UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Candice Kruszka and Alan Kruszka,

Plaintiffs,

v.

Novartis Pharmaceuticals Corporation,

Defendant.

Civil No. 07-2793 (DWF/JJK)

ORDER

John A. Girardi, Esq., and Molly B. Weber, Esq., Girardi & Keese; John J. Vecchione, Esq., Valad & Vecchione PLLC; Yvonne M. Flaherty, Esq., Elizabeth R. Odette, Esq., and Robert K. Shelquist, Esq., Lockridge, Grindal, Nauen, PLLP, counsel for Plaintiffs.

Donald R. McMinn, Esq., Katharine R. Latimer, Esq., and Peter J. Skalaban, Jr., Esq., Hollingsworth LLP; Amy R. Fiterman, Esq., Christine R. M. Kain, Esq., Demoya R. Gordon, Esq., James A. O'Neal, Esq., Joseph M. Price, Esq., Linda S. Svitak, Esq., and M. Joseph Winebrenner, Esq., Faegre Baker Daniels LLP, counsel for Defendant.

This matter came before the Court for pretrial hearing on July 16, 2014. Consistent with, and in addition to the Court's rulings and remarks from the bench, and based upon the memoranda, pleadings, and arguments of counsel, and the Court having reviewed the contents of the file in this matter and being otherwise duly advised in the premises, the Court hereby enters the following:

ORDER

1. Plaintiffs' Motion to Enforce the Pretrial Scheduling Order (Doc. No. [211]) is **GRANTED IN PART AND DENIED IN PART** as follows and consistent

with the Court's rulings from the bench and its Memorandum Opinion and Order on summary judgment (Doc. No. 202):

a. Plaintiffs' motion is **GRANTED** to the extent Plaintiffs seek to preclude Defendant from pursuing the depositions of Mr. Osland and McKesson Corporation. Defendants may not take these depositions, however, the Court reserves the right to order any *de bene esse* depositions on this matter should they become necessary over the course of trial.

b. Plaintiffs' motion is **DENIED** to the extent that Plaintiffs are precluded from arguing the Plaintiff Candice Kruszka ("Kruzska") received infusions of name brand Aredia® after January 2002, or after such time as Aredia® was no longer supplied to the Mercy Medical Center in Iowa as reflected in the Mckesson Sales Report.

c. Plaintiffs' motion is **DENIED** to the extent that the Court deems admissible the McKesson Sales Report attached to the declaration of Steve Lewis as a business record under Federal Rule of Evidence 803(6).

d. The Court expressly reserves the right to rule once all submissions are made by the parties on Defendant's Motion for Discovery Sanctions (Doc. No. [310]). However, irrespective of the Court's ruling on Defendant's motion for discovery sanctions pending before the Court, there are evidentiary implications relating to the complaint that was filed by Kruszka against generic pamidronate manufacturers Bedford Laboratories and APP Pharmaceuticals in 2011, *In re: Pamidronate Prods. Liab. Litig.*,

MDL No. 09-md-2120 (E.D.N.Y.) (the "lawsuit against Generic Manufacturers"), that will arise during the trial.

2. Defendant's Motion *in Limine* to Exclude Evidence of 2006 Mayo Clinic Consensus Statement (Doc. No. [220]) is **GRANTED IN PART AND DENIED IN PART** as follows:

a. The Court concludes that to the extent Plaintiffs seek to introduce the 2006 Mayo Consensus Statement to show what physicians *would* have done at the time of Kruszka's treatment, or that the guidelines themselves *would* have been released earlier, the evidence is presumptively inadmissible pursuant to the Court's Article 4 and Article 7 analysis.

b. However, assuming that proper foundation is established pursuant to Rule 104 of the Federal Rules of Evidence establishing notice to or knowledge on the part of Novartis and other entities and individuals within the medical pharmaceutical community, and if offered for issues other than those outlined in Section (a), above, examination of Plaintiffs' and Defendant's witnesses as it relates to the 2006 Mayo Clinic Consensus Statement shall be permitted, subject to whatever objections respective counsel make as each witness is questioned. The Court expressly reserves ruling on any Rule 803(18), Rule 403, or Rule 703 issues.

c. Absent further ruling by the Court, there shall be no reference to the 2006 Mayo Consensus Statement in the opening statements of either Plaintiffs or Defendant.

3. Defendant's Motion *in Limine* to Exclude Certain Documents Containing Hearsay Statements (Doc. No. [226]) is **GRANTED IN PART AND DENIED IN PART** as follows:

a. Subject to foundation being established, the statements made in reference to the drafting process of the "White Paper" from Dr. Schubert and Dr. Huff shall be presumptively admissible on one or both of the following grounds:

i. In the event the statements are introduced for the truth of the matter asserted, they shall be received as a business record pursuant to Rule 803(6).

ii. In the event the statements are received as non-hearsay, in other words regardless of the truth or falsity, for the purpose of showing what Novartis was told, and what, if any, reaction Novartis had to these statements, regardless of whether they were true or false.

iii. In the event the statements are received, they will not be received as pattern or habit evidence pursuant to Rule 404(b) or as admissions of a party opponent.

b. Counsel for the Plaintiffs stated at the pretrial hearing on July 16, 2014, that Plaintiffs will not be offering the September 2005 statement by Dr. Gultcher at an AAOMS Annual Meeting.

c. However, absent further ruling by the Court, there shall be no reference to the edits to or comments regarding the so-called "White Paper" in the opening statements of either Plaintiffs or Defendant.

d. The Court reserves the right to make additional rulings on issues related to the "White Paper" and edits and comments to the "White Paper" at trial.

4. Defendant's Motion *in Limine* to Exclude Speculative Testimony Regarding Other Treater's Knowledge and State of Mind (Doc. No. [233]) is **GRANTED IN PART AND DENIED IN PART** as follows:

a. The motion is **DENIED** to the extent Defendant seeks to exclude the testimony of Dr. Kraut.

b. Subject to foundation being established, testimony by Dr. Kraut relating to the general understanding of the dental profession as it related to ONJ at the time of Kruszka's treatment is presumptively admissible.

c. The Court reserves the right to limit the scope of Dr. Kraut's testimony at trial, if necessary.

d. However, any state of mind testimony by Dr. Kraut relating to what other doctors did or would have done is presumptively inadmissible.

5. Defendant's Motion *in Limine* to Exclude Evidence Related Only to Zometa® (Doc. No. [246]) is **DENIED** as follows:

a. The motion is **DENIED** to the extent Defendant seeks to exclude any and all documents and testimony relating only to Zometa®.

b. The Court reserves the right to examine Zometa®-only documents on a case-by-case basis at trial.

c. The Court notes the parties have agreed to not offer the "Zometa Turnaround Plan" which the Court otherwise deems inadmissible pursuant to Article 4.

6. Defendant's Motion *in Limine* to Exclude May 5, 2003 Email from Stefano Fratarcangeli to David Epstein (Doc. No. [252]) is **DENIED** as follows:

a. Subject to foundation being established, the email shall be presumptively admissible. The Court makes this decision pursuant to Rule 104 and Rule 403, finding that the issue of notice and knowledge of Novartis regarding bisphosphonate-related ONJ is relevant and not unduly prejudicial.

b. However, there will be no reference to the email in Plaintiffs' opening statement.

7. Defendant's Motion *in Limine* to Exclude Labeling and Dosing Issues Controlled by FDA (Doc. No. [258]) is **DENIED** as follows:

a. The Court declines to preclude Plaintiffs from offering evidence that Defendant should have changed the FDA-approved label by recommending a different dosing regimen, consistent with the analysis of

the court in *Dopson-Troutt v. Novartis Pharms. Corp.*, 975 F. Supp. 2d 1209, 1217-18 (M.D. Fla. 2013).

b. The Court reserves the right to exclude this evidence and testimony at trial, on a case-by-case basis.

8. Defendant's Motion *in Limine* to Exclude Evidence Post-Dating Plaintiff's Last Dose of NPC's Product, Brand-Name Aredia® (Doc. No. [264]) is **GRANTED IN PART AND DENIED IN PART** as follows:

a. The motion is **DENIED** as premature.

b. The Court declines to draw an absolute time boundary for all evidence post-dating Kruszka's last dose of name-brand Aredia®. Certain documents after January 2002 could bear on relevant issues. For example, certain documents could have been developed before, but published after, Kruzska's last dose. Certain documents may also tie to Aredia® insofar as questions of half-life are at issue.

c. The Court reserves the right to exclude this evidence and testimony at trial on a case-by-case basis.

9. Plaintiffs' Omnibus Motion *in Limine* to Exclude Certain Subjects of Evidence at Trial (Doc. No. [280]) is **GRANTED IN PART AND DENIED IN PART** as follows:

a. Plaintiffs' Motion with respect to Category 1 (all evidence, argument, comment, references, or eliciting any testimony which expands the use or efficacy of Aredia® or Zometa® beyond the FDA approved

indications at the time Mrs. Kruszka received the drugs as specified within the "four corners" of the package insert/label, including but not limited to statements calling Aredia® a "cancer drug," a "wonder drug," a "miracle drug," that Aredia® "prolongs life," "extends life," is "a pain reliever," "cures cancer," "fights cancer," or any statement that Mrs. Kruszka's life has been extended by Aredia®) is **GRANTED IN PART AND DENIED IN PART** as follows:

i. Defendant is not limited to the "four corners" of the package insert/label with respect to testimony or evidence of the efficacy or benefits of Aredia®, but the Court reserves the right to exclude this evidence and testimony at trial on a case-by-case basis.

ii. However, Defendant is precluded from using the following phrases as they relate to Aredia®: "wonder drug," "miracle drug," "prolongs life," "extends life," and "cures cancer," which are presumptively inadmissible under Article 4.

iii. Subject to foundation being established, the Court concludes that the statements "improves quality of life," "decreases potential skeletal related events," and "fights cancer" are presumptively admissible.

iv. The admissibility of this category of testimony will relate in substantial part to the treating physicians' testimony and evidence presented via medical records.

b. Plaintiffs' Motion with respect to Category 2 (any evidence, argument, comment, or testimony suggesting that Plaintiffs' damages may be offset by the benefits of Aredia®) is **GRANTED IN PART AND DENIED IN PART** as follows:

i. Defendant is precluded from arguing that damages may be offset by the benefits of Aredia®. The Court concludes that the benefits sought by Defendant are not the type contemplated by the Restatement (Second) of Torts § 902 justifying equitable relief. Even if the benefits at issue were of the kind contemplated by the Restatement (Second) of Torts § 902, on the record before the Court they would be entirely speculative.

ii. However, this ruling is to be consistent with the Court's decision above (Section 9.a.) as it relates to Plaintiffs' Motion with respect to Category 1 and the admissibility of testimony and evidence relating to efficacy and benefits of Aredia® generally.

c. Plaintiffs' Motion with respect to Category 3 (any evidence, whether direct or indirect, that Plaintiffs are covered by some form of

insurance for the incident in question) is **DENIED AS MOOT** and in accordance with the agreement of the parties.

d. Plaintiffs' Motion with respect to Category 4 (any evidence of irrelevant prior personal history, specifically that they filed for reorganization in Bankruptcy Court) is **GRANTED** as follows:

i. Testimony and all other evidence relating to Kruszka's personal bankruptcy filings are presumptively inadmissible pursuant to Rule 104 and Article 4, particularly pursuant to Rule 403.

ii. The Court also declines to assert the doctrine of judicial estoppel with respect to Plaintiffs' bankruptcy proceedings as Defendant has failed to adequately meet the factors or other considerations outlined in *Stallings v. Hussmann Corp.*, 447 F.3d 1041, 1047 (8th Cir. 2006).

10. Defendant's Objections to Plaintiffs' Designation of Prior Sworn Testimony for Dr. Marx, Dr. Salvatore Ruggerio, and Ray Watkins (Doc. No. [302]) is **GRANTED IN PART AND DENIED IN PART** as follows:

a. Plaintiffs shall present any testimony from Dr. Marx live. Dr. Marx is one of Plaintiffs' key witnesses. This cases deviates from most cases where the Court receives early requests to accommodate witnesses when there is concern over their availability, particularly for key witnesses. Here, the Court notes that Plaintiffs made no request for a continuance of

the trial or for different trial dates based on the unavailability of any witnesses. The decision of the court is also made pursuant to Rule 102 of the Federal Rules of Evidence and Rules 1 and 43 of the Federal Rules of Civil Procedure.

b. Plaintiffs may present testimony by Dr. Ruggerio, but it shall be limited to his testimony relating to his interactions and conversations with Novartis and its reactions, subject to other evidentiary determinations by the Court. The Court notes that evidence on this issue may or may not necessitate the use of Dr. Ruggerio's deposition testimony.

c. Plaintiffs may not present the testimony of Mr. Watkins. The decision of the court is also made pursuant to Rule 102 and Article 4 of the Federal Rules of Evidence and Rules 1 and 43 of the Federal Rules of Civil Procedure.

d. Defendant's request to submit a reply memorandum (Doc. No. [309]) is denied as moot in light of the Court's decision above.

11. Plaintiffs' Request for the Court to Take Judicial Notice of Voluntary Dismissal of Lawsuit Against Generic Manufacturers Signed by Counsel for Defendant (Doc. No. [305]) is **GRANTED IN PART AND DENIED IN PART** as follows:

a. Subject to foundation being established, the Court concludes that the testimony regarding the fact of and information relating to the filing of the lawsuit against Generic Manufacturers will be presumptively admissible.

The fact of a dismissal is of little probative value in a civil jury trial without an explanation as to what a dismissal represents, including but not limited to the factual and legal reasons for dismissal, all of which raise Rule 403 issues.

b. Absent further ruling by the Court, there shall be no reference to the lawsuit against Generic Manufacturers in the opening statements of either Plaintiffs or Defendant.

c. The Court reserves the right to limit the scope of testimony at trial, if necessary. The Court expects parties to make a Rule 104 offer of proof prior to referencing the lawsuit.

Opening Statements

12. Plaintiffs and Defendant shall each be allotted 45 minutes for opening statements.

Dated: July 23, 2014

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge