSOURI  
CENTRAL DIVISION**

CHRISTINE WINTER, Individually, )  
and as Personal Representative of the )  
Estate of RUTH BALDWIN, )  
 )  
Plaintiff, )  
 )  
v. )  
 )  
NOVARTIS PHARMACEUTICALS )  
CORPORATION, )  
 )  
Defendant. )

No. 06-4049-CV-C-MJW

**ORDER**

A pretrial conference was held on February 29, 2012, with counsel for all parties participating in person. The Court heard argument on the parties’ Daubert motions and motions in limine.

The Court’s rulings on the Daubert motions were set forth on the record at the conference, and will be finalized in a separate written order. The motions in limine were also ruled on the record at the February 29 conference. The instant order is a written summary of the rulings on the motions in limine.

**Plaintiff Christine Winter’s Motions in Limine**

I. Plaintiff’s motion seeking to exclude NPC’s Learned Intermediary Defense is denied. Defendant has not waived the applicability of the Learned Intermediary Doctrine to the facts before the Court. However, plaintiff asserts that the Missouri Court of Appeals for the Western Division has just issued an opinion which may change the Court’s view of this issue. Consequently, the Court will reserve a final ruling until the Court and parties have had an opportunity to analyze the decision.

II. Plaintiff’s motion seeking to exclude the February 14, 2012 Supplemental Report of Kelly Pendergrass, M.D., is granted as unduly prejudicial to the plaintiff. The detailed reasons for this decision are set forth in the record.

III. Plaintiff's motions seeking to exclude a multitude of evidence in subsections (a)-(j) as not relevant are denied. However, the Court will permit objections at trial on these issues. The Court notes, however, that subsection (f) is moot because the defendant has agreed not to ask Dr. Marx whether he examined plaintiff.

**Defendant Novartis Pharmaceuticals Corporation's Motions in Limine**

I. NPC's motion seeking to exclude ex parte statements by Ms. Baldwin is granted. However, if at trial these statements become relevant for purposes of cross-examination or rebuttal, plaintiff may bring the issues to the Court's attention for reconsideration.

II. NPC's motion seeking to exclude evidence based on incorrect duty to warn under Missouri law is granted. The Court will follow Missouri law on the issue of duty to warn. Missouri law on duty to warn is admissible for purposes of determining whether the warning at issue was adequate.

III. NPC's motion to exclude evidence which is dated or occurred after the date of October 21, 2004, is granted. However, plaintiff may seek reconsideration of this ruling, if she can show that documents dated after October 21, 2004, or other evidence occurring after October 21, 2004, is relevant to what occurred prior to the date of October 21, 2004.

IV. NPC's motion seeking to exclude evidence or argument that NPC should have warned prior to September 2003 is denied.

V. NPC's motion to exclude testimony concerning plaintiff's expert witnesses' experiences with ONJ patients is denied.

VI. NPC's motion to exclude Adverse Drug Experience Reports is granted, in part, and denied, in part. Any Adverse Drug Experience Reports prior to October 21, 2004, are admissible. Any reports after October 21, 2004, are not admissible unless plaintiff's counsel can show why they would be relevant.

VII. NPC's motion to exclude certain corporate documents is granted, in part, and denied, in part, as follows:

A) January 31, 2005 email from Petraglia is not going to be offered, and therefore, the motion to exclude is denied as moot;

B) June 15, 2005 email from Sabliska to Cook is admissible and the motion in limine is denied;

C) January 18, 2004 letter from Klein to Dunsire is admissible and the motion in limine is denied. However, the Court may reconsider this issue at trial if an objection is made by NPC at the time the document is offered;

D) March 12, 2004 email from Senior Medical Information Specialist Weiss is admissible, and the motion in limine is denied;

E) May 5, 2003 email from Fratarcangeli to Epstein is admissible and the motion in limine is denied;

F) June 20, 2003 email from Goessl to Hei is admissible, and the motion in limine is denied;

G) July 10, 2003 email from Goessl to Hei is admissible, and the motion in limine is denied; and

H) December 1, 2003 email from Linguri to Dunsire and attached agency is admissible and the motion in limine is denied.

VIII. NPC's motion to exclude statements in Ms. Baldwin's medical records is denied. However, at trial, the Court may reconsider as to specific entries if NPC raises an objection.

IX. The Court denies NPC's motion to exclude evidence regarding alternative dosing. The Court has reviewed the decisions of other courts which were submitted by the parties. While the email of January 29, 2003, is arguably prejudicial to NPC, it may be highly relevant to the issue of punitive damages. In addition, the email deals with a Japanese study on Zoledronic acid, the active ingredient in Zometa. The email discusses what NPC learned from the study on dosing regimes, and references Zometa on several different occasions. NPC can attempt to demonstrate to the jury through cross-examination why the email is not relevant.

X. NPC's omnibus motion in limine is granted, in part, and denied, in part.

A) To the extent some of these documents are the same as those set forth in Section VII, this Court rules consistent with those prior rulings. Further, only those portions of the "White Paper" underlined by Dr. Tarassoff, and then sent on with comments to the rest of the group are admissible as admissions by a party opponent. All

of the remaining out-of-court comments made by the panel of physicians and oral surgeons regarding NPC's draft "White Paper" on ONJ are excluded as hearsay.

B) NPC's motion to exclude testimony as to Dr. Noopur Raje is granted. Plaintiff may seek reconsideration at trial if necessary, but must ensure that issues are brought to the Court's attention first.

C) After withdrawal of the offer of evidence, NPC's motion seeking to exclude "Recommendations from the Osteonecrosis of the Jaw Advisory Panel" is denied as moot.

D) NPC's motion seeking to exclude a statement made by Dr. Jack Gotcher at the Annual AAOMS meeting in September 2005 is granted. If plaintiff seeks to offer this evidence for impeachment purposes at trial, she must first bring it to the Court's attention.

E) NPC's motion to exclude sales and marketing materials is denied. Plaintiff must lay the proper foundation, and the materials must be those from October 21, 2004, or before.

F) NPC's motion to exclude testimony or evidence that NPC misled, deceived, or defrauded FDA about Zometa is denied. However, Dr. Parisian cannot testify as to the subjective state of mind of anyone at NPC. Dr. Parisian will be allowed to testify consistent with the Court's ruling on the Daubert motion..

G) Miscellaneous

1. Motion to exclude evidence that articles concerning bisphosphonates in medical journals were actually "ghostwritten" by companies, including NPC, is granted consistent with prior rulings. Plaintiff further indicated at pretrial conference she had no intention of offering such evidence at trial.

2. NPC's motion to exclude evidence concerning foreign regulatory actions or materials is granted. However, the Court reserves ruling on whether the Australian email is admissible. The January 29, 2003 Epstein email with regard to the Japanese study is admissible as set forth above.

3. NPC's motion to exclude discovery disputes is granted. If there are any discovery disputes that parties want to raise in the presence of the jury, the parties are to discuss the issue with the Court first, out of the hearing of the jury.

4. NPC's motion seeking to exclude characterization of NPC counsel in a manner that could prejudice NPC is moot. Plaintiff has assured the Court she has no intention of characterizing defense counsel in this manner.

5. NPC's motion seeking to exclude reference to drug companies as having an incestuous relationship with the FDA is granted. Plaintiff assures the Court she has no intention of using the term "incestuous relationship" at trial. Nevertheless, the Court specifically directs Dr. Parisian not to make this specific statement. However, Dr. Parisian may discuss the type of relationship that exists between the FDA and drug companies.

6. NPC's motion seeking to exclude reference to Dr. Parisian as the "former Chief Medical Officer" is granted, in part. Plaintiff may not assert that Dr. Parisian was "the" former Chief Medical Officer of the FDA, but may assert she was "a" former Chief Medical Officer of the FDA.

7. NPC's motion seeking to exclude reference to dental pain that jurors may have experienced and the treatment they received is denied. Plaintiff is advised not to go too far with this type of reference. The Court will entertain an objection if appropriate at trial.

8. NPC's motion seeking to exclude expert opinions which may be offered in an attempt to allege "moral obligations" or "legal conclusions" is granted. This ruling is granted subject to relevant prior rulings on this issue, including the testimony of Dr. Parisian.

9. NPC's motion seeking to exclude evidence or argument regarding regulatory enforcement or interactions between FDA and NPC concerning drugs other than Aredia or Zometa is denied.

10. NPC's motion seeking to exclude references to Dr. Marx's lack of compensation for his testimony is denied.

11. NPC's motion seeking to exclude reference to NPC's corporate structure or the fact that NPC is based in Switzerland is granted, in part, and denied, in part. Plaintiff cannot make inappropriate argument referencing that this is a Swiss company and that "they are not one of us"; however, there is no basis for the parties to redact or alter any testimony relating to the fact that NPC is a corporation based in Switzerland for this purpose.

12. NPC's motion seeking to exclude reference to other litigation involving bisphosphonates is granted, in part, and denied, in part. The parties should avoid undue reference to other litigation. However, it may be necessary to reference sworn testimony from other litigation during trial, particularly during cross-examination. The parties should proceed consistent with the direction provided by the Court during the pretrial conference.

IT IS SO ORDERED. [142, 147]

Dated this 8<sup>th</sup> day of March, 2012, at Jefferson City, Missouri.

/s/ *Matt J. Whitworth*

MATT J. WHITWORTH  
United States Magistrate Judge