

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

BRUCE E. BOCK and BONNIE J. BOCK)	
AS PERSONAL REPRESENTATIVES)	
OF THE ESTATE OF WILLIAM M.)	Civil Action No. 2:10-cv-1338
BOCK, DECEASED,)	
)	U.S. District Judge Mark R. Hornak
Plaintiffs,)	
)	
v.)	
)	
NOVARTIS PHARMACEUTICALS)	
CORPORATION,)	
)	
Defendant.)	

OPINION

Mark R. Hornak, United States District Judge

Plaintiffs Bruce and Bonnie Bock, as personal representatives of the estate of William M. Bock (“Bock”), filed this case against the Defendant, Novartis Pharmaceuticals Corporation (“Novartis”), alleging that Bock developed a painful and permanently disfiguring condition commonly known as osteonecrosis of the jaw (“ONJ”) as a result of using Zometa, a prescription medication designed and manufactured by Novartis for the purpose of managing metastatic bone cancer. Pending before the Court is Novartis’ Motion for Summary Judgment (ECF No. 25) aimed at the remaining Counts II and III of the Complaint. This Court has jurisdiction pursuant to 28 U.S.C. § 1332. For the reasons which follow, Defendant’s motion is granted.

I. BACKGROUND

This pharmaceutical products liability lawsuit involves two prescription drugs manufactured by Novartis: Aredia and Zometa. Both drugs have been approved by the Food and Drug Administration (“FDA”) for the treatment and management of metastatic diseases of the bone such as hypercalcemia of malignancy, multiple myeloma, and bone metastases of certain

types of cancer. Defendant's Statement of Undisputed Facts ("DSUF"), ECF No. 27, ¶¶ 1-5.¹ However, both drugs are also associated with an enhanced risk of ONJ. *Id.* ¶¶ 7-13. Plaintiffs allege that Novartis failed to adequately and properly warn Bock and his medical providers of that risk. Compl., ECF No. 1, ¶¶ 41-45.²

A. Background Concerning Zometa and ONJ

The FDA initially approved Zometa for the treatment of hypercalcemia of malignancy in August 2001. DSUF ¶ 2. In September 2003, a published letter reported cases of ONJ in patients using Aredia and Zometa. *Id.* ¶ 7. On September 26, 2003, Novartis informed the FDA that it was revising the labeling on Aredia and Zometa to include the following language in the package inserts:

Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa® or other bisphosphonates, to concomitant drugs or other therapies (e.g. chemotherapy, radiotherapy, corticosteroid), to patient's underlying disease, or to other co-morbid risk factors (e.g. anemia, infection, pre-existing oral disease).

Id. ¶ 8.

In September 2004, NPC revised the labels on Aredia and Zometa again to include the following language in the "Precautions" section of the labels:

Osteonecrosis of the jaw (ONJ) has been reported in patients with cancer receiving treatment regimens including bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures

¹ The Court is familiar with Zometa from its prior consideration of similar lawsuits in *Rowland v. Novartis Pharm. Corp.*, 34 F.Supp.3d 556, 577 (W.D. Pa. 2014).

² Counts I, IV and V of Plaintiffs' Complaint have already been dismissed with prejudice. *See* Order Granting Motion to Dismiss Counts I, IV and V, ECF No. 24. Moreover, Plaintiffs have indicated that they do not oppose entry of judgment in favor of Novartis with respect to Count II. *See* Plaintiffs' Memorandum in Opposition, ECF No. 29, at 1. Thus, only Count III remains, and its disposition is addressed in this Opinion.

such as tooth extraction. Many had signs of local infection including osteomyelitis.

A dental examination with appropriate preventative dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g., cancer, chemotherapy, corticosteroids, poor oral hygiene).

While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

Id. ¶ 10. Novartis sent a “Dear Doctor” letter to oncologists and oral surgeons on September 24, 2004, informing them of the new warnings in the Aredia and Zometa prescribing information concerning ONJ and dental surgery. *Id.* ¶ 11. Both of Bock’s treating physicians, Dr. Mohammed Islam and Dr. Mounzer Agha, were on the mailing list for the Novartis “Dear Doctor” letter. *Id.* ¶ 28.

On or about May 5, 2005, Novartis sent another mailing to dentists informing them of the language concerning ONJ in the package inserts for Aredia and Zometa. *Id.* ¶ 13. That letter contained a recommendation that cancer patients:

- receive a dental examination prior to initiating therapy with intravenous bisphosphonates (Aredia® and Zometa®); and
- avoid invasive dental procedures while receiving bisphosphonate treatment. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. Clinical judgment by the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

Id.

B. Bock's Medical History

Bock was diagnosed with anemia, leucopenia, and hypercalcemia in August 2005. DSUF ¶ 15. Bock's oncologist, Dr. Islam, initially prescribed Aredia (or a non-Novartis generic) to address the hypercalcemia. *Id.* Dr. Islam testified that it was his general practice as an oncologist to familiarize himself with prescription medications by reading the prescribing information accompanying the medicine. Deposition of Dr. Mohammed Islam ("Islam Depo."), ECF No. 27-17, at 63-64. He stated that he believed he had reviewed the package insert for Aredia prior to prescribing it for Bock, but that he couldn't specifically remember doing so. *Id.* at 64. With respect to the risk of ONJ associated with Aredia, Dr. Islam testified as follows:

Q: In 2005 were you aware that osteonecrosis of the jaw was a potential side effect of Aredia?

A: Yes.

Q: And was that something you discussed with patients?

A: If I recollect, I'm sure I did.

Q: It was your general practice to discuss it with patients?

A: That's correct.

Q: That was true in 2005?

A: Absolutely. Yes.

Q: Given that it was your general practice, do you believe that you would have discussed it with Mr. Bock?

A: Yes.

Id. at 63.

On August 27, 2005, a CT scan revealed compression fractures and multilevel degenerative changes in Bock's spine. DSUF ¶ 19. On September 7, 2005, Dr. Islam diagnosed

Bock with multiple myeloma following a bone marrow aspirate and biopsy. *Id.* ¶ 20. At that time, Dr. Islam switched Bock from Aredia to Zometa because he believed Zometa had a shorter infusion time and was more effective at preventing skeletal complications. Islam Depo., ECF No. 27-17 at 66.

In September 2005, Bock's treatment shifted to a hematologist, Dr. Agha. DSUF ¶ 25. Dr. Agha elected to continue Bock on Zometa based on the multiple fractures in Bock's spine. *Id.* ¶¶ 32-33. Dr. Agha testified that he had been using Aredia and Zometa to treat myeloma patients since 2000 and typically prescribed it for "all" of his myeloma patients by 2005. *Id.* ¶ 26. Dr. Agha stated that he had been aware of the potential link between ONJ and Aredia/Zometa at the time that he began treating Bock based on his review of the Novartis "Dear Doctor" letters and packaging inserts, as well as his general awareness of case reports concerning ONJ in Zometa patients. Deposition of Dr. Mounzer Agha ("Agha Depo."), ECF No. 27-21, at 65-66. He characterized the ONJ risk as "very rare" and stated that he believed the benefits of Zometa for treating myeloma far outweighed the risks of ONJ. *Id.* at 78-80.

Dr. Agha's treatment notes reflect that he conveyed information to Bock about the potential link between ONJ and dental procedures during a meeting in March 2006:

[Bock] also will continue on Zometa indefinitely to protect his bones and that it also had an anti-myeloma effect. It was also explained to the patient that, if he had any problems with his teeth, he needs to inform us right away. It was also explained that any dental surgery can cause necrosis of the jaw, which is rare, but he may need to be on prophylactic antibiotics. This was explained in detail to the patient and the family.

Id. at 77-78; DSUF ¶ 38. Dr. Agha testified that his practice at all times has been to warn patients about the risks and rewards of Zometa and allow them to make their own treatment decisions:

Q: [A]s an oncologist, you weigh the risks versus the benefits of that therapy?

A: There's no comparison in this setting between the risk and the benefit. The risk is so small, and, for the most part, it is not life threatening or anything compared to the tremendous benefit people get from the drug.

Q: And do you tell your patients that when - -

A: Absolutely, even today.

Q: Now, not just with respect to biophosphonates, but any therapy that you recommend to the patient, do you express to them the risks of the therapy and the benefits of that therapy?

A: Correct.

Q: And where you may be able to give your opinion whether or not they should go on it or not, because you are recommending it, is it, ultimately, their decision whether or not to undergo the therapy?

A: Absolutely. The treatment is only guidelines and recommendations. Every patient chooses their own treatment.

Id. at 79-80. Under Dr. Agha's care, Bock continued to take Zometa until April, 2009. DSUF ¶ 33.

In February 2008, Bock visited his oral surgeon, Dr. Kent Galey, for extraction of a decayed tooth. Deposition of Dr. Galey ("Galey Depo."), ECF No. 27-27, at 28. Dr. Galey recalled seeing Zometa on the list of Bock's medications, but testified that he didn't think he was familiar with the drug at that time because "it was not a real hot issue for us in that time frame."

Id. at 31. When questioned at deposition as to whether he would have discussed the risks of dental surgery for a patient on Zometa with Bock, Dr. Galey testified as follows:

Q: Did you have any discussion with Mr. Bock at any point in time when you were treating him regarding Zometa and the possible side effect of osteonecrosis of the jaw?

A: Not according to my chart, and I have no recollection of that.

Q: Let me ask you this: Would it have been your practice, based on the information in the literature at the time, to have such a discussion with a patient once you learned that they were taking Zometa?

A: Yes.

Q: You indicated earlier that you don't specifically recall Mr. Bock, but based on your general practice in informing patients of potential risks of medications they may be on that might affect your treatment of them, do you believe you would have discussed the issue with Mr. Bock?

A: I believe I probably would have, yes.

Id. at 35-36. Dr. Galey also testified that Bock's tooth extraction was unavoidable, even in light of the increased risk of ONJ. *Id.* at 42. Dr. Galey subsequently performed three additional dental surgeries on Bock: a bone procedure known as a debridement in November 2008, another debridement in December 2008, and another tooth extraction in March 2009. DSUF ¶¶ 47-49.

In May 2009, another oral surgeon, Dr. Michael Kail, preliminarily diagnosed Bock with ONJ. *Id.* ¶ 51. Dr. Kail also observed that Bock required an additional tooth extraction and debridement. *Id.* ¶ 52. Dr. Kail "extensively" reviewed the risk that the surgery could "potentially aggravate the problems of the left maxilla secondary to osteonecrosis" with Bock, but Bock elected to go ahead with the procedure. *Id.* ¶¶ 53-54. Bock consented to another extraction and debridement in November 2010. *Id.* ¶ 57. Bock passed away on July 18, 2011. *Id.* ¶ 58.

At deposition, Dr. Islam and Dr. Agha were each questioned concerning their current practices with respect to Aredia and Zometa. Dr. Islam testified that he still prescribes Aredia and Zometa to patients with multiple myeloma. DSUF ¶ 23. When asked whether he would prescribe either drug to a patient who "presented to you today like Mr. Bock," Dr. Islam answered in the affirmative. *Id.* ¶ 24. Dr. Agha agreed:

Q: [S]ince you treated Mr. Bock, has your biophosphonate therapy recommended for patients like Mr. Bock changed at all?

A: No.

Q: So you still put them on monthly Zometa?

A: Correct.

Q: And you keep them on that indefinitely?

A: Correct.

Q: And has that changed since you became aware of the potential relationship between biophosphonate therapy and osteonecrosis of the jaw?

A: No.

DSUF ¶ 41.

II. STANDARD FOR REVIEW

Federal Rule of Civil Procedure 56(c)(2) provides that summary judgment shall be granted if the “pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Rule 56(e) further provides that when a motion for summary judgment is made and supported, “an opposing party may not rely merely on allegations or denials in its own pleading; rather, its response must – by affidavits or as otherwise provided in this rule – set out specific facts showing a genuine issue for trial. If the opposing party does not so respond, summary judgment should, if appropriate, be entered against that party.”

A material fact is a fact whose resolution will affect the outcome of the case under applicable law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The moving party has the initial burden of proving to the district court the absence of evidence supporting the non-moving party's claims. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Country Floors, Inc.*

v. Partnership Composed of Gepner and Ford, 930 F.2d 1056, 1061 (3rd Cir. 1990). Further, “[R]ule 56 enables a party contending that there is no genuine dispute as to a specific, essential fact ‘to demand at least one sworn averment of that fact before the lengthy process of litigation continues.’” *Schoch v. First Fidelity Bancorporation*, 912 F.2d 654, 657 (3rd Cir. 1990) (quoting *Lujan v. National Wildlife Federation*, 497 U.S. 871 (1990)). The burden then shifts to the non-movant to come forward with specific facts showing a genuine issue for trial. *Matsushita Elec. Indus. Company v. Zenith Radio Corp.*, 475 U.S. 574 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460-461 (3rd Cir. 1989) (the non-movant must present affirmative evidence - more than a scintilla but less than a preponderance - which supports each element of his claim to defeat a properly presented motion for summary judgment).

III. DISCUSSION

In order to state a claim for negligent failure to warn under Pennsylvania law, a plaintiff must show that (1) the defendant manufacturer owed a duty to the plaintiff; (2) the manufacturer breached that duty; and (3) that breach was the proximate cause of the plaintiff's injuries. *Salvio v. Amgen*, 810 F.Supp.2d 745, 752 (W.D. Pa. 2011) (internal citations omitted). The plaintiff must also prove that the manufacturer was at fault. *Id.*

In failure to warn cases involving prescription drugs, Pennsylvania courts apply the learned intermediary doctrine:

[T]he manufacturer of a prescription drug known to be dangerous for its intended use, has a duty to exercise reasonable care to inform those for whose use the article was supplied of the facts which make the product likely to be dangerous. However, the warnings which are required to be given by the manufacturer must be directed to the physician, not the consumer. This is so because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects

associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as it is for the prescribing physician to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug. Thus, in an action against a drug manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate.

Daniel v. Wyeth Pharm., Inc., 15 A.3d 909, 924 (Pa. Super. Ct. 2011) (quoting *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. Ct. 1990)). Thus, by warning the consumer's physician, the manufacturer discharges its duty to the consumer. *Salvio*, 810 F.Supp.2d at 752.

The sole issue raised in Novartis' summary judgment motion is whether Bock's injuries were proximately caused by the alleged inadequacy of the Aredia and Zometa warnings. In order to establish proximate causation under Pennsylvania law, a plaintiff must "show that with a different warning, the prescribing doctor would have changed his prescribing practices, *and* the plaintiff's injury would have been avoided." *Rowland*, 34 F.Supp.3d at 577 (emphasis in original); *see also Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996) (holding that "plaintiffs must . . . establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided."). The evidence introduced "must be of sufficient weight to establish . . . some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug." *Demmler*, 671 A.2d at 1155 (quoting *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir.1992)). This "plainly and centrally fact-intensive" inquiry is undertaken on a case-by-case basis. *Rowland*, 34 F.Supp.3d at 573-74.

In seeking summary judgment, Novartis contends that Bock has failed to adduce any evidence from which it might be inferred that a different warning would have changed the course of his treatment and prevented injury. Several Pennsylvania decisions have granted summary judgment on the basis of a lack of proximate cause under such circumstances. In *Demmler*, for example, the court granted summary judgment on a failure to warn claim because the plaintiff failed to present evidence that “a more thorough or more explicit warning would have prevented [her] use of [the drug]” or “that a different warning would have altered [her] use of [the drug] in accordance with [her doctor’s] instructions. *Demmler*, 671 A.2d at 1155-56. Similarly, in *Lineberger v. Wyeth*, the court found the record to be “devoid of evidence to support [plaintiff’s] argument that a different warning would have altered [her doctor’s] prescribing methods vis-à-vis [plaintiff].” *Lineberger*, 894 A.2d 141, 150-51 (Pa. Super. Ct. 2006). The court ultimately granted summary judgment because “the plaintiff’s physician testified that a different warning would not have changed his decision to prescribe the drug in question.” *Id.* See also *Adams v. Wyeth*, 2005 WL 1528656, at *4 (Pa. Ct. Com. Pl. 2005) (“[Plaintiff] had the burden to establish proximate cause by coming forward with evidence of sufficient weight showing that had Wyeth provided an adequate warning . . . Dr. Gillett would have changed his prescribing habits and she would not have received the drug. This she failed to do.”) (citations omitted); *Parkinson v. Novartis Pharm. Corp.*, 5 F.Supp.3d 1265, 1274 (D. Or. 2014) (granting summary judgment on proximate cause and noting that “numerous courts have held an allegedly deficient warning from a prescription product’s seller cannot be the proximate cause of the plaintiff’s injuries when a prescribing physician would still take the same course of action if he or she had been warned differently or ‘more adequately’ warned”) (collecting cases).

On the other hand, courts have denied summary judgment when presented with evidence that the plaintiff's prescribing physician had been unaware of the risk of injury created by the drug and would have acted differently had he or she been aware of that risk. In *Simon v. Wyeth Pharm., Inc.*, 989 A.2d 356, 375 (Pa. Super. Ct. 2009), the plaintiff's prescribing physician testified that he would still have "no qualms" about prescribing the drug at issue to the plaintiff despite new information suggesting an increased risk of breast cancer, but indicated that he would have warned the plaintiff about that risk. *Id.* at 374-75. He also acknowledged that he had changed his standard practices to include such warnings in his discussions with his patients about the drug. *Id.* Moreover, the plaintiff testified that she would not have taken the drug had she been warned of the risks. *Id.* at 375. On this basis, the court held that the plaintiff had provided sufficient evidence that "a more complete labeling of [the drug] would have altered the prescribing practices of the [prescribing physician] and [plaintiff's] use of the drug." *Id.*

Similarly, in *Daniel v. Wyeth Pharm., Inc.*, the court upheld the denial of a motion for judgment notwithstanding verdict on the issue of proximate cause where the prescribing physician testified that, had he been provided with a different warning about the risk of breast cancer inherent to the drug in question, he would have "passed this information along to [the plaintiff] and emphasized it during their discussions regarding the risks associated with taking the drug." *Daniel*, 15 A.3d 909, 925 (Pa. Super. Ct. 2011). The court also credited the plaintiff's testimony that, had she been warned about the risk of breast cancer, she would have declined the drug. *Id.* at 925.

This Court's decision in *Rowland* is also instructive. The first named plaintiff there, Rowland, began taking Zometa in 2004. 34 F.Supp.3d at 574. Her prescribing physician could not recall whether he had been aware of the association between Zometa and ONJ at the time

that he prescribed the drug. *Id.* He indicated, however, that ONJ had become “a very big concern” with Zometa patients since that time. *Id.* He testified that he still prescribed Zometa to his patients, but that he had changed his standard procedures and warnings so as to spend a “greater amount of time . . . describing the risk of [ONJ].” *Id.* at 575. Moreover, Rowland testified that she would not have taken Zometa if she had been apprised of the risk of developing ONJ. *Id.* The Court concluded that “a genuine issue of fact exists as to proximate cause because if given a different warning [on the label], Dr. Waas would likely have advised Ms. Rowland of the risk of [ONJ], and she could have refused to take the drug.” *Id.*

With respect to a second *Rowland* plaintiff, Orr, the record reflected that his physician had not been aware of the risk of ONJ at the time that he prescribed Zometa. *Id.* The physician maintained that a different warning label would not have changed his decision to prescribe the drug, but that he would have “counseled [Orr] about the risk and benefits of the treatment and let him make an informed decision.” *Id.* He also testified that he had altered his prescribing habits with respect to Zometa by changing the duration of the treatment and instructing patients to have a dental evaluation before taking the drug. *Id.* A second treating physician agreed that, if given an adequate warning, he would still choose to prescribe the drug but would make sure to explain the risks to his patient. *Id.* Finally, Orr testified that he would have declined the drug if the risk of ONJ had been fully explained to him and if the risk had been categorized as greater than three percent. *Id.* The Court concluded that the aforementioned testimony created a genuine issue of material fact because full disclosure of Zometa’s risks “may have induced Mr. Orr to refuse to take the drug, which in turn would have prevented his injury.” *Id.*

The Court reached a different result with respect to the final *Rowland* plaintiff, Machen. *Id.* at 576. Machen’s physician, Dr. Finley, could not recall whether he had warned Machen

about the risk of ONJ at the time that he first prescribed Zometa. *Id.* at 576-77. However, the record reflected that Dr. Finley had signed a standardized Zometa administration form that contained information about the risks of ONJ. *Id.* at 577. Dr. Finley testified that the proper standard of care would have been to give Machen the form, but that he was not sure if he had done so. *Id.* He also testified that he had recently changed his procedures to require Zometa patients to undergo a dental exam and have a dental clearance form. *Id.*

Significantly, the Court observed that the record contained no evidence that Machen would have refused to take Zometa even if he had been informed of the risk. *Id.* at 578. Moreover, Machen's expert witnesses opined that his ONJ would not have been prevented by a dental examination and that the tooth extraction that ultimately precipitated Machen's development of ONJ had been medically unavoidable. *Id.* Based on that record evidence, the Court concluded that Machen had failed to create a triable issue of fact as to whether a different warning label would have changed his physician's prescribing practices and prevented his injury. *Id.*

In this case, a careful review of the record reveals a complete absence of the type of evidence that precluded summary judgment in *Simon, Daniel, and Rowland* (with respect to plaintiffs Rowland and Orr). Unlike the situation in each of those cases, Bock's physicians were already well aware of the risk of ONJ at the time that they prescribed the drug. Islam Depo. at 63; Agha Depo. at 65-66; DSUF § 28. Both physicians testified that they would certainly have discussed that risk with Bock, allowing him to make an informed decision as to his treatment. Islam Depo. at 63; Agha Depo. at 76-78; DSUF ¶38. Indeed, Dr. Agha's treatment notes reflect that he had a "detail[ed]" conversation with Bock concerning those risks. *Id.* Moreover, both physicians indicated that they would still prescribe the drug today if presented with a patient

such as Bock because, in their medical judgment, the benefits of the drug significantly outweigh the risks. DSUF ¶¶ 24, 41; Agha Depo. at 78-80.

Due to Bock's passing in 2011, the record also lacks any testimony from the Plaintiff concerning the warnings that he received or what decision he might have made if given a different warning – a critical factor in each of the aforementioned cases. *See Simon*, 989 A.2d at 375 (plaintiff testified that she would not have taken the drug had she been informed of the risks); *Daniel*, 15 A.3d at 925 (same); *cf. Rowland*, 34 F.Supp.3d at 577 (granting summary judgment where there was no evidence in the record that Machen would have declined Zometa even if adequately warned). That said, the record does reflect that Bock consented to each of the unavoidable dental procedures that ultimately precipitated his ONJ despite being thoroughly warned as to the potential risks. Galey Depo at 35-36; DSUF ¶¶ 53-54, 57. *See Rowland*, 34 F.Supp.3d at 578 (noting that summary judgment was appropriate in part because plaintiff Machen's "tooth extractions were necessary due to other health concerns."). Each of these factors supports a grant of summary judgment as to proximate cause.

Bock argues that the Court should not grant summary judgment without first hearing expert testimony concerning what information the Aredia and Zometa warning labels should have provided. However, the issue raised in the instant motion is proximate cause, rather than the adequacy of the warnings. *See Rowland*, 34 F.Supp.3d at 572-73 (granting summary judgment against Machen based on lack of proximate cause despite finding that the adequacy of the warning was an issue for the jury). As noted above, Bock has failed to adduce any evidence from which the Court might infer that either of Bock's physicians would have prescribed the drug differently had they been presented with a different warning or that Bock would have refused the drug under such circumstances.

Bock next cites several cases for the proposition that summary judgment is precluded where there is evidence that a material change in the prescribing doctor's practice has occurred. See Plaintiff's Memorandum in Opposition ("Pl. Memo."), ECF No. 29, at 8; see, e.g., *Simon*, 989 A.2ds at 374-76 (finding proximate cause where physician would have "no qualms" about prescribing the drug at issue, but had changed his warning practices). Bock relies entirely on Dr. Agha's statement that his current practice is to "hold [Zometa] for a month before any dental procedures . . .". See Agha Depo. at 62-63. Bock contends that this "material change" in Dr. Agha's procedures might have prevented Bock's injury. Pl. Memo. at 8-9. However, Dr. Agha's deposition plainly demonstrates that he utilized the same practices in 2005:

Q: Does [the 2004 Novartis "Dear Doctor" letter] provide any type of guidance to the practitioner as to what they should be doing?

A: The most important thing was about the avoiding evasive dental procedures which is still valid.

Q: So even today you tell your patients that you're putting on biophosphonate therapy?

A: I go beyond this, because I believe that biophosphonates are very important, so I would not stop the drugs. What I usually do is hold the drug for a month before any dental procedures, and I have them get the dental procedure, and then I have them restart the drug.

Q: Now, today, if you have a patient such as Mr. Bock that comes in and is not on a biophosphonate therapy, and you intend to put him on a biosphosphonate, would you tell him to get a dental examination before that treatment begins?

A: So unless they have . . . real significant dental issues, usually the treatment benefit outweighs any potential risk of [ONJ]. . . . But what we would do is we would initiate biosphosphonate therapy, and if at any time a significant dental issue comes out, I would hold the drug, let them take care of it, and then come back.

* * * * *

Q: And is that true today as well?

A: Correct.

Q: And that was treatment –

A: True today, yes.

Q: And that was true back in 2005?

A: Right.


Agha Depo. at 63-64.

Finally, Bock contends that the deposition testimony provided by Dr. Agha and Dr. Islam lacks credibility and must be evaluated by a jury. However, Bock has not pointed to any evidence in the record that might contradict either physician's testimony. It is axiomatic that a plaintiff cannot survive a well-supported summary judgment motion by simply asserting that the opposing witnesses lack credibility. *See, e.g., Grobelny v. Baxter Healthcare Corp.*, 341 F. App'x 803, 807-08 (3d Cir. 2009) (accepting the truth of a treating physician's testimony as to the adequacy of a warning for purposes of summary judgment because the opposing party had failed to present any evidence that might have undermined the physician's credibility); *Waskovich v. Morgano*, 2 F.3d 1292, 1296 (3d Cir. 1993) (noting that facts testified to in "deposition testimony . . . if there is no contradictory evidence . . . may be accepted as true for summary judgment purposes without an assessment of the credibility of the witness").

In sum, Bock has failed to present any evidence that might create a triable issue of fact as to whether his injuries could have been avoided with a different warning. As such, summary judgment is warranted.

IV. CONCLUSION

For the foregoing reasons, Defendant's Motion for Summary Judgment is granted. An appropriate Order will issue.

A handwritten signature in black ink, appearing to read 'Mark R. Hornak', written over a horizontal line.

Mark R. Hornak
United States District Judge

Dated: October 7, 2015

cc: All Counsel of Record