UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

KARLEEN HOGAN, surviving spouse and executor of the Estate of Timothy Hogan, deceased,	:	**MEMORANDUM DECISION AND ORDER**
Plaintiff,	:	06 Civ. 0260 (BMC) (RER)
-against-	:	
NOVARTIS PHARMACEUTICALS CORPORATION,	:	
Defendant.	:	

COGAN, District Judge.

The parties have filed a significant number of motions *in limine*. This decision disposes of the motions that the parties have advised the Court continue to be disputed, and it grants, in part, defendant's motion to exclude the testimony of one of plaintiff's experts, while limiting the testimony of the other two.

BACKGROUND

Before the Court are the parties' motions *in limine*, including defendant's motion to exclude testimony of plaintiff's experts pursuant to Rule 702 of the Federal Rules of Evidence and Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993). Familiarity with the underlying proceeding is presumed. Although plaintiff pled other causes of action in the complaint, according to the Joint Pretrial Order (JPTO), she is now pursuing only two common law claims: breach of implied warranty and failure to warn of the risk of developing osteonecrosis of the jaw ("ONJ") from defendant's intravenous drug, Zometa.

In short, plaintiff's theory of the case, as articulated by counsel at the Final Pretrial Conference (hereinafter "Conference"), is that defendant knew or should have known about the risk of developing bisphosphonate-induced ONJ ("BONJ") before June, 3 2005 – the date that Timothy Hogan's doctors temporarily halted the Zometa infusions because they concluded that it was contributing to his jaw condition. According to plaintiff, if a proper warning had been given any time before March 4, 2003, when Hogan began the infusions, his oncologist, Dr. Pryzgoda, would not have recommended Zometa or at least would have referred Hogan for a dental examination. The examination would have in turn obviated the need to remove teeth while receiving Zometa, thereby decreasing the risk of developing BONJ. A proper warning *after* March 4, 2003, goes the theory, would have led Dr. Pryzgoda to insist that the therapy be stopped. Additionally, plaintiff claims that had Hogan's dentists and oral surgeon, Dr. Brown, been on notice about ONJ, they would have prevented Dr. Brown from extracting Hogan's teeth.

DISCUSSION

I. Plaintiff's Experts

A. Dr. Suzanne Parisian

Unclear under this articulation of the case is where Dr. Suzanne Parisian's testimony fits. Plaintiff has offered Dr. Parisian as a "regulatory expert to opine on regulatory and labeling issues . . . to testify on these issues under federal law." Her 120-page report discusses: (1) the "role, process and functions" of the FDA and the responsibilities of pharmaceutical drug sponsors within the FDA's regulatory framework; (2) defendant's conduct regarding the FDA's approval process for Zometa, and its predecessor, Aredia; (3) defendant's investigation and interactions with the FDA; and (4) defendant's communication of ONJ's risks to health care providers. Describing her role in this litigation, Dr. Parisian stated that, "I'm here not as . . . the

expert in Aredia and Zometa. I am here as the expert on FDA issues involving Aredia and Zometa."

As both she and plaintiff's counsel articulate it, most of her testimony is irrelevant to the present action. See Fed. R. Evid. 402; see also Daubert, 509 U.S. at 597 (holding that Rule 702 of the Rules of Evidence requires the Court to ensure that the expert's testimony is not only reliable but also "relevant to the task at hand"). Plaintiff has not asserted a federal claim for violating FDA regulations and fails to mention them anywhere in her pleading. Even her opposition to defendant's motion for summary judgment before the MDL Court failed to raise the regulations to suggest that they informed her state law claim. See Restatement (Third) of Torts: Products Liability § 4(b).

More importantly, the JPTO – describing the claim in common law terms only – makes no such disclosure, and at the Conference, plaintiff's counsel declined the Court's invitation to identify an FDA regulation that required certain information to have been on Zometa's label that would bear on plaintiff's common law claims. Counsel only confirmed that plaintiff is "not claiming there is some *per se* violation of the regulations;" that defendant's duty to warn comes exclusively from the common law; and that in fact he would prefer to keep federal law out of the case but feels compelled to include an expert on the regulations because one of the defenses seems to be compliance with the FDA.[1]

Plaintiff cannot have her cake and eat it too; she cannot bring common law claims not grounded in FDA regulations only to present an expert to opine on whether defendant violated those regulations. By the same token, the Court will not permit defendant to litigate the case in

[1] Although I am not persuaded that plaintiff would be able to admit a federal regulatory expert based on an anticipated defense, see e.g., Benedict v. United States, 822 F.2d 1426, 1428 (6th Cir. 1987) ("plaintiff has no duty to anticipate or negate a defense theory in plaintiff's case-in-chief"), as I explain in more detail below, defendant will not be permitted to inject federal law into an action that is pled in terms of state law only.

the shadow of the FDA. This action is past the summary judgment stage where defendant appeared to have abandoned its preemption defense, and both of its defenses presented in the JPTO are based on causation rather than any contention that the FDA regulations forced defendant to discharge its common law duty in a way that made it impossible to comply with state law. See Wyeth v. Levine, 129 S. Ct. 1187, 1199-204 (2009) (holding that despite the FDA's observation that states' failure-to-warn claims threaten its role in the approval process of labeling, FDA regulations do not preempt state law); Mason v. Smithkline Beecham Corp., 596 F.3d 387, 391 (7th Cir. 2010) (observing that after Wyeth, the manufacturer must provide clear evidence that the FDA would have rejected the proposed change in the drug's label before a common law failure-to-warn claim is preempted). Nor has defendant claimed that as a matter of state law, defendant's purported compliance with FDA regulations precludes a judgment in favor of plaintiff. See In re Methyl Tertiary Butyl Ether Prods. Liab. Litig., 438 F. Supp. 2d 291, 301 (S.D.N.Y. 2006) ("In general, while Congressional regulation is relevant to tort liability, it is not dispositive."); Restatement (Third) of Torts: Products Liability § 4 cmt. e. ("most product safety statutes or regulations establish a floor of safety below which product sellers fall only at their peril, but they leave open the question of whether a higher standard of product safety should be applied"). Thus, as the parties agreed at the Conference, the FDA is mostly irrelevant to this action.

Reaffirming the Court's observation at the Conference, any evidence or testimony discussing the FDA, its regulations, and upcoming meetings, will not be admitted without independent probative value; evidence that reveals nothing more than responsiveness to the FDA is irrelevant. The Court may, of course, permit evidence that tends to show the extent of

defendant's knowledge (or lack thereof) of BONJ or the *initial* letters to the FDA proposing a labeling change, which is one way that pharmaceutical companies provide warnings.[2]

I recognize that under Rhode Island law, in determining whether defendant exercised its duty to warn, it will be "held to an *expert* standard of care." Castrignano v. E.R. Squibb & Sons, 546 A.2d 775, 782 (R.I. 1988) (emphasis added). Defendant may therefore show that it "carefully monitor[ed] the new developments and research that pertain[ed]" to Zometa. Id. at 782-83. To that end, expert testimony on the topic of pharmacovigilance may help the jury understand what pharmaceutical companies generally do to anticipate and prevent adverse drug reactions.

The Court has considered whether Dr. Parisian is qualified to testify on this topic under the rather flexible standard test set out by the Second Circuit. See Stagl v. Delta Air Lines, Inc., 117 F.3d 76 (2d Cir. 1997); see also In re Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007) (Weinstein, J.) ("If the expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude the

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[2] At the Conference, the Court provided an example of evidence fitting into the first category but added a caveat:

> The Court: And if we are not talking about compliance or non-compliance with FDA procedures, which to me has all kinds of danger, prejudicial impact, then I don't know why I would let you show their dealings with the FDA unless you show me that on some occasion the FDA delivered a study to them that said, here's what happened when you use this drug. And if you have hard evidence like that, which I doubt you do, but if you have something like that, I probably would cut out all of the other things we have been talking about as to notice, because that would be as good a notice as you are going to get.

Nevertheless, as the Court also observed, there is the chance that if enough testimony about the FDA trickles in accompanied by probative evidence from either side, it could open the floodgates:

> The Court: [Addressing defendant's counsel] I heard today Novartis say several times the FDA requires us. This is going to be a door opening situation for you. I really don't expect to hear the initials "FDA" during your case.
>
> Mr. Berger: Your Honor, understood. Your Honor, and if I don't hear them, then the plaintiff will have nothing to rebut. But by the same token, I don't expect to hear them from the plaintiff on direct.

testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent.").[3] Even under this test, however, Dr. Parisian is not qualified.

Dr. Parisian's *curriculum vitae*, as Judge Spatt observed in a case that was part of the same multidistrict litigation, is dominated by a specific type of work: "[a]lthough briefly a general practitioner, Dr. Parisian's work experience has primarily been with regulatory agencies." Deutsch v. Novartis Pharms. Corp., No. 09-CV-4677, 2011 U.S. Dist. LEXIS 22755, at *122-23 (E.D.N.Y. Mar. 8, 2011). This experience has included a stint as a Medical Officer with the FDA's Offices of Health Affairs and Device Evaluation. Since leaving the FDA in 1995, Dr. Parisian has been consulting different entities and individuals regarding FDA requirements. Yet she has never worked for a pharmaceutical company – although she consults them regarding FDA regulations – and while at the FDA, was never part of the Center for Drug Evaluation and Research.

Given this background, I find that she is unqualified to opine on the potentially relevant testimony she offers in her report regarding pharmaceutical companies' internal operating procedures and other standards with which she claims manufacturers voluntarily elect to comply. See Deutsch, 2011 U.S. Dist. LEXIS 22755, at *138 (excluding Dr. Parisian's testimony regarding what a "reasonable manufacturer would do" and "industry standards" because she "has never worked at a pharmaceutical company or with a pharmaceutical company outside of her interactions with companies involved in FDA processes"). The jury would be assisted by an

[3] Although defendants have not requested Daubert hearings for any of the plaintiff's three experts, the Court has carefully reviewed the record to consider whether its further development through these hearings would aid the Court in its role as a gatekeeper. See generally United States v. Williams, 506 F.3d 151, 160-61 (2d Cir. 2007); 4 Weinstein's Federal Evidence § 702.02[6][b]; see also Oddi v. Ford Motor Co., 234 F.3d 136, 154 (3d Cir. 2000) (holding that where the evidentiary record is "far from scant" a hearing is not necessary). I find that the present record is sufficient to reach the conclusions about each expert, particularly because none of the objections are based on disputed evidence. See, e.g., See e.g., Rexall Sundown, Inc. v. Perrigo Co., 651 F. Supp. 2d 9, 25 n.4 (E.D.N.Y. 2009) (observing that the disputed objections are based on written material rather than any issues that require a hearing); Humphrey v. Diamant Boart, Inc., 556 F. Supp. 2d 167, 173 n.3 (E.D.N.Y. 2008) (finding a hearing not necessary where objections to the testimony do not raise factual issue).

expert who could explain how pharmaceutical companies test their drugs and collect data; as an expert, however, Dr. Parisian, could testify only to what the FDA requires. Accordingly, Dr. Parisian's testimony is excluded in its entirety.

I am mindful that without Dr. Parisian and defendant's mention of its efforts to cooperate with the FDA, the jury will be operating in a universe that is devoid of the heavy regulatory framework that affects the development and marketing of pharmaceutical products. Nevertheless, I find that the benefits of excluding this evidence outweighs its costs; the Court's review of the submitted exhibits and Dr. Parisian's report reveal that some of the battlegrounds the parties have chosen are simply not the ones pled in the complaint or stated in the JPTO. And as the parties seem to agree at the Conference, even if the FDA's role in this litigation were properly described, it would be a side show; if the Court allowed Dr. Parisian to testify, the side show would turn into the main event. Thus, the jury's task will be a narrow one and involve the application of state law only.

B. Dr. Robert Marx

Dr. Robert Marx is a board-certified oral and maxillofacial surgeon. He has particular expertise in bone diseases, was among the first to identify BONJ in one of his textbooks, and has treated dozens of patients with ONJ. Dr. Marx contacted defendant in 2003 to discuss what appeared to him to be BONJ cases. But his cooperation with defendant ended when his corroboration with defendant on an academic article went sour, and he concluded that defendant was "not taking responsibility for complications caused by [its] products." Plaintiff has offered him primarily as a causation and treatment expert, to testify whether bisphosphonate drugs like Zometa can cause a unique form of ONJ (BONJ), whether Hogan had BONJ, and what steps can be taken to prevent and treat this condition.

The MDL Court has already found Dr. Marx qualified to opine on general and specific causation as well as on treatment and preventive measures for ONJ. The objections before me are based on testimony that the MDL Court did not address. Specifically, defendant seeks to exclude Dr. Marx's opinion and supporting testimony that defendant's efforts in manipulating publication of an article discussing ONJ "demonstrated bad faith." Defendant also argues that Dr. Marx cannot reliably testify whether any patients in the Zometa clinical trials conducted by defendant had BONJ, and that he lacks expertise in designing trials to opine on whether they were flawed.

Plaintiff did not request punitive damages in her case, and after the MDL Court remanded the case, plaintiff confirmed on the record through counsel that she is not seeking them. Additionally, the Court bifurcated the trial, and the instant submissions are for the liability stage only. As a result, testimony of bad faith conduct is excluded as irrelevant. See Fed. R. Evid. 402. To minimize dispute at trial about the breadth of this exclusion, I note that aside from mentioning what literature was available to defendant on the topic – testimony to which defendant does not appear to object – the Court will also allow Dr. Marx to testify as a fact witness to describe, briefly, the content of his interactions with defendant to show when defendant first knew about ONJ.

I also note my concern that all of plaintiff's experts, to some degree, are being proffered as "superlawyers" to serve as scientifically informed advocates of conclusions that plaintiff wants the jury to reach and which belong only in summation, not expert testimony. Plaintiff is therefore cautioned that the Court will have little patience with digression; Dr. Marx may testify when he first contacted defendant about ONJ cases but must keep his characterizations of defendant's responses and opinion regarding its conduct to himself.

Dr. Marx's opinion on whether participants in defendant's clinical trial had BONJ, on the other hand, is both relevant and reliable. In 2005, defendant reviewed data from its clinical trials of Aredia and Zometa and reported to the FDA that there were six patients whose records are "consistent with a potential diagnosis of ONJ." When defendant sought to exclude Dr. Marx's testimony in the multidistrict litigation, it submitted an expert report by Dr. Eric Carlson, who reviewed these records and concluded that none of the six individuals had ONJ. Dr. Marx disagrees; in his rebuttal report, he concludes that "[d]espite the relatively poor quality of the research data . . . it is my opinion . . . that five of these six individuals likely suffered from [BONJ]." He then explains the grounds for his conclusion for each patient.

Defendant objects to this testimony, calling it "pure speculation" because the record from these clinical trials does not note whether any patient had an exposed jawbone for more than eight weeks – a key measure, according to Dr. Marx himself, of BONJ. But Dr. Marx offers more than just speculation. He has looked for other indications of the condition to reach his conclusions about each patient: "debridement of the mandible," "lesions in the mandible not related to myeloma," "bony necrosis of the mandible," "excision of right mandibular bone," "failure to respond to adequate osteomyelitis treatment" to name some. Defendant does not argue that any of these conditions are not reliable indicators of ONJ. How definitive Dr. Marx's conclusion about BONJ can be without relying on what he himself has labeled a key component of an accurate diagnosis is a matter properly explored on cross-examination. See McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1044 (2d Cir. 1995) (observing that faults in an expert's use of a particular methodology "go to the weight, not the admissibility, of his testimony"). This is the conclusion reached by Judge Spatt, and I find no reason to disagree. See Deutsch, 2011 U.S. Dist. LEXIS 22755, at *81-82 ("Given that exposed bone may have been present but not

recorded, it would be unfair to permit Novartis experts to use the absence of a reference to exposed bone to conclude [that BONJ] was not present, and then preclude the Plaintiffs from showing that the records contain other indicia of [BONJ] that make it likely exposed bone was present, but not recorded."). Moreover, defendant does not contend that it looked for eight-week exposed jawbones when collecting data in the clinical trials; it argues only that without its notation, Dr. Marx cannot reliably testify on whether the patients had BONJ. Thus, this is not a case, like Amorgianos v. Amtrak, 303 F.3d 256 (2d Cir. 2002), cited by defendant, where the expert has available data but fails to utilize it. Id. at 267.

In reaching this conclusion, the Court notes that plaintiff's response to this objection is based on defendant's admissions, rather than Dr. Marx's report. Even if these exhibits are admitted at trial, it is unclear why Dr. Marx should be the one to present them. Cf., Highland Capital Mgmt., L.P. v. Schneider, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005) ("While an expert must of course rely on facts or data in formulating an expert opinion, an expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence.") (internal citation omitted). The jury will not have an expert recount the contents of documents that did not form the basis of his opinion.

Finally, defendant objects to the part of Dr. Marx's testimony criticizing the designs of its clinical studies. In his rebuttal report, Dr. Marx observed that defendant's reports generated during these studies show "a serious deviation of proper research data recording . . . ." Dr. Marx admitted in his deposition that he has never planned or managed any clinical trials intended to study the effect of any drugs on humans. Plaintiff counters that Dr. Marx does not need this experience to criticize defendant's failure to include any oral cavity specialist to conduct jaw and mouth examinations. I disagree.

The jury may well conclude that given the available literature at the time on BONJ, defendant should have included oral cavity specialists in their clinical trials. Dr. Marx, however, is not qualified to offer his opinion on this topic. He would not, for instance, have the expertise to opine on the level of probability for developing a certain medical condition that pharmaceutical companies should tolerate before including specialists to monitor it during their trials. Dr. Marx is therefore precluded from criticizing the clinical trials. But, as Judge Spatt observed, this does not mean that Dr. Marx cannot note the lack of records when explaining his opinion on whether the trials included patients with BONJ. See Deutsch, 2011 U.S. Dist. LEXIS 22755, at *84.

C. Professor Wayne Ray

Prof. Ray is an epidemiologist with "extensive experience . . . designing, executing and analyzing pharmacoepidemiologic studies." Id. at 86. He frequently works with the FDA, performing studies to assess adverse medication reactions. Plaintiff offers him to opine on the question of general causation – that is, whether bisphosphonate drugs make the occurrence of ONJ more likely. To reach his conclusions, Prof. Ray has performed a meta-analysis, which is a way to evaluate statistical data based on the results of several independent studies. The MDL Court did not address Prof. Ray's testimony.

Defendant objects to his testimony based on its reliability and Dr. Ray's qualifications. In arguing the latter, defendant asserts that Prof. Ray has never published a meta-analysis study nor is he a medical doctor and did not consult one in performing this study. These objections have been raised at least twice before, and like the two courts that have rejected them – one of which, Bessemer v. Novartis Pharmaceuticals Corporation, No. MIDL-1835-08 (N.J. Super. Ct. April 30, 2010), did so after holding an evidentiary hearing – I find them to be without merit. See

Deutsch, 2011 U.S. Dist. LEXIS 22755, at *97-98 ("That Prof. Ray has never published a meta-analysis is not equivalent to him never having performed such an analysis . . . . Prof. Ray does not need to be an oncologist or a dental surgeon or any other type of medical doctor to analyze the data and studies for a relationship between a pharmaceutical drug and a disease. As a pharmacoepidemiologist, designing, executing, analyzing, and evaluating studies on this very subject is precisely Prof. Ray's area of expertise."); Bessemer, No. MIDL-1835-08, at *6-7 (noting that Prof. Ray has "used meta-analyses on numerous occasions throughout his career").[4]

Defendant takes issue with Prof. Ray's methodology, particularly with the control group he used in his study. Prof. Ray compared patients who received bisphosphonate treatment for less than three months with those who received it for a longer period. Defendant argues that the three month period is arbitrary as it was based on an academic article that itself was not grounded in solid data. Defendant's argument is flawed for two reasons. First, it goes to weight, not admissibility. See McCullock, 61 F.3d at 1044. Second, it is unclear how using the more traditional non-user control group as opposed to short-term bisphosphonate patients could inflate, rather than deflate, the probability of causation. See also Deutsch, 2011 U.S. Dist. LEXIS 22755, at *100-01 (observing that using the three-month point gleaned from the article was within Prof. Ray's expertise because he is "qualified to evaluate a study and to extrapolate information to design a study.").

Defendant also claims that Prof. Ray aggregated non-randomized studies for his meta-analysis. That is true, but as Prof. Ray explained in his deposition and expert report, he did not believe that any randomized trials have been designed to detect ONJ, so he was left with cohort

[4] Like it did in Deutch, defendant here "selectively quotes from Prof. Ray's deposition" to argue that he "deviated from his usual practice of collaborating with a medical doctor or clinician." Deutsch, 2011 U.S. Dist. LEXIS 22755, at *97-98. In the submitted deposition, Prof. Ray testifies that "when it comes to the analysis of data or review of other studies" he does not necessarily consult with medical doctors.

studies. While perhaps less than ideal, I am not convinced that basing a meta-analysis on cohort studies is *per se* unreliable, particularly when the expert relies on more than just a few studies and disregards others not arbitrarily, as defendant suggests, but only when he found them to lack data regarding the duration of the therapy – a key variable in the analysis. The objection therefore goes to weight, rather than admissibility. See Amorgianos, 303 F.3d at 267; In re Pfizer Inc. Sec. Litig., No. 04-CV-9866, 2010 U.S. Dist. LEXIS 26927, at *21 (S.D.N.Y. March 22, 2010) ("Plaintiffs' critiques of Dr. Wei's choices regarding which trials to include in his own meta-analysis, the origins of the data he used, the date at which he undertook his meta-analysis, and at whose behest he performed his analysis all go to the weight of Dr. Wei's testimony.").

Next, defendant contends that Prof. Ray made no statistical adjustment to account or control for potential "confounders" – extraneous variables that can produce false positives. Again, this argument goes to weight. Prof. Ray considered the confounding factors in his reports, acknowledged several studies and publications, and provided a "reasonable explanation" for discounting them. Deutsch, 2011 U.S. Dist. LEXIS 22755, at *102-03 (internal citation and quotation marks omitted). I therefore decline to exclude this part of his testimony.

But defendant does raise one aspect of Dr. Marx's opinion that is problematic. Defendant seeks to exclude Prof. Ray's opinion that a conclusion regarding bisphosphonate's causation of ONJ could have been reached in 2003. It asserts that none of the publications Prof. Ray used for his study had been published as of 2003, and that even Dr. Marx, on whose submission Prof. Ray relies for his conclusion, now acknowledges that prior to 2007, there was no certainty regarding BONJ. Plaintiff responds by quoting the only parts of Prof. Ray's report where he offers the conclusory observation that a causation determination could have been made in 2003. Perhaps as a preview to what Prof. Ray would be asked at trial, plaintiff then shifts to address a different

question – when could *defendant* have known that its drug was causing ONJ? Answering this question, plaintiff alludes to "certain internal documents" of the defendant that Prof. Ray has reviewed.

Judge Spatt rejected defendant's objection, observing that "the fact that causation has not been proved to a scientific certainty does not prevent experts from opining on the likelihood of causation." Id. at 109. The Court noted in reaching this conclusion that Prof. Ray did not rely on the cohort studies from his meta-analyses, instead basing this part of his opinion on Dr. Marx's reported cases of BONJ in 2003 and on the increase of adverse event reports for which he found no credible alternative explanation. "Having already found Prof. Ray's causation opinions based on case reports to be admissible, and in light of the liberal standard of admissibility," the motion to exclude this conclusion, the Court held, must be rejected as the objections went to its weight rather than admissibility. Id. at 110.

I respectfully disagree. As explained earlier, whether a determination about causation in 2003 could have been made is a critical question in this litigation – it was the year that Hogan began his Zometa treatment. An expert's conclusion that such a determination could have been reached has the potential to sway the jury all by itself. I am concerned that, once again, plaintiff is attempting to use an expert witness to make her closing argument rather than relate scientific conclusions. See In re Air Crash Disaster at New Orleans, Louisiana, 795 F.2d 1230, 1233 (5th Cir. 1986) (noting that "the trial judge ought to insist that a proffered expert bring to the jury more than the lawyers can offer in argument"); In re Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 283 (E.D.N.Y. 2007) (Weinstein, J.) ("Expert testimony should not merely reiterate arguments based on inferences that can be drawn by laypersons; those can properly be advanced by the parties in their summations."). I am therefore hesitant to attribute the weaknesses in Prof.

Ray's methodology with respect to this conclusion to mere weight. See Amorgianos, 303 F.3d at 267 ("In deciding whether a step in an expert's analysis is unreliable, the district court should undertake a rigorous examination of the facts on which the expert relies."); Deutsch, 2011 U.S. Dist. LEXIS 22755, at *107 ("Even where the expert's methodology is reliable for some purposes, the court must determine whether it is a reliable way to draw a conclusion regarding the particular matter to which the expert testimony was directly relevant. Expert testimony that is merely subjective belief or unsupported speculation should be excluded.").

In reaching his conclusion, Prof. Ray relies not on the methodology that this Court and others have found reliable – his meta-analysis of cohort studies – but on a letter to the editor of a medical journal written by Dr. Marx (describing cases of ONJ), and, as it appears from a graph and a footnote in his report, on the number of ONJ cases reported to the FDA and known to defendant. These are hardly markings of a reliable methodology and instead strike me as plaintiff's attempt to elevate and advocate the value of individual evidence by having it recounted by an expert. Accordingly, Prof. Ray is precluded from testifying on when causation could have been established.

II. Defendant's Remaining Motions *in Limine*

A. Motion (1)[5]: the scope of the duty to warn

Defendant moves to exclude any evidence suggesting that it had a duty to "warn dental providers or other non-prescribing health care practitioners" about the risk of developing ONJ from Zometa. It contends that the "learned intermediary doctrine," which has been neither adopted nor rejected in Rhode Island, precludes this evidence. According to defendant, the doctrine provides that drug manufacturers discharge their duty to warn if they provide an adequate warning to prescribing physicians alone; no warnings to other health care providers are

[5] The numbers and letters of the individual motions are ones provided by the parties in their briefs.

necessary under this interpretation of the rule. Even if the doctrine is not applied, defendant argues, plaintiff has not presented any experts to show that warnings to Hogan's non-prescribing medical professionals were warranted. Plaintiff responds only that the learned intermediary doctrine would likely not be adopted in Rhode Island as "courts have been moving away" from it.

Much ink has been spilled by commentators[6] and courts[7] alike debating the soundness of the doctrine; fortunately, this Court need not weigh in as plaintiff's position is not inconsistent with the doctrine's accepted adaptation. Ironically, the doctrine was born as a sword only to be used as a shield. The term was coined in Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966), where the Court affirmed a judgment against a pharmaceutical company. The Court approved the trial judge's jury instructions, which provided that if the jury finds that the manufacturer knew about its drug's side-effects, it had a duty to warn the "medical profession;" the Eighth Circuit explained that the purchaser's doctor was a "learned intermediary" and could have properly advised his patient about the known risks of the drug. Almost two dozen state supreme courts (not counting lower courts and federal courts sitting on diversity) have since adopted the doctrine and apply it to absolve a drug manufacturer from a duty to warn the ultimate user of the drug. See State ex rel. Johnson & Johnson Corp. v. Karl, 220 W. Va. 463, 467-68, 647 S.E.2d 899 (2007) (disagreeing with other courts' calculations, finding that a "mere" twenty-two states have expressly adopted the doctrine).

Defendant takes advantage of the language – perhaps case-specific narrow language – used by most courts in referring to the learned intermediary. As an illustration, one case cited by

[6] See, e.g., Plant, Nancy, The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment, 81 Iowa L. Rev. 1007 (1996).

[7] See, e.g., State ex rel. Johnson & Johnson Corp. v. Karl, 220 W. Va. 463, 647 S.E.2d 899 (2007).

defendant observes that the doctrine requires "adequate warnings to *prescribing physicians*" before holding the manufacturer liable for a failure to warn. Hurley v. Heart Physicians, P.C., 898 A.2d 777, 783, 278 Conn. 305 (Conn. 2006) (emphasis added). To defendant's credit, Hurley is not an outlier; courts routinely identify the "prescribing physician" as the learned intermediary. But none of the cases in defendant's long list stand for the proposition that prescribing physicians are the *only* treating medical professionals who must be warned.

Nor is there anything in the rationale behind the doctrine that counsels in favor of defining the "learned intermediary" narrowly to exclude other treating medical professionals. Broadly speaking, the learned intermediary rule seeks to preserve the doctor-patient relationship and allows the doctor to interpret the dangers involved in taking a drug; a warning to the patient, the rationale suggests, even if practical, could be detrimental as the patient may not properly weigh the drug's risks against its benefits. See Karl, 220 W. Va. at 469, 647 S.E.2d at 905 (collecting cases). Whatever one thinks of these justifications, it is difficult to see how they counsel against requiring drug manufacturers to warn non-prescribing treating doctors and advise them how to approach a drug's potential side effect. See Stevens v. Novartis Pharms. Corp., 358 Mont. 474 , 247 P.3d 244, 260 (2010) (defining the learned intermediary as any healthcare professional responsible for making decisions related to the patient's case); McEwen v. Ortho Pharm. Corp., 270 Ore. 375, 528 P.2d 522, 528-30 (1974) ("Although the . . . drug manufacturer's duty to warn has been discussed most often with reference to the prescribing physician, the [doctrine's] reasoning applies with equal force to the treating physician . . . [who] may be more likely to observe the actual symptoms of the drug's untoward consequences.").

It is unsurprising then that the Third Restatement of Torts – which unlike its predecessor, explicitly refers to the doctrine – provides that, generally, the warning must be given to

"prescribing and *other health-care providers* who are in a position to reduce the risks of harm in accordance with the instructions or warnings." Restatement (Third) of Torts: Products Liability § 6(d)(1) (emphasis added). Nor is it surprising that courts citing to the Third Restatement continue to refer to "prescribing physicians" as the learned intermediary; the Restatement's position is not in tension with the prevailing view of the doctrine. See e.g., In re Zyprexa Prods. Liab. Litig., No. 06-CV-2798, 2009 U.S. Dist. LEXIS 69864, at *54 (E.D.N.Y. July 27, 2009) (Weinstein, J.). The Supreme Court of Rhode Island has traditionally drawn on the Restatement for its products liability jurisprudence, see e.g., Ritter v. Narragansett Electric Co., 109 R.I. 176, 283 A.2d 255, 263 (1971), and has cited approvingly other provisions of the Third Restatement of Torts. See e.g., Calise v. Hidden Valley Condo. Ass'n, 773 A.2d 834, 846 n.13 (R.I. 2001). I see no reason to expect Rhode Island, if it were to adopt the learned intermediary rule, to offer an unusual interpretation of it, thereby rejecting the current edition of the Restatement.

Defendant's alternative contention for excluding this evidence – that plaintiff has not offered any experts to suggest that warnings to non-prescribing doctors were warranted – is also unpersuasive. Dr. Marx, who as described earlier, is qualified to opine on treatment of ONJ and preventive strategies, states in his expert report that proper prevention protocols recommend that dentists remove unsalvageable teeth before beginning bisphosphonate treatment and that they avoid oral surgical procedures such as tooth extractions any time after. This has significance for the present action. Hogan had all his molar teeth removed after he began his Zometa treatment, and as plaintiff's counsel suggested at the Conference, plaintiff will present testimony from Hogan's oral surgeon and dentists that would substantiate the allegation that a proper warning would have led to a pre-treatment checkup of his mouth and post-treatment abstention from

tooth-extraction because the doctors would have made different recommendations (or at least disclosures) to Hogan. Defendant's motion to exclude this evidence is therefore denied.

B. Motions (3) and (4): extractions and sequestrectomy

For the same reasons, defendant's motion to exclude evidence that it should have warned of the ONJ risk arising from dental extractions is also denied. Although pursuant to this Court's previous Order applying Rule 407 of the Federal Rules of Evidence to this action, plaintiff may not present the new label that may have included a sufficient warning, she may draw on Dr. Marx's testimony to argue that *some* warning should have been given prior to Hogan's extractions.

Plaintiff may also use Dr. Marx's testimony as described in his report to present evidence that a sequestrectomy was ill-advised. This is a closer call as Dr. Marx's report refers to "oral surgical procedures" but does not suggest what alternative there is to removing a dead bone or how its removal could aggravate the condition. Nevertheless, defendant's challenge based on foundation and relevance is rejected because Dr. Marx provides the foundation and common sense supplies the relevance – if oral surgical procedures are to be avoided, then this oral procedure should have awaited Hogan's completion of his Zometa therapy. But if plaintiff hopes to present this testimony at the liability stage, she must fill the gaps identified above. And she must do so with a witness whom she has designated as an expert, which does not include Dr. Brown.

C. Motion (2): post-injury conduct

Defendant's motion to exclude "evidence of post-injury corporate conduct" is also denied. As discussed earlier, corporate conduct by itself is irrelevant, but it is clear that defendant seeks to exclude *any* of its documents that are dated after December, 2003, which is

the date when Hogan had his teeth extracted. This evidence may be probative of general causation regardless of its date and may show defendant's knowledge about ONJ before June, 2005 – the point at which a warning would no longer have significance.

D. Motions (6) and (19): Dr. Marx's testimony

The motion to exclude Dr. Marx's testimony based on his experience with other patients is denied as this experience is the foundation for his expert opinion. Defendant can undermine his conclusion about specific causation on cross-examination by probing the similarity of those patients' conditions to that of Hogan's. As an expert, Dr. Marx has more leeway than defendant would allow; he can draw on Hogan's reports to form his opinion without discussing the matter with any of Hogan's treating doctors or pathologists. See 13 Weinstein's Evidence Manual § 13.03[2]. If asked, he may infer, based on his review of those records, that despite what the other medical professionals thought at the time, Hogan indeed had BONJ and that certain procedures made that condition worse. Finally, as an expert on ONJ, he can also provide the jury with background information on the condition even if it involves a description of procedures that Hogan did not require; the seriousness of ONJ is relevant to whether defendant should have provided warnings even if the risk of developing ONJ was far from certain. Thus, defendant's motion to exclude miscellaneous aspects of his testimony is denied in part.

It is denied only in part because defendant raises valid concerns with other aspects of Dr. Marx's potential testimony. First, although defendant fails to point the Court to any specific testimony, plaintiff is cautioned that Dr. Marx will not be permitted to simply relay a pathologist's opinion on a matter that falls outside of his expertise. See United States v. Mejia, 545 F.3d 179, 197 (2d Cir. 2008). Second, Dr. Marx may not testify to the state of mind of any of the doctors who worked on Hogan's case; he can only opine on their diagnoses. He cannot

therefore speculate that "[h]ad the pathologist been more aware of ONJ, I think he might have rendered a different diagnosis." Plaintiff is going to have to persuade the jury to reach this conclusion on their own based on the experts' testimony of what happened as a scientific matter. I decline to rule on the remaining objections to his testimony, including whether the pathologist was prejudiced to look for Hogan's cancer or whether he was misled to look for multiple myeloma as defendant cites to excerpts that have not been submitted with its motion. Likewise, if plaintiff seeks to have Dr. Marx read Zometa's label, I will rule on the objection at trial.

E. Motions (7), (8), (9), and (11): defendant's emails

The balance of defendant's motions in limine, excluding the ones that the parties have advised the Court have been resolved, requires less discussion. The January 29, 2003 email from David Epstein describing a Japanese study will not be admitted. While its probative value is limited – the study was not related to ONJ and does not disclose a plan to suppress the study – the email's mention of profits is unduly prejudicial. The motion to exclude Linda Weiss' March 12, 2004 email is also granted, but only in part. This email is easy enough to redact; the first paragraph shows what defendant knew about ONJ in 2004, while the second paragraph plans defendant's response. The former is highly probative and the latter is not, instead tending to show bad faith corporate conduct. The second paragraph must therefore be redacted if the email is admitted.

The motion to exclude the May 5, 2003 email from Stefan Fratarcangel, however, is denied. Whether or not defendant followed up on the plan to suppress Dr. Ruggiero's publication, the letter could be argued to show defendant's knowledge about ONJ at a crucial juncture in Hogan's treatment. Similarly, the June 20 and July 10, 2003 emails from Dr. Carsten

Goess will be admitted as they could be highly probative of defendant's knowledge about ONJ at a time when a warning, according to plaintiff, was particularly important.

F. Motion (10): statements about the "White Paper" by members of a panel

I grant in part the motion to exclude out-of-court statements by members of a panel of physicians and oral surgeons who provided comments regarding the "White Paper." Defendant offers a few examples, and the Court is persuaded that the emails cited should not be admitted as they have the double dose of undue prejudice with the jury, potentially taking the out-of-court statements by nonparties for their truth and drawing conclusions about bad faith corporate conduct. But I decline to draw a blanket exclusion for all the out-of-court statements from members of the panel who provided comments about the White Paper; if there are any more emails than the ones provided by defendant, I will rule at trial whether their probative value is sufficiently high to warrant admission.

G. Motion (12): Dr. Raje's presentation

Although I am inclined to grant the motion to exclude Dr. Raje's testimony as it unclear how it can be anything other than inadmissible hearsay, it is apparent from the parties' arguments at the Conference that the objection is over a particular videotaped presentation that Dr. Raje gave in September, 2005. Plaintiff has agreed to redact portions of the tape; before ruling on this evidence, I will review the proposed version along with any of her deposition testimony that would support the plaintiff's argument that her statements in the presentation are only transmissions of defendant's knowledge about ONJ.

H. Motion (13): recommendations from the ONJ Advisory Panel

The motion to exclude recommendations from the ONJ Advisory Panel held in March, 2005 is granted. The Panel was held to address a different drug – albeit with the same active

ingredient – given to patients with conditions different from the ones for which Zometa is usually prescribed. Therefore, the recommendations are not directly relevant to Hogan's claims. Given the date of the document, nearing the time when Hogan resumed Zometa despite ONJ concerns and after his tooth extractions, it is also not sufficiently probative of defendant's knowledge of ONJ to overcome its undue prejudice.

I. Motion (17): ADE reports

The motion to preclude admission of adverse drug experience reports is denied. Individual reports and the total number of ONJ reports before June, 2005 can establish notice regardless of whether Hogan's jaw condition was not similar to any of the patients described in the reports.

J. Motion (19)(b) and (c): evidence about the FDA and foreign material

I will preclude any evidence that seeks to establish, without more, that defendant misled the FDA regarding Zometa; as discussed earlier, however, evidence with independent probative value, such as showing notice, will be admitted. Likewise, I do not see the relevance of foreign regulatory actions and materials. But defendant fails to present any specific evidence for both motions, so at this stage, they must be denied.

II. Plaintiff's Remaining Motions *in Limine*

A. Motions (i) and (j): plaintiff's complaint and her attorneys' role

Many of plaintiff's motions are painted in broad strokes, without any reference to specific evidence. And some are supported by nothing more than conclusory statements of law. For instance, it is unclear what evidence plaintiff seeks to exclude when she moves to preclude defendant's references to her complaint, much less why that evidence would not be relevant. Similarly vague is the plaintiff's motion to exclude references to "ONJ and bisphosphonate drugs

being generated by plaintiffs or plaintiffs' attorneys." Relevant questions that can come under this broad exclusion include those posed to experts, asking to describe when they reached their conclusions. Both of these motions are therefore denied.

B. Motion (a): plaintiff's medical condition

Plaintiff moves to exclude any evidence mentioning Hogan's medical condition or that of his family. This motion is denied as the evidence could come in to explain specific causation. I deny without prejudice her motions to exclude evidence bolstering the unchallenged character or traits of defendant's employees and any evidence about other drugs manufactured by defendant as plaintiff again does not point to any specific evidence. The Court reminds the parties, however, that corporate conduct is not an issue in this case.

C. Motion (c): effectiveness of the warnings

Plaintiff also seeks to exclude any suggestion that mentioning too many warnings of serious injuries would have "dilute[d] the effectiveness of warnings generally." Unlike the previous motions, this goes to the heart of the case – whether the risk of developing ONJ was sufficiently high to warrant adding yet another warning to the label. This argument would be relevant and the motion is therefore denied.

D. Motion (d) and (g): characterizations of Zometa

The Court denies the motions to preclude references to Zometa as the "standard of care" and characterizations of the drug that plaintiff believes go beyond its approved use and label. Defendant is permitted to offer evidence of the drug's intended use and benefits to undercut proximate cause, and show, for instance, that Dr. Pryzgoda would have prescribed Zometa to Hogan even if he knew everything there was to know about the risk of developing ONJ. If defendant makes too much of this evidence by calling Zometa, as plaintiff expects, a "miracle

drug," plaintiff is free to challenge it in her closing statement; if a witness does it, plaintiff is just as free to exploit it on cross-examination or perhaps by calling rebuttal witnesses.

E. Motion (e): current clinical trials

Although at this stage, I must deny the motion to preclude defendant's mention of current clinical trials, this evidence will likely be irrelevant given corporate conduct is not tried in this case. I deny it only because, as plaintiff's counsel admitted, post- 2005 evidence can still be probative of general causation.

F. Motion (f): compliance with the FDA

The motion to exclude comments about the absence of FDA sanctions, however, need not be approached with the same caution – as explained earlier, that evidence is irrelevant, and the motion is therefore granted.

CONCLUSION

For the reasons provided above, defendant's Motion *in Limine* to Exclude Testimony of Plaintiff's Experts [360] is granted in part and denied in part. Dr. Parisian's testimony is excluded in its entirety; Dr. Marx and Professor Ray may testify to the extent provided in this Order. Defendant's Motion *in Limine* to Exclude Certain Subjects of Evidence at Trial [376] is granted in part and denied in part as outlined in this decision and the Order dated April 6, 2011. Plaintiff's Motion *in Limine* to Exclude Certain Subjects of Evidence at Trial is granted in part

and denied in part. Additionally, the parties shall have until April 28, 2011 to submit the joint letter that has previously been ordered so that they can also remove those exhibits and deposition designations that would be inconsistent with the rulings in this Order.

SO ORDERED.

Dated: Brooklyn, NY
August 23, 2011

Signed electronically/Brian M. Cogan

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U.S.D.J.