UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

PRESCOTT ARNOLD,

Plaintiff,

v. CASE NO. 8:06-cv-1709-T-23MAP

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.
_____/

ORDER ON OMNIBUS MOTION #1

In an "omnibus motion *in limine*" (Doc. 74), Novartis seeks a series of evidentiary exclusions. Arnold responds (Doc. 86) in opposition. The issues, as denominated by Novartis in "Motion #1" of document 74, are resolved as follows:

A. Mrs. Arnold never treated with Aredia

This objection is sustained to the extent that in questions, in argument, and otherwise, the attorneys must take care to practice, and in witnesses' answers the attorneys must endeavor to elicit, only the precise use of the terms "Zometa," "Aredia," and "pamidronate," which are not synonyms and which shall not be used interchangeably. Counsel must observe and maintain the distinction between each one and the other two.

B. Tooth extraction by Jones

Jones's statement to Mrs. Arnold and other events in the pertinent history are admissible, at least over this relevancy objection. However, Jones's supposition about what treatment he might have administered (or excluded) as the treating physician of Mrs. Arnold, unless that supposition was his then-existing determination and is otherwise unobjectionable, is inadmissible.

C. Treatment of non-party patients

Novartis objects to evidence of treatment of other ONJ patients by John Peterson and Robert Marx. Arnold explains that this evidence is pertinent to Peterson's and Marx's expertise, which is perhaps true to the extent of establishing their knowledge of patients with the same diagnosis and treatment as Mrs. Arnold. Ruling on this objection is deferred until the witness testifies because the purpose and probative value of the testimony and the extent of the detail necessary to achieve a stated, legitimate, evidentiary purpose is unclear in these papers.

D. Decisions by other patients

Novartis objects to evidence of the rejection of Zometa by other patients. The objection is sustained. This evidence ranges unproductively far from the claims and defenses in this action.

E. Evidence pertaining to punitive damages

Novartis objects to admission of evidence pertaining to punitive damages. With respect to evidence pertaining solely or principally to punitive damages, the motion is granted because punitive damages is not an issue in this action. With respect to other evidence, the normal test of Rules 401 through 403 (or another rule in the proper circumstance) will govern admissibility.

F(1). Duty to recommend a dental examination

Because Mrs. Arnold reportedly needed no dental examination and because her extractions were reportedly "necessary and unavoidable," Novartis seeks to exclude evidence of "an alleged duty to recommend a dental examination" before treatment with Zometa or Aredia and "to avoid . . . invasive dental procedures." Arnold responds that Novartis sends a "Dear Doctor" letter to recommend dental examination and to warn against invasive procedures and that "this is the standard of care." Arnold established little foundation of relevance of this evidence to the present case, which involves failure to warn of a danger and not breach of the standard of care. This objection is sustained without prejudice to Arnold's raising the issue at trial – of course, not within the hearing of the jury – if a predicate of relevance appears.

F(2). Duty to warn dental care provider

Novartis seeks to exclude evidence and argument based on a duty to warn persons other than the prescribing physician – "the learned intermediary" – of risks about which Novartis knew or should have known. Arnold argues that the duty is broader and includes a duty to warn, at least, a dentist, who did not prescribe but who reportedly could, if warned, mitigate the injury. Although Arnold asserts that "there is no question" about the reach of the duty in Florida to warn others beyond a prescribing physician, *Hoffman-LaRoche v. Mason*, 27 So. 3d 75 (1st DCA Fla. 2009); *Levine v. Wyeth*, 2010 WL 5137424 (M.D. Fla. 2010); and *Sager v. Hoffman-LaRoche*, 2012 WL 3166630 (N.J. Super. App. Div. 2012), establish that Florida law at this moment limits the duty to warn to the prescribing physician. Judge Presnell's ruling in *Guenther v. Novartis*, 2013 WL 4648449 (M.D. Fla 2013), and his instruction to the jury in that action, Case No. 6:08-cv-456 (Doc. 291 at 137; Doc. 276 at 15) ("The duty to warn is fulfilled by an adequate warning given to prescribing and other healthcare providers who are in a position to reduce the risk of harm to the patient."), might (or might not) express a wise rule, the Restatement's rule, or even the future rule in Florida, but no authority is cited by Arnold (and none is available) to establish that "other healthcare providers" are part of Florida's present rule governing a pharmaceutical manufacturer's duty to warn.

In *Guenther*, Judge Presnell cites the use in *Buckner v. Allergan Pharmaceuticals, Inc.*, 400 So. 2d 820, 822 (Fla. 5th DCA 1981), of the phrase "those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs" as suggesting an expanded duty to warn. Just a few paragraphs further, however, *Buckner* explains and focuses:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

400 So. 2d at 822. As recently as *Guarino v. Wyeth*, 719 F.3d 1245 (11th Cir. 2013), Florida's rule has retained its force:

> Under Florida law, "it is clear that the manufacturer's duty to warn of [a prescription drug's] dangerous side effects [is] directed to the physician rather than the patient." *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989). That is so because the prescribing physician, acting as a "learned intermediary" between the manufacturer and consumer of the drug, weighs the drug's benefits against its potential harms in deciding whether it is appropriate to the patient's course of treatment. *Id.* "The learned intermediary rule is a corollary to the rule that a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products." *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995). "Pharmaceutical manufacturers discharge their duty to warn the learned intermediary by way of a package

> insert which accompanies each vial of vaccine." *E.R. Squibb & Sons, Inc. v. Farnes*, 697 So. 2d 825, 827 (Fla. 1997) (internal quotation marks omitted); *see Buckner v. Allergan Pharms., Inc.*, 400 So. 2d 820, 822 (Fla. Dist. Ct. App. 1981) ("A manufacturer of a dangerous commodity, such as a drug, does have a duty to warn but when the commodity is a prescription drug we hold that this duty to warn is fulfilled by an adequate warning given to those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs.").

719 F.3d at 1250.

The objection is sustained accordingly.

F(4). Evidence pertaining to advertisements or other promotional material

Absent the establishment of a proper factual predicate that Mrs. Arnold's oncologist or Mrs. Arnold viewed, or otherwise acquired timely knowledge of, promotional material, the objection to introduction of that material is sustained. This action questions the circumstances actually affecting Mrs. Arnold and her doctors and not some hypothetical or abstract patient or doctor.

G. References to Reclast

Novartis moves to exclude evidence of an advisory panel on Novartis's Reclast, which is reportedly not a treatment intended for cancer patients. Arnold says "it is clearly relevant" but omits to identify the issue to which this evidence is relevant. The evidence is probably irrelevant and, if relevant, probably fails the test of Rule 403. Ruling is deferred, but Arnold may not offer this evidence without notice in advance (as always, outside the hearing of the jury) to the court and Novartis.

H. Articles on ONJ as proof of causation

Novartis objects to evidence and argument about the number of articles supporting a particular view on the subject of causation. Arnold responds only that "[t]his is scientific literature that [has] been allowed and admitted in all trials . . ." in the Middle District. This evidence is received, if at all, only in accord with Rule 803(18), Federal Rules of Evidence. In all events, the literature itself is inadmissible. With a proper foundation, a statement from the literature might enter evidence in an answer from an expert witness to a proper inquiry.

I. Evidence of Arnold's decision to follow her oncologist's recommendation

Novartis objects to evidence "that Mrs. Arnold would not have taken Aredia/pamidronate or Zometa if she had been warned about any risk of ONJ." This objection is sustained for the reasons stated in the ruling in paragraph F(2).

J(1 through 3). Internal NPC documents

As each party concedes, this action presents an issue, although presented in more than one claim for relief, about the alleged failure to adequately warn Mrs. Arnold's prescribing physician about risks allegedly associated with Zometa and Aredia. If the warnings were adequate, the plaintiff's case fails despite the subjective intent and character of the manufacturer; if the warnings were inadequate, the plaintiff's case succeeds despite the subjective intent and character of the manufacturer. Causation exists or not regardless of intent and character. Damages

resulted or not regardless of intent and character. Even if otherwise unobjectionable, evidence of less than commendable intent and character tends to inflame and must offer a dominant tendency to inform. These three contested memoranda are admissible, if at all, to show knowledge of some relevant fact (perhaps a fact inconsistent with, or explanatory of, some present contention by a party or witness). Because the state of the trial record will inform the Rule 403 balance, this objection is overruled without prejudice to renewal if Arnold offers a contested exhibit at trial.

ORDERED in Tampa, Florida, on July 1, 2014.

STEVEN D. MERRYDAY
UNITED STATES DISTRICT JUDGE