

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA**

JOHN BARTOLI,	:	
Plaintiff	:	CIVIL ACTION NO. 3:13-0724
v.	:	
		(JUDGE MANNION)
NOVARTIS PHARMACEUTICALS CORPORATION,	:	
Defendant	:	

ORDER

In light of the memorandum issued this same day, **IT IS HEREBY ORDERED THAT:**

- (1) Defendant's motion to exclude the testimony of Dr. Skubitz, (Doc. [183](#)), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** as to Dr. Skubitz's observations regarding the incidence of ONJ in his own patients after he implemented a reduced dosing regimen, and **DENIED** as to testimony regarding the benefits of alternative dosing, the benefits of pre-therapy dental screening, and incidence of ONJ;
- (2) Defendant's motion to exclude the testimony of Dr. Marx, (Doc. [185](#)), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** as to testimony regarding whether NPC engaged in "bad faith" conduct, and the adequacy of the clinical trials. Defendant's motion is **DENIED** as to opinions

on preventative dental screenings, the opinion that some of the clinical trial patients had ONJ, general causation opinions based on adverse event reports, and opinion of the biological mechanism by which BPs allegedly cause ONJ;

- (3) Defendant's motion to exclude the testimony of Dr. Suzanne Parisian, (Doc. [187](#)), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** as to testimony of NPC's intent, pharmaceutical industry ethical standards, ghostwriting, and undisclosed company funding of publications, and causation. Defendant's motion is **DENIED** as to opinions regarding regulatory compliance and the reasonableness of NPC's conduct in its interactions with the FDA and compliance with FDA regulations;
- (4) Defendant's motion to exclude the testimony of Prof. Wayne Ray, (Doc. [189](#)), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** as to the Table 6 meta-analysis and the use of the word "rare" in relation to the incidence rate. Defendant's motion is **DENIED** as to the Table 5 meta-analysis, the biological plausibility that BPs cause ONJ, the opinion that a causation determination could have been reached in 2003, and an opinion that the incidence rate of ONJ in BP users is 5%, and;

(5) Defendant's motion to exclude the testimony of Dr. James Vogel, (Doc. [191](#)), is **GRANTED IN PART AND DENIED IN PART**. Defendant's motion is **GRANTED** to the extent that Dr. Vogel may not opine as to the intent or motive of NPC. Defendant's motion is **DENIED** as to testimony regarding pre-dental screenings, incidence rate of ONJ in patients, alternative BP dosing regimens, and the biological mechanism by which BPs affect the jaw bone.

s/ Malachy E. Mannion
MALACHY E. MANNION
United States District Judge

Date: April 17, 2014

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