IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

HERBERT FUSSMAN, individually and as ADMINISTRATOR OF THE ESTATE OF RITA FUSSMAN,	)	
Plaintiff,	)	
v.	)	1:06CV149
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Defendant.	)	

ORDER AND MEMORANDUM OPINION

This matter is presently before the Court on multiple pre-trial motions, including Defendant's Motion for Summary Judgment [Doc. #47]. These various motions came before the Court during a hearing on various pre-trial matters on September 28, 2010. The present Order and Memorandum Opinion solely addresses Defendant's Motion for Summary Judgment.

I. BACKGROUND

This case involves claims by Herbert Fussman, individually and as the Administrator of the Estate of Rita Fussman, ("Plaintiff") against Novartis Pharmaceuticals Corporation ("Defendant" or "Novartis") related to injuries suffered by Mrs. Fussman allegedly caused by certain of Defendant's prescription medications known as Aredia and Zometa. Mrs. Fussman began taking Aredia in June 2001 while she was being treated for a recurrence of breast cancer. The Aredia was prescribed by Mrs. Fussman's oncologist, Dr. Heather Shaw. In November 2001, Dr. Shaw switched Mrs. Fussman's prescription from Aredia to Zometa. Mrs. Fussman continued on the Zometa until June 2005, with a one-month break in October 2004. Plaintiff

contends that bisphosphonates, including Aredia and Zometa, can cause bisphosphonate-related Osteonecrosis of the Jaw ("ONJ"), and that the Aredia and Zometa taken by Mrs. Fussman caused Mrs. Fussman to develop ONJ. During the time that she was taking the Aredia and Zometa, Mrs. Fussman underwent multiple dental procedures and experienced significant dental problems. Plaintiff contends that Defendant failed to adequately warn Mrs. Fussman and her medical providers of the risk of ONJ associated with Aredia and Zometa.

This case was originally filed in this Court but was transferred to the Middle District of Tennessee Multi-District Litigation ("MDL") related to Aredia/Zometa claims. After discovery concluded in the MDL Court, Defendant filed Motions for Summary Judgment with the MDL Court. In the MDL Summary Judgment motions, Defendant asserted that the warnings it had provided were adequate as a matter of law, but on this issue, the MDL Court specifically found that "there are genuine issues of material fact as to the adequacy of Defendant's warnings." Defendant also alleged that summary judgment should be granted because Plaintiff could not establish proximate causation. On the question of proximate causation, Defendant alleged that Plaintiff had not shown that additional warnings would have made any difference in the behavior of Mrs. Fussman and her physicians or prevented her ONJ. However, on this issue, the MDL Court found that Plaintiff had "offered sufficient proof to show that there are genuine issues of material fact as to whether the alleged failure to warn was a proximate cause of Mrs. Fussman's injuries" because: (1) Mrs. Fussman testified that "knowing what she does now about Aredia and Zometa and her jaw problems, she would not have taken either of those drugs"; and (2) Mrs. Fussman's dentists, Dr. Shroer and Dr. Wagoner, both testified that their treatment for

Mrs. Fussman would have been different if they had known about bisphosphonates and ONJ. The MDL Court therefore denied Defendant's Motion for Summary Judgment with respect to Plaintiff's claims for negligent failure to warn and breach of implied warranty based on failure to provide adequate warnings. As a result of this determination, the MDL Court remanded the case back to this Court for trial on Plaintiff's claims for Negligent Design and Negligent Failure to Warn (which were both based on the alleged failure to warn), Breach of Implied Warranty, and Loss of Consortium.

II. PRESENT MOTION FOR SUMMARY JUDGMENT

Following the remand to this Court, the parties took the deposition of Dr. Shaw, Mrs. Fussman's oncologist, who had been unavailable during the MDL proceedings. Based on the deposition of Dr. Shaw, Defendant filed this additional Motion for Summary Judgment alleging that Plaintiff cannot now establish a genuine issue of material fact on the question of proximate causation, specifically contending that Plaintiff cannot establish that the alleged lack of adequate warnings to Dr. Shaw was the proximate cause of Plaintiff's injury.

Under North Carolina law, "'[p]roximate cause is a cause which in natural and continuous sequence, unbroken by any new and independent cause, produced the plaintiff's injuries, and without which the injuries would not have occurred, and one from which a person of ordinary prudence could have reasonably foreseen that such a result, or consequences of a generally injurious nature, was probable under all the facts as they existed.'" Gaines v. Cumberland County Hospital System, Inc., 692 S.E.2d 119, 122 (N.C. Ct. App. 2010) (quoting Hairston v. Alexander Tank & Equipment Co., 310 N.C. 227, 233, 311 S.E.2d 559, 565 (1984). North

Carolina courts have cautioned that "'it is only in exceptional cases, in which reasonable minds cannot differ as to foreseeability of injury, that a court should decide proximate cause as a matter of law. Proximate cause is ordinarily a question of fact for the jury, to be solved by the exercise of good common sense in the consideration of the evidence of each particular case' . . . . [and] '[c]ausation is an inference of fact to be drawn from other facts and circumstances.'" Id. (quoting Williams v. Carolina Power & Light Co., 296 N.C. 400, 403, 250 S.E.2d 255, 258 (1979) and Turner v. Duke University, 325 N.C. 152, 162, 381 S.E.2d 706, 712 (1989)).

In considering Defendant's present Motion for Summary Judgment, the Court notes that Defendant's Motion is based on two underlying contentions. First, Defendant contends as a legal matter that in a prescription drug case based on negligent failure to warn, North Carolina law requires that proximate cause be established only through the prescribing physician, not other treating physicians or medical professionals. As such, Defendant contends that Dr. Shaw is the only relevant actor in establishing proximate cause. Second, Defendant contends that Plaintiff cannot establish proximate cause through Dr. Shaw because (a) the requisite causal link is broken because Dr. Shaw independently became aware of the alleged connection between bisphosphonates and ONJ, notwithstanding the warnings (or lack of warnings) provided by Defendant; and (b) Plaintiff cannot establish that Dr. Shaw would have acted any differently even if she had been given additional warnings. Each of these contentions will be considered in turn.

First, Defendant contends that proximate cause can be established only through Mrs. Fussman's prescribing physician, Dr. Shaw, and not Plaintiff's other treating physicians or

medical professionals. However, no North Carolina state court decision has adopted such a limitation. Instead, the North Carolina Court of Appeals has specifically concluded that proximate cause may be established based on failure to warn not only the prescribing physician, but also other "foreseeable" treating medical professionals pursuant to "standard principles of negligence law." See Holley v. Burroughs Wellcome Co., 74 N.C. App. 736, 746, 330 S.E.2d 228, 235 (1985). In affirming this decision, the North Carolina Supreme Court concluded that proximate cause could be established based on expert testimony that "the failure of medical personnel to timely recognize and treat [plaintiff's] condition was in part due to defendants' inadequate warnings and overpromotion," thus extending proximate cause to treating medical personnel (not just the prescribing physician), based on information provided by the manufacturer to the medical profession generally through "medical journals, professional literature distributions and package inserts." See Holley v. Burroughs Wellcome Co., 318 N.C. 352, 360-61, 348 S.E.2d 772, 776-77 (1986). Pursuant to this analysis, proximate cause may be established through other health-care providers, not just the prescribing physician.[1] This analysis is consistent with the Restatement of Law (Third), which provides that a drug is defective if adequate warnings are not provided to "prescribing and other health-care providers who are in a position to reduce the risk of harm in accordance with the instructions or warnings."

[1] In this regard, the Court notes that the MDL Court has already determined that under North Carolina law, Plaintiff has "offered sufficient proof to show that there are genuine issues of material fact as to whether the alleged failure to warn was a proximate cause of Mrs. Fussman's injuries" because Mrs. Fussman's other health care providers, particularly Dr. Shroer and Dr. Wagoner, testified that their treatment for Mrs. Fussman would have been different if they had known about bisphosphonates and ONJ. The Court will not revisit that determination.

Restatement of Torts (Third) § 6 and comment (c) ("Beyond informing prescribing health-care providers, a drug or device manufacturer may have a duty under the law of negligence to use reasonable measures to supply instructions or warnings to nonprescribing health-care providers who are in positions to act on such information so as to reduce or prevent injury to patients.").[2]

Defendant nevertheless contends that this rule as set out in Holley has been supplanted by the relevant provisions of the North Carolina Products Liability Law, N.C. Gen. Stat. § 99B-5. Under Section 99B-5(a), to establish a claim for product liability against a manufacturer based on inadequate warnings, a claimant must prove (1) that the manufacturer acted unreasonably in failing to provide adequate warning or instruction; (2) that the failure to provide adequate warning or instruction was the proximate cause of the harm for which damages are sought; and (3) that the manufacturer either (a) knew or should have known at the time the product left the manufacturer's control that the product, without an adequate warning, created an unreasonably

[2] The Court notes that the analysis set out in Holley would apply in cases where other medical personnel, beyond just the prescribing physician, were in a position to recognize the plaintiff's adverse reaction to the drug and take steps that would have reduced her risk of injury. See Holley, 318 N.C. at 360-61, 348 S.E.2d at 776-77; see also Stanback v. Parke, Davis & Co., 657 F.2d 642, 645 n.4 (4th Cir. 1981) ("In certain failure to warn cases . . . it is possible to establish evidence of causation . . . by showing that a properly warned physician could have detected early signs of an adverse reaction to a drug and reduced the injury."). The present case raises such claims because Plaintiff contends, *inter alia*, that other medical personnel, including Dr. Schroer and Dr. Wagoner, could have taken steps to reduce her risk of injury, but did not because of the inadequate warnings provided by Defendant in the package inserts, promotional material, and medical literature. In contrast, Defendant contends that the causation determination must be limited to the prescribing physician's initial prescribing decision, citing Stanback, 657 F.2d at 645. However, the Fourth Circuit in Stanback, applying Virginia law, specifically noted that such a limitation was only appropriate in that case because "there is no specific treatment the physician can use to stop" the adverse reaction to the drug. See Stanback, 657 F.2d at 645 n.4. Thus, such a limitation would not apply if the adverse reaction can be treated or the risk of injury subsequently reduced, as Plaintiff contends in the present case.

dangerous condition that posed a substantial risk of harm to a reasonably foreseeable claimant, or (b) became aware or in the exercise of ordinary care should have known after the product left the manufacturer's control that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and "failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances." See N.C. Gen. Stat. § 99B-5(a). In addition, the Court notes that even if the claimant can establish all of the elements of his claim, Section 99B-5(c) goes further to create an affirmative defense for manufacturers and sellers of prescription drugs. Specifically, § 99B-5(c) provides that "[n]otwithstanding subsection (a) of this section, no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product." Under this "safe harbor," a prescription drug manufacturer is not liable for alleged failure to warn a consumer directly if (1) the manufacturer provided an adequate warning to the prescribing physician; and if (2) the FDA does not require direct consumer warnings for the product. Thus, the adequacy of the warning provided to the prescribing physician is the key concern in establishing this defense. This concern is demonstrated within the North Carolina Pattern Jury Instructions, whereby this "safe harbor" is presented to the jury as an affirmative defense on which the defendant bears the burden of proof, requiring the defendant to prove that it provided an adequate warning or instruction to

the prescribing physician who prescribed the drug to the plaintiff. In the present case, the MDL Court has already determined that there are genuine issues of material fact regarding the adequacy of the warnings provided by Defendant. As such, it would be appropriate to present this defense to the jury for determination in this case. However, the Court will not extend this defense beyond the statutory language. Therefore, to the extent that Defendant contends that as a legal matter, § 99B-5(c) provides more than an affirmative defense or otherwise alters the proximate cause analysis in this case, the Court rejects that contention.

Moreover, even if the Court accepted Defendant's legal contentions in this regard and limited the proximate cause analysis to only Dr. Shaw, the Court would still find that there are genuine issues of material fact related to Dr. Shaw. As noted above, Defendant contends that Plaintiff cannot establish proximate cause through Dr. Shaw because (a) the requisite causal link is broken because Dr. Shaw independently became aware of the alleged connection between bisphosphonates and ONJ, notwithstanding the warnings (or lack of warnings) provided by Defendant; and (b) Defendant further contends that Plaintiff cannot establish that Dr. Shaw would have acted any differently even if she had been given additional warnings. On the first point, that is, the "independent knowledge" contention, Defendant contends that Dr. Shaw independently became aware of a case report regarding a potential association between bisphosphonates and ONJ, and therefore no additional warnings from Defendant were required. However, it appears that based on the deposition testimony, Dr. Shaw does not recall exactly what she knew about bisphosphonates and ONJ or when she learned of the potential association, and she may even now be unaware of the risks and connection alleged by Plaintiff

between bisphosphonates and ONJ. As a result, there are genuine issues regarding what Dr. Shaw independently knew about bisphosphonates and ONJ. In addition, the Court notes that Defendant's allegation that Dr. Shaw had "independent knowledge" of the alleged risks would not necessarily support summary judgment on this claim. See Holley, 318 N.C. at 357-60, 348 S.E.2d at 775-77 (holding that even where the prescribing physician stated that he was independently aware of the risks, there were still genuine issues of fact precluding summary judgment on proximate cause, because the physician relied in part on the medical literature, which was potentially affected by the package inserts and promotional information from the drug manufacturer). Therefore, the alleged "independent knowledge" of Dr. Shaw would not warrant summary judgment in this case.

With respect to whether Dr. Shaw would have acted any differently even if she had been given additional warnings, Defendant contends that Dr. Shaw stated during her deposition that she would have continued to recommend the Aredia and Zometa to Mrs. Fussman even if Defendant had provided additional warnings. However, Dr. Shaw also indicated that she would have provided other advice to Mrs. Fussman prior to Mrs. Fussman's dental procedures, although she said it was "hard to say" exactly how the advice would have differed because the connection with ONJ "wasn't even on her radar screen." It also appears that Dr. Shaw did in fact change her treatment advice for other patients receiving bisphosphonates after receiving a "Dear Doctor" letter from Defendant regarding the need for dental screenings. Therefore, there is a genuine issue with respect to whether Dr. Shaw would have provided different treatment advice to Mrs. Fussman had the additional warnings been provided.

Finally, the Court notes that Dr. Shaw also testified that her practice was to discuss risks and potential adverse events with her patients, and Mrs. Fussman testified that she would not have taken the drug if she had been warned of the potential connection between bisphosphonates and ONJ. In these circumstances, there is a genuine issue with respect to whether additional warnings from Defendant would have been provided by Dr. Shaw to Mrs. Fussman, who claims that she would have then refused the drug. Thus, unlike cases where the prescribing physician testifies that he or she would have prescribed the drug without advising the patient of the risks or providing the warnings to the patient, e.g., Stanback v. Parke, Davis & Co., 657 F.2d 642, 645 (4th Cir. 1981), in the present case, the prescribing physician, Dr. Shaw, indicated that it was her practice to provide the warning information and potential side effects to her patients. As noted above, Mrs. Fussman testified that she would have ceased the bisphosphonate treatment had she been warned of the potential side effects. Cf. Stanback, 657 F.2d at 645-46 (finding no evidence of causation where the prescribing physician's "decisions and actions would not have been affected in the least by the communication of an adequate warning" but noting that "in a failure to warn case when the evidence suggests that a physician might have heeded an adequate warning . . . it is clear that the failure to warn could make a difference and would be a cause in fact of an injury"). For all of these reasons, and having considered the evidence presented, the Court concludes that there are genuine issues of material fact precluding summary judgment in this case.

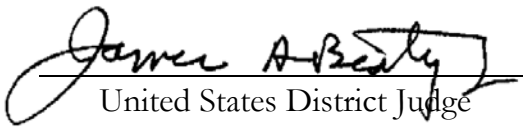
III. CONCLUSION

Therefore, having considered Defendant's Motion for Summary Judgment, the Court

declines to adopt Defendant's legal contention that proximate cause must be established only through the prescribing physician. Moreover, even if the Court accepted that legal contention, the Court would still conclude that there are genuine issues of material fact regarding whether proximate cause could be established through Dr. Shaw. Given that the MDL Court has already determined that this case should be resolved by a jury, the Court finds that there is nothing in Dr. Shaw's deposition that would change that result at this stage of the matter.

IT IS THEREFORE ORDERED that Defendant's Motion for Summary Judgment [Doc. #47] be DENIED.

This, the 18th day of October, 2010.



United States District Judge