UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Nº 12-CV-1421 (JFB)(WDW)

BRIAN BEE & DONNA BEE,

Plaintiffs,

VERSUS

NOVARTIS PHARMACEUTICALS CORP.,

Defendant.

MEMORANDUM AND ORDER
May 9, 2014

JOSEPH F. BIANCO, District Judge:

Plaintiffs Brian Bee ("Bee" or "plaintiff") and Donna Bee ("D. Bee") (collectively, "plaintiffs") bring this products liability action against Novartis Pharmaceuticals Corporation ("Novartis," "NPC," or "defendant"), alleging that Novartis's drugs Zometa and Aredia, prescribed to Bee as part of a regimen to treat his ankylosing spondylitis, osteoporosis, and bone pain, caused him to develop osteonecrosis of the jaw ("ONJ").[1] Plaintiffs allege claims of strict liability, negligent manufacture, negligent failure to warn, breach of express warranty, breach of implied warranty, and loss of consortium against defendant. They assert that Novartis (1) negligently (i) tested Aredia and Zometa and (ii) failed to warn about the drugs' potential risks and precautions that could be taken to minimize such risks; (2) is strictly liable for (i) Aredia's and Zometa's allegedly defective design and manufacturing, and (ii) its failure to warn of the possible risk of ONJ; and (3) breached its products' express and implied warranties.[2]

[1] Osteonecrosis is a medical term for bone death arising from poor blood supply to the bone. (*See* Compl. ¶ 1.) Plaintiffs refer to the condition as "BRONJ," or bisphosphonate related osteonecrosis of the jaw. (*See* Pls. Opp'n to Def. Mot. for Summ. J. ("Pls. Opp'n") at 1.) For reasons set forth *infra*, the Court concludes that there are genuine issues of material fact as to whether the bisphosphonates at issue in this case (specifically, Aredia and Zometa) caused plaintiff's injury. Accordingly, the Court refers to the alleged risk and injury at issue here as "ONJ" instead of BRONJ.

[2] In their opposition, plaintiffs voluntarily dismiss the express warranty and manufacturing defect claims. (*See* Pls. Opp'n at 25 ("Plaintiff does not oppose judgment on express warranty or manufacturing (as opposed to design) defect but implied warranty claims survive.").) Accordingly, the Court grants defendant's motion for summary judgment as to the manufacturing defect and express warranty claims.

Presently before the Court are several motions brought by Novartis. These include six *Daubert* motions seeking to exclude the testimony of plaintiffs' case-wide experts, and a motion for summary judgment. Because Novartis's six *Daubert* motions against plaintiffs' case-wide experts address issues beyond the scope of the pending summary judgment motion, the Court limits its analysis here to those arguments raised in the motion for summary judgment. Where certain of these arguments touch upon other *Daubert* motions raised previously in this litigation, these are addressed as necessary for purposes of resolving the summary judgment motion.

Turning to the summary judgment motion itself, Novartis contends that summary judgment in its favor is warranted because the uncontroverted evidence in the record shows that (1) Novartis had no duty to warn of risks associated with taking Aredia and Zometa for treatment of ankylosing spondylitis or osteoporosis; (2) Novartis adequately warned prescribers about the risk of ONJ associated with the challenged medications once it became aware of such a risk; (3) plaintiffs cannot show that Novartis's warning as to ONJ was the proximate cause of Bee's injury; (4) plaintiffs have no evidence that Aredia and Zometa substantially caused Bee's ONJ, nor do they offer admissible expert testimony in support of the same; (5) plaintiffs proffer no evidence showing that either Aredia or Zometa differed in any way from design specifications; (6) because Novartis provided an adequate warning, plaintiffs' strict liability, negligence, and breach of implied warranty claims, which rely on allegations that Aredia and Zometa's warnings were defective, must fail; (7) plaintiffs point to no evidence showing that Novartis made an express warranty upon which Bee or his doctor relied; and (8) because a loss of consortium claim is a derivative claim, and plaintiff's other claims all fail, summary judgment is warranted to defendant as to this claim.

After careful consideration of the parties' arguments and a full review of the record, the Court denies Novartis's motion for summary judgment its entirety for the following reasons.

I. BACKGROUND

This case is part of "Wave III" of a multidistrict litigation in the United States District Court for the Middle District of Tennessee ("the MDL Court"). The Court has taken the facts set forth below from the parties' depositions, affidavits, exhibits, and respective Rule 56.1 Statements of Facts. The Court construes the facts in the light most favorable to the non-moving party. *See Capobianco v. City of New York*, 422 F.3d 47, 50–51 (2d Cir. 2005). Unless otherwise noted, where a party's 56.1 statement is cited, that fact is undisputed or the opposing party has not pointed to any evidence in the record to contradict it.[3]

A. Plaintiff's General Medical History

Plaintiffs Brian and Donna Bee are New York residents. (Def. Rule 56.1 Statement ("Def. 56.1") ¶ 96; Pls. Rule 56.1 Response ("Pls. 56.1") ¶ 96.) Plaintiff has suffered from several medical conditions over the years.[4] By 1995, at the age of twenty-nine, plaintiff had a history of Schmorl's nodes,[5]

[3] Additionally, although the parties' Rule 56.1 statements contain specific citations to the record in support of their statements, the Court generally cites to the Rule 56.1 statements, rather than to the underlying citations to the record.

[4] Plaintiff began smoking at the age of twenty-one, and smoked about a pack of cigarettes a day until approximately January 2011, when he quit for good. (*See* Def. 56.1 ¶ 1; Pls. 56.1 ¶ 1.)

[5] Schmorl's nodes "are protrusions of the cartilage of

vertebral compression deformity, vertebral bone spur,[6] and osteochonditis.[7] (Def. 56.1 ¶ 2.) That same year, doctors also diagnosed plaintiff with ankylosing spondylitis, "'a chronic systemic inflammatory disease that primarily attacks the axial skeleton and adjacent structures.'" (*Id.* ¶ 7 (quoting Michael Weisman, Ankylosing Spondylitis 5 (2011)).) Plaintiff's medical problems continued as he entered his thirties, being diagnosed in July 1996 with multiple collapsed vertebrae, and in September 1996, with osteoporosis. (*Id.* ¶¶ 8–9.)

Bee's youth, as well as the severity of his medical condition, made him a unique patient for doctors. (Def. 56.1 ¶¶ 101, 107.) In light of plaintiff's poor bone condition, doctors referred Bee to an oncologist, Dr. Edward Samuel ("Dr. Samuel"), in August 1996 to determine whether a malignancy had caused his vertebrae to weaken and collapse; tests, however, were negative. (*Id.* ¶ 10; *see also* Pls. 56.1 ¶ 10.) After conducting various examinations, Dr. Samuel concluded that plaintiff did not have cancer. (Def. 56.1 ¶ 11; Pls. 56.1 ¶ 11.) Nevertheless, Dr. Samuel—whose practice consisted predominantly of cancer patients (*see* Def. 56.1 ¶ 102)—offered to treat plaintiff by using some of the same methods he applied to his cancer patients. (*Id.* ¶ 12; Pls. 56.1 ¶ 12.) Dr. Samuel hoped to strengthen plaintiff's bones in order to prevent further fractures or associated pain. (Def. 56.1 ¶ 107; Pls. 56.1 ¶ 107.) In October 1996, Bee was prescribed the oral bisphosponate, Fosamax, an approved drug for strengthening the bones of patients with osteoporosis. (Def. 56.1 ¶¶ 13–14; Pls. 56.1 ¶¶ 13–14.)

Plaintiff's health problems continued. After October 1996, he continued to lose height, and bone scans showed several of his vertebrae to be deteriorating. (Def. 56.1 ¶ 15; Pls. 56.1 ¶ 15.) The tests also showed formation of new Schmorl's nodes and increasingly abnormal bone signals. (Def. 56.1 ¶ 16; Pls. 56.1 ¶ 16.)

As time passed, Fosamax proved to be a difficult drug for plaintiff; it hurt his stomach and he had trouble regularly taking it. (Def. 56.1 ¶ 17; Pls. 56.1 ¶ 17.) Accordingly, on August 27, 1997, Dr. Samuel, based on his medical judgment and the available literature at the time, decided to switch plaintiff to Aredia, a drug that would similarly aid Bee's pain and bone problems, but which did not have the same side effects as Fosamax. (Pls. 56.1 ¶ 18; *see also* Def. 56.1 ¶¶ 18, 104.)[8] Plaintiff, after thinking it over, decided to make the switch.[9] (*See* Pls. 56.1 ¶ 104.) In contrast to

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the intervertebral disc through the vertebral body endplate and into the adjacent vertebra." (Def. 56.1 ¶ 3 (quoting Stedman's Medical Dictionary 1222–23 (27th ed., 2000)).)

[6] A bone spur, also known in the medical field as an osteophyte, is "a bony excrescence or osseous outgrowth." (Def. 56.1 ¶ 4 (quoting Doreland's Illustrated Medical Dictionary 1336 (30th ed., 2003)).)

[7] Osteochondritis is "inflammation of both bone and cartilage." (Def. 56.1 ¶ 4 (quoting Doreland's Illustrated Medical Dictionary 133 (30th ed., 2003)).)

[8] When Dr. Samuel began prescribing Aredia for plaintiff, the doctor had been board certified in internal medicine, hematology, and oncology for at least fifteen years, and had prior experience treating osteoporosis with bisphosphonates. (Def. 56.1 ¶ 122; Pls. 56.1 ¶ 122.)

[9] Plaintiff testified that he was "[d]esperate to find a solution" to manage his pain, and also, to curb the development of his osteoporosis when he first began seeing Dr. Samuel. (Def. 56.1 ¶ 103; Pls. 56.1 ¶ 103; *see also* Def. 56.1 ¶ 115 (stating that Bee testified he was willing to take whatever Dr. Samuel prescribed him, even if it was intended for other conditions, on account of the extreme pain that he was in); Pls. 56.1 ¶ 115 (noting that Bee carefully considered those

Fosamax, an oral medication, Aredia was an intravenous bisphosphonate "indicated for the treatment of hypercalcemia of malignancy, bone metastases from certain types of cancer, multiple myeloma, and Paget's disease." (Def. 56.1 ¶ 19.) Although plaintiff did not have any of these specific conditions (*see* Pls. 56.1 ¶ 19), it was hoped that Aredia would allow him to receive the bisphosphonates he needed without causing the problems he experienced when trying to ingest them gastrointestinally (*id.* ¶ 18). For a cancer patient, the recommended dose of Arcadia is a 90 mg intravenous infusion over ninety minutes; plaintiff received such cancer-level doses from August 27, 1997 through October 2002. (Def. 56.1 ¶¶ 20–21; Pls. 56.1 ¶¶ 20–21.)[10] Plaintiff received all of his Aredia infusions in New York. (Def. 56.1 ¶ 97; Pls. 56.1 ¶ 97.)

As plaintiff underwent these medical treatments, his health status altered over the years. For instance, by 1998, plaintiff's osteoporosis had worsened to severe osteoporotic bone disease. (Def. 56.1 ¶ 25; Pls. 56.1 ¶ 25.) By June of 2000, plaintiff developed a hunched back, or "90 degree severe kyphosis," which required surgery that included fusing several of his spinal vertebrae and implanting surgical rods. (Def. 56.1 ¶ 26; Pls. 56.1 ¶ 26.) Plaintiff subsequently received the corticosteroid prednisone; although defendant contends that plaintiff received this "periodically" (Def. 56.1 ¶ 27), plaintiffs assert that Bee only had two treatments of the drug during 2000 and 2002, and that Dr. Samuel "prescribed [p]rednisone for Bee for a short period in July 2001 because of an acute severe exacerbation of Bee's back pain accompanied by left sided sciatica" (Pls. 56.1 ¶ 27). Plaintiff was advised that prednisone could possibly have an adverse impact on his osteoporosis should it be taken for an extended period of time. (Def. 56.1 ¶ 28; Pls. 56.1 ¶ 28.)

In 2002, plaintiff was diagnosed with arthritis and early osteoarthritis. (Def. 56.1 ¶ 29; Pls. 56.1 ¶ 29.) That same year, he suffered back pain so severe that he was on bed rest for two weeks. (Def. 56.1 ¶ 30; Pls. 56.1 ¶ 30.) In December 2002, plaintiff, under Dr. Samuel's guidance, began taking Zometa, "an intravenous bisphosphonate indicated for hypercalcemia of malignancy, the treatment of bone metastases from certain types of cancer, multiple myeloma, and Paget's disease." (Def. 56.1 ¶ 23; *see also id.* ¶ 104.) Bee took Zometa through September 2004. (*Id.* ¶ 24; Pls. 56.1 ¶ 24.) He received all of his infusions in New York. (Def. 56.1 ¶ 97; Pls. 56.1 ¶ 97.) It seems that after plaintiff stopped taking Zometa, his skeletal disease continued to progress, and his pain, while fluctuating in intensity levels, continued. (Def. 56.1 ¶ 33; Pls. 56.1 ¶ 33.)

In 2005, plaintiff was diagnosed with right deep vein thrombosis, a pulmonary embolism, chronic obstructive pulmonary disease, and peptic ulcer disease. (Def. 56.1 ¶¶ 31–32; Pls. 56.1 ¶¶ 31–32.) In May 2007, plaintiff had another spinal fusion surgery in which more of his vertebrae were fused together and additional instruments were implanted into his spine for support. (Def. 56.1 ¶ 34; Pls. 56.1 ¶ 34.)

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drugs he was willing to take and noting another drug he elected not to take due to its side effects).)

[10] Although defendant asserts that plaintiff received such doses of Aredia on an "almost monthly" basis during this time period, plaintiffs clarify that "approximately 10 of the treatments took place over two months apart, with 4 of those instances occurring more than three months apart," and that "[t]hey were less than that, depending upon whether practitioners evaluated Bee and determined that the treatment was appropriate." (Pls. 56.1 ¶ 21.)

B. Plaintiff's Dental History

From 1999 through 2003, plaintiff experienced various dental difficulties. Specifically, he had periodontal disease, bleeding gums, multiple dental caries, dental fillings, painful and sensitive teeth, a root canal, and a mobile tooth.[11] (Def. 56.1 ¶ 37; Pls. 56.1 ¶ 37.) In May 2003, Bee informed Dr. O'Lear that he was experiencing pain in his lower-right mouth; Dr. O'Lear noticed that several of the teeth he had previously restored in plaintiff's mouth were missing fillings, and further, that other teeth might be in need of root canals. (Def. 56.1 ¶ 38; Pls. 56.1 ¶ 38.) Several months later, Dr. O'Lear referred plaintiff to an oral surgeon, Dr. Thomas Arcati ("Dr. Arcati"), upon discovering that plaintiff had "rampant caries." (Def. 56.1 ¶ 39; Pls. 56.1 ¶ 39.)

According to Dr. Arcati, plaintiff failed to disclose that he was taking Zometa. (Def. 56.1 ¶ 118; Pls. 56.1 ¶ 118.) Dr. Arcati also testified that he was aware of a relation between bisphosphonates and ONJ as of September 2003, and stated that he would not have extracted plaintiff's teeth had he known that plaintiff was taking Zometa. (Def. 56.1 ¶ 119.)

After examining plaintiff's mouth, Dr. Arcati determined that surgery was needed; of the sixteen non-restorable teeth in plaintiff's mouth, Dr. Arcati extracted eight of those in October 2003 and the remaining eight in November 2003. (Def. 56.1 ¶¶ 40–41; Pls. 56.1 ¶¶ 40–41.) Dr. Arcati found plaintiff to be healing well following both surgeries. (Def. 56.1 ¶ 42; Pls. 56.1 ¶ 42.) A little over three months later, in March 2004, plaintiff visited Dr. Arcati again, this time with exposed bone that required Dr. Arcati to smooth a large bone spicule in plaintiff's mandible. (Def. 56.1 ¶ 43; Pls. 56.1 ¶ 43.) Plaintiffs contend this was not the only visit that Bee made to Dr. Arcati in March 2004; instead, they claim that Bee visited him approximately six times "with exposed bone, jaw pain and other related issues." (Pls. 56.1 ¶ 43.) During this time, Dr. Arcati encouraged plaintiff to quit smoking; he also noted that the area from which he had removed the spicule was healing well. (*Id.* ¶ 44; *see also* Def. 56.1 ¶ 44.)

In late March 2004, plaintiff had exposed bone on both his right mandible and left maxilla; he returned to Dr. Arcati, who instructed plaintiff to return for weekly treatment. (Def. 56.1 ¶¶ 45–46; Pls. 56.1 ¶¶ 45–46.) Because of travel limitations, plaintiff did not see Dr. Arcati again until late April. (Pls. 56.1 ¶ 47.) At that time, Dr. Arcati referred plaintiff to Dr. Salvatore Ruggerio ("Dr. Ruggiero"), an oral surgeon, whom plaintiff visited approximately two and a half months later. (Def. 56.1 ¶ 48; Pls. 56.1 ¶ 48.)

After examining plaintiff, Dr. Ruggiero concluded that plaintiff's exposed bone likely was attributable to bisphosphonate use. (Def. 56.1 ¶ 49; Pls. 56.1 ¶ 49.)[12] Bee, who was taking Zometa at the time, went for two more infusions of Zometa during his

[11] Although no records indicate whether plaintiff visited the dentist between July 1993 and December 1997, plaintiff asserts that he visited his dentist, Dr. Brian O'Lear ("Dr. O'Lear") during this time for routine cleanings. (Pls. 56.1 ¶ 35.) In December 1997, plaintiff visited Dr. O'Lear to have several cavities filled. (Def. 56.1 ¶ 36; Pls. 56.1 ¶ 36.)

[12] Although defendant contends that Dr. Ruggiero believed plaintiff's exposed bone "was *likely* secondary to bisphosphonate use," (Def. 56.1 ¶ 49 (emphasis added)), plaintiffs assert that "there is no doubt in Dr. Arcati's mind that Bee's ONJ was *caused* by his bisphosphonate use," and that "none of Bee's treating physicians have ever challenged the origin of Bee's ONJ as being something other than bisphosphonate use" (Pls. 56.1 ¶ 49).

treatment with Dr. Ruggiero. (Def. 56.1 ¶ 50; Pls. 56.1 ¶ 50.) According to plaintiffs, Bee asked Dr. Ruggiero if stopping of the Zometa treatments would help his condition; plaintiffs contend that the doctor informed him it would not, as "once it's in your system it's always going to be there." (Pls. 56.1 ¶ 50.) It appears that Bee also informed Dr. Samuel of Dr. Ruggiero's determination that plaintiff's exposed bone was due to the bisphosphonates; when Dr. Samuel saw the exposed bone in plaintiff's mouth, he ultimately decided to cease treatment, which occurred in September 2004. (Def. 56.1 ¶ 110; Pls. 56.1 ¶ 110.)

In November 2004, plaintiff went back to Dr. Arcati; when Dr. Arcati saw him the following month, the exposed bone in plaintiff's maxilla had healed, and the exposed bone in his right mandible area was improving. (Def. 56.1 ¶¶ 51–52; Pls. 56.1 ¶¶ 51–52.) Dr. Arcati instructed plaintiff to return in a few days for another debridement.[13] (Def. 56.1 ¶ 53; Pls. 56.1 ¶ 53.) After December 2004, plaintiff did not see Dr. Arcati for nearly three years. (Def. 56.1 ¶ 54; Pls. 56.1 ¶ 54.) During that next visit (on November 16, 2007), Dr. Arcati saw and debrided a large sequestrum on plaintiff's right mandible. (Def. 56.1 ¶ 55; Pls. 56.1 ¶ 55.) A bone pathology report issued at that time noted that there was necrotic bone with "associated bacterial debris and inflammation consistent with bisphosphonate related osteonecrosis." (Def. 56.1 ¶ 56; Pls. 56.1 ¶ 56.) Approximately a week later, Dr. Arcati observed plaintiff's soft tissue to have healed; Dr. Arcati stated it was the "healthiest this area has looked." (Def. 56.1 ¶ 57; Pls. 56.1 ¶ 57.) Since that time, plaintiff has not suffered any further exposed bone in his mouth. (Pls. 56.1 ¶ 58.)

C. Aredia, Zometa, and the FDA

The United States Food and Drug Administration (the "FDA") approved Aredia—an intravenous bisphosphonate manufactured by Novartis—as safe and effective for treatment of hypercalcemia of malignancy in 1991, as well as for Paget's disease (in 1994), multiple myeloma (in 1995), and bone metastases arising from breast cancer (in 1996). (Def. 56.1 ¶¶ 59–60; Pls. 56.1 ¶¶ 59–60.)

Approximately a decade after approving Aredia, the FDA approved Zometa—also a Novartis-manufactured intravenous bisphosphonate—as a safe and effective treatment for hypercalcemia of malignancy; the FDA also approved Zometa's labeling. (Def. 56.1 ¶ 61; Pls. 56.1 ¶ 61.) In 2002, the FDA approved Zometa for treatment of multiple myeloma. (Def. 56.1 ¶ 62; Pls. 56.1 ¶ 62.) Both Zometa and Aredia presently remain on the market as FDA-approved drugs, although their labeling has changed over the years. (Pls. 56.1 ¶¶ 63–64.)

Neither Aredia nor Zometa are approved for the treatment of osteoporosis, ankylosing spondylitis, or general bone pain. (Def. 56.1 ¶ 69.) Plaintiffs note, however, that the main ingredient in Zometa, zoledronic acid, is the same active ingredient in a different drug, Reclast, which has been approved for osteoporosis. (Pls. 56.1 ¶ 69.) Plaintiffs contend that Novartis's sales persons were encouraging the use of Zometa for osteoporosis on account of this ingredient. (*Id.*) Defendant counters that the dose and dosing regimen for Reclast differs from that of Zometa, and further, that "[n]either Reclast nor Zometa was FDA approved for

[13] Debridement is "the removal of foreign material and devitalized or contaminated residue from or adjacent to a traumatic or infected lesion until surrounding healthy tissue is exposed." *Bisson v. Sec'y of Dep't of Health & Human Servs.*, No. 98-121V, 2003 WL 21730914, at *9 n.10 (Fed. Cl. June 30, 2003) (citation and internal quotation marks omitted).

the treatment of osteoporosis during the time that [plaintiff] was treated with Aredia and Zometa." (Def. Mem. in Supp. of Mot. for Summ. J. in the *Bee* Case ("Def. Summ. J. Mot.") at 6 n.8).)

Aredia and Zometa are "medicine[s] proven to reduce the incidence of pathologic fractures and spinal cord compression in patients with multiple myeloma and whose cancers have spread to the bone." (Def. 56.1 ¶ 70; Pls. 56.1 ¶ 70.)[14] Although the parties contest the extent to which Zometa has successfully served as an anti-cancer treatment (*compare* Def. 56.1 ¶ 71, *with* Pls. 56.1 ¶ 71), or the extent to which either Aredia or Zometa have extended patients' lives or significantly impacted the treatment of metastatic cancer to the bone (*compare* Def. 56.1 ¶ 73, *with* Pls. 56.1 ¶ 73), plaintiffs' expert, Dr. Robert Marx ("Dr. Marx"), has acknowledged both Aredia and Zometa to have "dramatically extended life, reduced skeletal complications, reduced pain, and thus improved the quality of life" for patients who have taken these drugs (Def. 56.1 ¶ 72; Pls. 56.1 ¶ 72). In sum, Aredia and Zometa have been approved for treatment of various conditions; plaintiff, however, did not have one of the conditions for which these drugs had specifically been approved at the time he was taking the medications. (Def. 56.1 ¶ 74; Pls. 56.1 ¶ 74.)

D. Novartis's Response to Reports of Osteonecrosis of the Jaw

The medical condition of ONJ is not a recent medical development. Medical literature reports the existence of ONJ, or at least a condition similar to it, as early as at least the 19th century, well before Aredia or Zometa came onto the market in approximately 1977. (Def. 56.1 ¶¶ 75, 78; Pls. 56.1 ¶ 75.)[15]

There were no reports of ONJ during the animal studies of Aredia and Zometa. (Def. Summ. J. Mot. at 7.) Defendant contends that there also were no reported events in the clinical trials leading to the FDA's approval of these drugs for their labeled indications. (Def. 56.1 ¶ 76.)[16] Defendant also contends that it did not receive its first report of a patient who was taking Aredia and/or Zometa and developed ONJ until December 6, 2002. (*Id.* ¶ 79.) Plaintiffs dispute this, asserting that "there were at least 6 incidents of ONJ in [Novartis's] clinical trials" (Pls. 56.1 ¶ 76), and that "Novartis had cases of ONJ in its Aredia and Zometa clinical trials going back to 1991" (*id.* ¶ 79).

Within fifteen days of receiving the ONJ-patient news in December 2002, Novartis reported the adverse event to the FDA and began an investigation, reviewing the animal and other studies conducted prior to the marketing of Aredia and Zometa, to determine whether osteonecrosis of any site—not simply the jaw—had occurred during the pre-clinical studies.

[14] Although defendant describes Aredia and Zometa as "the standard of care medicines" for purposes of treating these conditions (Def. 56.1 ¶ 70), plaintiffs claim that these medications may only be construed as such on account of Novartis's alleged failure to warn of the true risks concerning ONJ associated with the drug (Pls. 56.1 ¶ 70).

[15] Plaintiffs assert that a condition called, "phossy jaw," was reported as early as the 19th century in workers who had been exposed to white phosphorous. (Pls. 56.1 ¶ 75.) Although "phossy jaw" appears to have disappeared as a medical condition following the banning of white phosphorous in manufacturing processes, plaintiffs contend that it essentially reappeared when Aredia and Zometa came onto the market. (*Id.*)

[16] Defendant notes one exception to this statement: a single report of osteonecrosis in the rib and femur of a dog that received a dose of zoledronic acid equivalent to eight times the approved human dose. (Def. 56.1 ¶ 76.)

(Def. 56.1 ¶ 80; Pls. 56.1 ¶ 80.) Additionally, in June 2003, Novartis reviewed several medical databases, including Medline, Embase, Biosos, Current Contents, and International Pharmaceuticals Abstracts, to determine whether any publications addressed the occurrence of osteonecrosis arising in animals taking bisphosphonates. (Def. 56.1 ¶ 81; Pls. 56.1 ¶ 81.) Defendant contends that it was unable to identify any articles specifically mentioning osteonecrosis as being caused or occurring with the use of bisphosphonates in animals. (Def. 56.1 ¶ 81.) Plaintiffs counter this, arguing that Novartis's head of Zometa's preclinical studies testified that Novartis had a 1981 study showing ONJ as occurring in rats with exposure to bisphosphonates as early as 1986. (Pls. 56.1 ¶ 81.) According to defendant, before January 2003, no cases, specifically identified as osteonecrosis of the maxillofacial area (including the jaw), had appeared in Novartis's worldwide post-marketing safety database. (Def. 56.1 ¶ 82.) Defendant also states that, as of 2002, it understood that bisphosphonates were being considered as a potential preventative treatment for osteonecrosis. (Def. 56.1 ¶ 85.)

On September 26, 2003, Novartis informed the FDA that it had decided to revise the Adverse Reactions section of Aredia and Zometa's labeling so that it reflected the recent reports of ONJ with the intravenous intake of bisphosphonates. (Def. 56.1 ¶ 83; Pls. 56.1 ¶ 83.) Specifically, Novartis informed the FDA that it was altering its labeling language. (Def. 56.1 ¶ 86.) Such label alteration is permissible pursuant to the FDA's "Changes Being Effected" regulations ("CBE"). (Def. 56.1 ¶ 87; Pls. 56.1 ¶ 87.) Novartis made its label change under a "CBE 0," which allowed it to make the label change as quickly as possible under FDA regulations. (Def. 56.1 ¶ 88; Pls. 56.1 ¶ 88.) The FDA accepted this label change as submitted. (Def. 56.1 ¶ 89; Pls. 56.1 ¶ 89.) In February 2004, Novartis made an additional revision to the informative language associated with Zometa; specifically, it edited the Post-Marketing Experience section of the Zometa label to state: "Although causality cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged." (Def. 56.1 ¶ 90; Pls. 56.1 ¶ 90.)

On February 27, 2004, the FDA approved the following label revision:

> Cases of osteonecrosis (primarily involving the jaws) have been reported in patients treated with bisphosphonates. The majority of the reported cases are in cancer patients attendant to a dental procedure. Osteonecrosis of the jaws has multiple well documented risk factors including a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids) and co-morbid conditions (e.g. anemia, coagulopathies, infection, pre-existing oral disease). Although causality cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged.

(Def. 56.1 ¶ 91; Pls. 56.1 ¶ 91.)

On September 24, 2004, Novartis updated Zometa's drug label again to warn physicians about the possible link between Zometa use and ONJ. (Def. 56.1 ¶¶ 92–93.) That same month, Novartis also sent a "Dear Doctor" letter to over 17,200 hematologists, urologists, oral surgeons, and oncologists, both alerting physicians to the change in Zometa's labeling, and highlighting the relevant label language, including:

> Precautions: Osteonecrosis of the jaw (ONJ) has been reported in

> patients with cancer receiving treatment regimens including bisphosphonates . . . A dental examination with appropriate 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 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.

(Def. 56.1 ¶ 93.) Members of the medical community received this letter. (Def. 56.1 ¶ 94; Pls. 56.1 ¶ 94.) However, plaintiff asserts that, by the time of these warnings in September 2004, he had had tooth extractions and had developed a case of osteonecrosis of the jaw.

II. PROCEDURAL HISTORY

On February 2, 2007, plaintiffs filed the instant action against defendants in the district court for the District of Columbia. The Judicial Panel on Multidistrict Litigation subsequently transferred this case to the Middle District of Tennessee ("the MDL Court"), pursuant to 28 U.S.C. § 1407, on April 13, 2007, pursuant to a Conditional Transfer Order. On January 9, 2012, the Judicial Panel on Multidistrict Litigation directed remand of the case to the transferor court (*i.e.*, the district court for the District of Columbia). On March 6, 2012, plaintiffs filed an unopposed motion to transfer the case to the Eastern District of New York. Judge John D. Bates granted the motion, and the case was transferred to this Court on March 22, 2012.

Magistrate Judge William D. Wall handled pretrial matters and discovery. On November 19, 2012, defendant filed a motion "to advise the Court of pending summary judgment motions and to request consolidated *Daubert* briefing." (ECF No. 20.) Before the case was transferred, the parties had engaged in summary judgment and *Daubert* briefing, in accordance with the MDL Court's scheduling order. Thus, defendant asked this Court to consider the pending motions and to hold argument to address the same. Plaintiffs agreed that this Court should address the pending motions. On January 2, 2013, this Court held a telephone conference with the parties to discuss the pending motions, and it set a briefing schedule for the consolidated motions. The parties submitted their respective motions in compliance with the scheduling order. The Court held oral on May 3, 2013. This matter is fully submitted, and the Court has considered all of the parties' submissions.

III. STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 56(a), a court may grant a motion for summary judgment only if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Gonzalez v. City of Schenectady*, 728 F.3d 149, 154 (2d Cir. 2013). The moving party bears the burden of showing that he or she is entitled to summary judgment. *Huminski v. Corsones*, 396 F.3d 53, 69 (2d Cir. 2005). "A party asserting that a fact cannot be or is genuinely disputed must support the assertion by: (A) citing to particular parts of materials in the record, including depositions, documents,

electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials; or (B) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1). The court "is not to weigh the evidence but is instead required to view the evidence in the light most favorable to the party opposing summary judgment, to draw all reasonable inferences in favor of that party, and to eschew credibility assessments." *Amnesty Am. v. Town of W. Hartford*, 361 F.3d 113, 122 (2d Cir. 2004) (quoting *Weyant v. Okst*, 101 F.3d 845, 854 (2d Cir. 1996)); *see Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) (summary judgment is unwarranted if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party").

Once the moving party has met its burden, the opposing party "'must do more than simply show that there is some metaphysical doubt as to the material facts . . . . [T]he nonmoving party must come forward with specific facts showing that there is a *genuine issue for trial*.'" *Caldarola v. Calabrese*, 298 F.3d 156, 160 (2d Cir. 2002) (alteration and emphasis in original) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986)). As the Supreme Court stated in *Anderson*, "[i]f the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." 477 U.S. at 249–50 (citations omitted). Indeed, "the mere existence of *some* alleged factual dispute between the parties alone will not defeat an otherwise properly supported motion for summary judgment." *Id.* at 247–48 (emphasis in original). Thus, the nonmoving party may not rest upon mere conclusory allegations or denials but must set forth "'concrete particulars'" showing that a trial is needed. *R.G. Grp., Inc. v. Horn & Hardart Co.*, 751 F.2d 69, 77 (2d Cir. 1984) (quoting *SEC v. Research Automation Corp.*, 585 F.2d 31, 33 (2d Cir. 1978)). Accordingly, it is insufficient for a party opposing summary judgment "'merely to assert a conclusion without supplying supporting arguments or facts.'" *BellSouth Telecomms., Inc. v. W.R. Grace & Co.*, 77 F.3d 603, 615 (2d Cir. 1996) (quoting *Research Automation Corp.*, 585 F.2d at 33).

IV. DISCUSSION

A. Failure to Warn (Strict Liability and Negligence)

Plaintiffs assert that Novartis (1) negligently failed to test Aredia and Zometa, (2) negligently failed to warn about (i) the drugs' potential risks or (ii) available precautions to minimize such risks, and (3) failed to adequately warn as to the risk of ONJ. Plaintiffs also bring a cause of action sounding in strict liability, *i.e.*, that Novartis defectively designed and manufactured Aredia and Zometa. Defendant counters that (1) Novartis had no duty to warn Bee's physicians as to off-label uses of the drugs, (2) the warnings that Novartis gave were adequate, (3) no evidence in the record shows that, had a different warning issued, Bee's use of Aredia or Zometa might have been different, and (4) plaintiffs proffer no evidence that Aredia and Zometa substantially caused Bee's ONJ.

In order to establish a *prima facie* case for failure to warn under New York law,[17] a plaintiff must show the following: (1) the manufacturer had a duty to warn; (2) the

[17] It is uncontested that New York law governs the substantive claims at issue. (*See* Def. Summ. J. Mot. at 9; Pls. Opp'n. at 18.)

manufacturer breached the duty to warn in a manner that rendered the product defective, *i.e.*, reasonably certain to be dangerous; (3) the defect was the proximate cause of the plaintiff's injury; and (4) the plaintiff suffered loss or damage. *See McCarthy v. Olin Corp.*, 119 F.3d 148, 156 (2d Cir. 1997) (citing *Becker v. Schwartz*, 46 N.Y.2d 401, 410 (1978)); *see also In re Fosamax Prods. Liab. Litig.*, 924 F. Supp. 2d 477, 486 (S.D.N.Y. 2013); *Mustafa v. Halkin Tool, Ltd.*, No. 00-CV-4851, 2007 WL 959704, at *17 (E.D.N.Y. Mar. 29, 2007). These *prima facie* elements of a failure to warn claim remain the same under New York law regardless of whether they sound in negligence or strict liability. *See Martin v. Hacker*, 83 N.Y.2d 1, 8 n.1 (1993); *see also Fane v. Zimmer, Inc.*, 927 F.2d 124, 130 (2d Cir. 1991) ("'Regardless of the descriptive terminology used to denominate the cause of action . . . where the theory of liability is failure to warn, negligence and strict liability are equivalent.'" (quoting *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 97 (N.Y. App. Div. 1979))).

Generally, a manufacturer has a duty to warn (1) "against latent dangers resulting from foreseeable uses of its product of which it knew or should have known," and (2) "of the danger of unintended uses of a product provided these uses are reasonably foreseeable." *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (1998); *see also State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 F. App'x 8, 10 (2d Cir. 2011). "This duty is a continuous one, and requires that the manufacturer be aware of the current information concerning the safety of its product." *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1345–46 (E.D.N.Y. 1992). "Liability for failure to warn may be imposed based upon either the complete failure to warn of a particular hazard or the inclusion of warnings that are insufficient." *Fisher v. Multiquip, Inc.*, 949 N.Y.S.2d 214, 218 (N.Y. App. Div. 2012) (citation and internal quotation marks omitted).

Typically, summary judgment is appropriate where a plaintiff has not introduced any evidence that a manufacturer knew or should have known of the danger at issue. *See Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 93–94 (S.D.N.Y. 2001); *see also Wolfgruber*, 423 N.Y.S.2d at 97–98 (granting defendant summary judgment in failure to warn case when there were no disputed facts). On the other hand, "the *adequacy* of a warning generally is a question of fact," best reserved for trial. *Kandt v. Taser Int'l, Inc.*, No. 09-CV-0507, 2012 WL 2861583, at *3 (N.D.N.Y. July 10, 2012) (emphasis added) (quoting *Fisher*, 949 N.Y.S.2d at 218); *see also Urena v. Biro Mfg. Co.*, 114 F.3d 359, 366 (2d Cir. 1997) ("'The adequacy of the instruction or warning is generally a question of fact to be determined at trial and is not ordinarily susceptible to the drastic remedy of summary judgment'" (quoting *Beyrle v. Finneron*, 606 N.Y.S.2d 465, 465 (N.Y. App. Div. 1993))). When evaluating failure to warn liability, a court must conduct an "intensely fact-specific" analysis, "including but not limited to such issues as feasibility and difficulty of issuing warnings in the circumstances; obviousness of the risk from actual use of the product; knowledge of the particular product user; and proximate cause." *Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 440 (S.D.N.Y. 1999) (quoting *Liriano*, 92 N.Y.2d at 243) (internal quotation marks omitted).

Where a manufacturer owes a duty to warn, it can satisfy this obligation by "warn[ing] of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." *Davids v. Novartis Pharm. Corp.*, 857 F. Supp. 2d 267, 286 (E.D.N.Y. 2012) (quoting *Sita v. Danek Med., Inc.*, 43

F. Supp. 2d 245 (E.D.N.Y. 1999)) (alternation in original and internal quotation marks omitted). In the prescription drug context, courts have recognized that a manufacturer's duty to warn extends to a patient's doctor (and not to the patient himself) pursuant to the "learned intermediary" rule. *See Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980) (stating that "the manufacturing defect is to warn the doctor, not the patient"). The logic underlying this rule is that "[t]he doctor acts as an 'informed intermediary' between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, and prescribing and supervising their use." *Davids*, 857 F. Supp. 2d at 286 (quoting *Glucksman v. Halsey Drug Co., Inc.*, 553 N.Y.S.2d 724, 726 (N.Y. App. Div. 1990)) (internal quotation marks omitted).[18] Thus, if a defendant fails to adequately warn a patient's physician of the dangers presented by a given pharmaceutical, and the patient suffers an injury on account of such failure to warn, a failure to warn claim may lie. That being said, where a treating physician elects "not to inform a patient of a side effect," this "acts as an intervening cause which shields the drug manufacturer from any possible liability under a failure to warn theory." *Krasnoplosky*, 799 F. Supp. at 1346.

Similarly, where a defendant can show, via "specific facts," that any given warning would have been futile—either because any such warnings would not have been heeded or because the injury would have occurred, regardless of the given warnings—a defendant will have successfully rebutted the general presumption that "'a user would have heeded warnings if they had been given, and that the injury would not have occurred.'" *Adesina v. Aladan Corp.*, 438 F. Supp. 2d 329, 338 (S.D.N.Y. 2006) (quoting *G.E. Capital Corp. v. A. O. Smith Corp.*, No. 01-CV-1849, 2003 WL 21498901, at *5 (S.D.N.Y. July 1, 2003)); *see In re Fosamax*, 924 F. Supp. 2d at 486 (explaining that heeding presumption "may only be rebutted by specific facts showing that the warning would have been futile"). If a defendant can make such a showing, a plaintiff will not be able to establish the proximate causation element of a failure to warn claim. 438 F. Supp. 2d at 338.

Novartis argues that it is entitled to summary judgment as to the failure to warn claims because plaintiffs cannot show (1) that Novartis had a duty to warn, (2) that Novartis breached that duty, or (3) that Bee's injury was proximately caused by the alleged breach. Based on the evidence in the record, construed most favorably to plaintiffs, the Court concludes that genuine issues of material fact preclude summary judgment on these grounds. The Court addresses each element in turn.

[18] Courts have questioned whether the scope of this doctrine is limited simply to the prescribing physician, or whether it also may extend to non-prescribing, treating doctors. *See, e.g., Hogan v. Novartis Pharm. Corp.*, No. 06-CV-0260, 2011 WL 1533467, at *10 (E.D.N.Y. Apr. 24, 2011) (citing cases discussing the broader scope of the learned intermediary doctrine to any healthcare professional involved in decisions concerning a patient's care); *see also Davids*, 857 F. Supp. 2d at 287 (noting that "other courts have recognized that proximate causation can be satisfied for purposes of the learned intermediary doctrine where a non-prescribing physician testifies that the physician was aware of the patient's use of a given drug and would have recommended taking the patient off of that medication if a different warning had been given"). The Court considers the scope of this doctrine for purposes of this case in greater detail *infra*.

1. Duty to Warn

a. The Parties' Arguments

At the outset, Novartis claims that any alleged duty to warn only extended to plaintiff's prescribing physicians (and not to any members of the dental community, such as plaintiff's dentists) pursuant to the learned intermediary doctrine. (*See* Def. Summ. J. Mot. at 11.) Novartis also contends that it had no duty to warn of the contested risks at issue here because plaintiff was engaged in off-label use of Aredia and Zometa. (*See id.*) That is, Aredia's and Zometa's labels clearly indicated the FDA-approved use for these particular drugs, and neither osteoporosis nor ankylosing spondylitis were listed as conditions for which these drugs were to be prescribed. (*See id.*) Accordingly, defendant argues that Bee's use of these drugs—for non-FDA approved purposes—was not foreseeable, and thus, Novartis held no duty to warn Bee's physicians as to these drugs' associated risks. (*See id.* at 11 ("[B]ecause [Novartis] has warned that Aredia and Zometa are only intended for FDA approved uses, [plaintiff's] use of these drugs was unforeseeable and [Novartis] owed no duty to warn the prescriber of these drugs to [plaintiff] of risks associated with his Aredia and Zometa uses."); Def. Reply in Supp. of Summ. J. ("Def. Reply") at 2–3; *id.* at 3 ("[Novartis] owed no duty to warn a doctor prescribing [plaintiff] these drugs about the risks associated with his off-label Aredia and Zometa use.").) An additional argument Novartis raises in support of ONJ-unforeseeability here is that this case is distinguishable from other Aredia/Zometa lawsuits in that, unlike those other cases, Bee was not a cancer patient at the time he took the drugs. (*See* Def. Mot. to Advise Court of Pending Summ. J. Mots. & Request Consol. Briefing ("Def. Mot. to Advise") at 5 ("Mr. Bee's claim presents issues that no other plaintiff's trial case has addressed because his doctor prescribed Aredia and Zometa for severe osteoporosis related to a rare orthopedic condition, ankylosing spondylitis. This is not one of the metastatic cancers to bone for which Novartis developed, labeled, and sold Aredia and Zometa and for which the litigation-wide experts identified by the Plaintiffs' Steering Committee developed their reports.").) Thus, because Bee was a non-cancer patient using these drugs in an off-label context, Novartis again contends that it held no duty to warn.

Plaintiffs counter that Novartis had a duty to warn because it was foreseeable that a patient treated with Aredia and/or Zometa might develop ONJ. (*See* Pls. Opp'n at 18–20.) Plaintiffs assert that the issue of foreseeability goes *not* to whether the drugs here were used in an intended or off-label fashion (as defendant so frames it), but instead, to whether there was a risk of developing ONJ if and when a patient was treated with these drugs. In other words, if a patient might develop ONJ after taking Zometa and/or Aredia—particularly if such a patient had dental procedures performed while taking such medications—and such a risk was foreseeable, defendant had a duty to warn, period (*i.e.*, regardless of whether the drug use was in an off-label context). (*See id.* at 19–20 ("Novartis knew very early on that for most patients ONJ is triggered by a tooth extraction or other invasive dental procedure. . . . Novartis knew that the risk of ONJ in users of its drugs was greatly increased when the patient had a tooth extracted or oral surgery.").)

Turning to the scope of this duty, plaintiffs assert that Novartis's duty extended not only to Bee's prescribing physicians, but also to the "oral maxillofacial and dental communities." (*See* Pls. Opp'n at 19 (citing *Lindsay*, 637 F.2d at

92).)[19] Plaintiffs contend that, because it is foreseeable that patients with more tooth decay than the average individual likely will go to the dentist, Novartis—which "knew very early on" that a tooth extraction, or other form of invasive dental procedure, would trigger ONJ in most patients with the condition of ONJ, and that the risk of ONJ increased in users of Novartis' drugs where such users had dental medical procedures—held a duty to warn that extended to plaintiff's dentists and oral surgeons. (*Id.* at 19–20 (citing Decl. of John J. Vecchione ("Vecchione Decl.") Ex. 32, Email of Carsten Goessel ("Goessel Email"); *see also id.* at 20 (stating that Novartis kept "the information oncologists and oral maxillofacial surgeon[s] had apart from one another"(citing Vecchione Decl. Ex. 23, Email from Stefano Fratarcangeli ("Fratarcangeli Email")).)

b. Analysis

As is apparent from their respective framing of the issue, the parties dispute both whether the alleged risk at issue (ONJ) was foreseeable, and the scope of foreseeability. As previously set forth, Novartis argues that the question of foreseeability goes to the particular purpose for which plaintiff was taking the drugs—here, in an off-label capacity for a non-cancer patient's treatment of ankylosing spondylitis and osteoporosis. Plaintiffs, on the other hand, assert that the issue of foreseeability goes simply to whether a patient taking these particular drugs stood the risk of developing ONJ, regardless of whether he or she had cancer, and regardless of whether it was an intended-or-off-label-use context.

"There are differences with respect to whether warnings are required for the off-label use of a drug." *Blain v. SmithKline Beecham Corp.*, 240 F.R.D. 179, 194 (E.D. Pa. 2007). As noted in *Blain*,

> Some states require no warning, *see Robak v. Abbott Labs.*, 797 F. Supp. 475, 476 (D. Md. 1992), while others have varying levels of requirements for adequate warning of an off-label use. *Miles Labs., Inc. v. Superior Court*, 133 Cal. App. 3d 587, 184 (1982) (manufacturer liable for failure to warn of risks of off-label uses of its product if the manufacturer knew or should have known of the off-label use and that use accounted for a significant portion of the manufacturer's sales of the drug); *Peterson v. Parke Davis & Co.*, 705 P.2d 1001, 1003 (Colo. Ct. App. 1985); *Reeder v. Hammond*, 336 N.W.2d 3, 5–6 (Mich. Ct. App. 1983) (intervening negligence of a physician precludes the manufacturer's liability for failure to warn of risks of off-label use).

Id. at 194–95. Cases from other federal courts applying state law have expressly found that a pharmaceutical manufacturer had a duty to warn of risks associated with off-label use. *See, e.g.*, *McNeil v. Wyeth*, 462 F.3d 364, 370–71 (5th Cir. 2006) (under Texas law, plaintiffs can pursue failure to warn action despite off-label use of drug); *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 628–29 (E.D. Pa. 2008) (concluding, under New Jersey law, that manufacturer owed duty to warn of dangers associated with off-label uses of drugs where manufacture knows or should have known of danger of side effects); *Southern*

[19] In making this argument, plaintiffs note that only New Jersey has adopted defendant's more limited view of the duty to warn (as limited solely to prescribing physicians), and further, that Judge Spatt of the District Court of the Eastern District of New York ruled against Novartis's interpretation of this same issue in a similar case. (Pls. Opp'n at 19.)

v. Pfizer, Inc., 471 F. Supp. 2d 1207, 1218 (N.D. Ala. 2006) (recognizing, under Alabama law, that drug's manufacturer owed duty to warn about potential dangers of using prescription drug for an off-label to patient's prescribing physician by drug's manufacturer.); *Woodbury v. Janssen Pharm., Inc.*, Civ. A. No. 93-7118, 1997 WL 201571, at *9 (N.D. Ill. Apr. 10, 1997) (recognizing, under Illinois law, that pharmaceutical manufacturer has duty to warn of any dangers associated with off-label use of product if such dangers were reasonably known).

As a general rule, under New York law, "[t]he manufacturer's duty is to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." *Martin v. Hacker*, 83 N.Y.2d 1, 8 (1993). The "warning must be commensurate with the risk involved in the ordinary use of the product." *Id.* at 11 (citation and internal quotation marks omitted). Further, to avoid liability, drug manufacturers have a two-fold "continuing obligation," as well. *Baker v. St. Agnes Hosp.*, 421 N.Y.S.2d 81, 85 (N.Y. App. Div. 1979); *see also Glucksman v. Halsey Drug Co.*, 553 N.Y.S.2d 724, 726 (N.Y. App. Div. 1990). First, they "must keep abreast of knowledge of [their] products as gained through research, adverse reaction reports, scientific literature and other available methods. Second, and equally important, [they] must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession." 421 N.Y.S.2d at 85 (citations omitted). In addition, "off-label drug usage is not unlawful, and the FDA's drug approval process generally contemplates that approved drugs will be used in off-label ways." *United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012).

Synthesizing such principles, a patient prescribed an off-label use of a drug may be a reasonably foreseeable user of the product, such that a manufacturer has a duty to warn of all known adverse effects associated with such use. Novartis cites to no New York case law (and the Court could not find any) holding that a pharmaceutical company is not required to warn of the dangers of off-label uses of its drugs, despite having information of such dangers. In *Sita*, a medical device case cited by Novartis, the warning at issue stated that nearly all of the components of the medical device were intended for specific uses "only." 43 F. Supp. 2d at 259–60. Intended use and approved use are distinct, however, and there is no evidence that Novartis expressly stated that its drugs should only be used for FDA approved purposes. Moreover, the Second Circuit also has recognized, in dictum, that "[p]hysicians and pharmaceutical manufacturers can be held liable for off-label drug use through medical malpractice and negligence theories of liability." *Caronia*, 703 F.3d at 168 n.11 (citing *Boyle v. Revici*, 961 F.2d 1060 (2d Cir. 1992); *Sita v. Danek Med. Inc.*, 43 F. Supp. 2d 245 (E.D.N.Y. 1999); *Retkwa v. Orentreich*, 584 N.Y.S.2d 710 (N.Y. Sup. Ct. 1992)). Therefore, under New York law, the Court finds that a drug manufacturer can have a duty to warn even in cases involving off-label use.

Thus, to determine whether defendant had a duty to warn, the Court must first consider whether the potential development of ONJ was a foreseeable, or reasonably foreseeable, risk to Novartis for those patients who might take its drugs. *See Liriano*, 92 N.Y.2d at 237 (noting that a manufacturer's duty to warn is triggered where the company knew or should have known of "latent dangers resulting from foreseeable uses of its product" or "of the danger of unintended uses . . . provided

these uses [were] reasonably foreseeable"). On reviewing the evidence in the record, the Court concludes that plaintiffs have raised genuine issues of material fact that preclude summary judgment as to whether defendant knew or should have known (and when) about the risk of developing ONJ upon taking the aforementioned medications.

Specifically, plaintiffs point to a 1981 study involving rats showing a connection between bisphosphonates and ONJ, which, according to the testimony of Jonathan Green, the head of Zometa preclinical studies, allegedly was in defendant's possession as early as 1986. (*See* Pls. Opp'n at 22; *see also id.* Vecchione Decl. Ex. 22, Dep. of Jonathan Green ("Green Dep.") at 125–27).) Plaintiffs also reference multiple cases of ONJ allegedly reported during Aredia and Zometa's clinical trials, which date back to 1991. (Pls. Opp'n at 22; *see also id.* Vecchione Decl. Ex. 19, Email and Attachments of Annmarie Petraglia, Jan. 27, 2005 ("Petraglia Doc.").)

Novartis disputes this evidence, asserting that the first case of bisphosphonate-induced ONJ was not reported to it until December 6, 2002. (*See* Def. Summ. J. Mot. at 13 (citing Def. 56.1 ¶ 79).) Thus, when Bee first began his Aredia therapy (in August 1997), defendant had no notice "of a single case of ONJ in bisphosphonate users, and no published data existed that rendered ONJ a 'knowable' risk." (*Id.* (citing Def. 56.1 ¶¶ 79, 81–82, 99).) Defendant notes that plaintiffs' expert, Dr. Suzanne Parisian ("Dr. Parisian"), has testified to the same, stating that she "agrees that, prior to approval of Aredia and Zometa, no published study indicated necrosis of the jaw in bisphosphonate users." (*Id.* (citing Def. 56.1 ¶ 100 Ex. 91, Dep. of Dr. Suzanne Parisian ("Parisian Dep.") at 209).) Defendant does not explicitly address plaintiffs' evidence claiming a link, as early as the 1980s, between bisphosphonates treatment and the development of ONJ, or the presence of ONJ in Novartis's early 1990s Aredia clinical trials. Instead, Novartis simply states that "plaintiffs have no evidence that [Novartis] knew or should have known about a possible risk of ONJ prior to September 2003." (Def. Summ. J. Mot. at 12.)

On reviewing the parties' arguments and supporting evidence, it is clear that the question of what was foreseeable to Novartis, and when, is a disputed issue of material fact in this case. The parties have presented evidence that shows more than unsupported speculation or conclusory assertions, on both sides, as to whether Novartis knew, or should have known, of the risk of developing ONJ while taking Aredia and/or Zometa during the period relevant to this dispute. The fact that such drugs were possibly prescribed to cancer patients more often than not, or that such drugs might be used in on-or-off label capacity during the pre-warning phase does not weaken the medical evidence to which plaintiff directs the Court's attention, which (if credited) largely shows a correlation between bisphosphonate usage and the development of ONJ. This evidence does not affirmatively show that the correlation between these drugs and developing ONJ was exclusively dependent on a patient's cancer status or, for that matter, the drugs' use in an intended or off-label context. Summary judgment is only appropriate where the moving party (Novartis) can show that there is "no genuine dispute as to any material fact" and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *see Gallo v. Prudential Residential Servs., L.P.*, 22 F.3d 1219, 1223 (2d Cir. 1994) (noting that moving party bears burden of proving there is no genuine

issue of material fact). Novartis has not carried that burden here.

2. Adequacy of the Warnings

Although Novartis's main position is that it had no duty to warn in light of Bee's off-label usage of the medications, Novartis also argues that it fulfilled its obligation to adequately warn physicians of any danger or risk posed by Aredia and/or Zometa. (*See* Def. Summ. J. Mot. at 12–19.) In support of its argument, defendant points to the following evidence: (1) the adverse event report from December 2002 showing a link between the treatment drugs and ONJ, which Novartis asserts was the first such report it received concerning such a risk (*see* Def. 56.1 ¶ 79; *see id.* Ex. 72); (2) exhibits showing that once Novartis received the December 2002 adverse event report, it immediately alerted the FDA and promptly put into action steps to implement a label change in 2003 (*see* Def. Summ. J. Mot. at 13; *see also* Def. 56.1 ¶¶ 86–93); (3) evidence (including a September 2003 letter to the FDA requesting a revision of the Adverse Reactions section to the Aredia and Zometa labeling (Def. 56.1 Ex. 76), a March 2004 letter confirming the FDA's acceptance of the proposed Adverse Reactions-labeling change (*id.* Ex. 82), a letter indicating that Novartis revised its Post-Marketing Experience section of the Zometa label in February 2004 to add additional language concerning the risk of ONJ (*id.* Ex. 83), a letter indicating that the FDA approved the proposed February 2004 labeling revision (*id.* ¶ 91), and a "Dear Doctor" letter, sent to more than 17,200 hematologists, urologists, oral surgeons, and oncologists, warning that ONJ had been reported in cancer patients receiving bisphosphonate treatment (*id.* ¶¶ 92–94; *id.* Ex. 87)) indicating defendant's efforts to alert the medical community of the discovered correlation between bisphosphonate treatments and the development of ONJ following the December 2002 alert; (4) evidence showing that the FDA approved defendant's labels for Aredia and Zometa throughout the time when Bee was undergoing treatment with these drugs (*see* Def. 56.1 ¶¶ 59–64); and (5) excerpts from plaintiffs' experts' testimonies suggesting that Novartis was not in possession of information concerning the risk of ONJ before 2002 or 2003 (*see id.* ¶ 100). Based on this evidence in the record, defendant contends that it satisfied its duty to warn by issuing adequate warnings—once it had notice of the drugs' associated risks—to Bee's prescribing physicians at the time period relevant to this dispute. (*See generally* Def. Summ. J. Mot. at 12–14.)

Plaintiffs argue that defendant's warnings were inadequate because they were not issued until long after Novartis had notice of the risk of ONJ in patients receiving bisphosphonate treatment with Aredia and Zometa. (*See* Pls. Opp'n at 21–22.) Plaintiffs again direct the Court's attention to evidence indicating there were cases of ONJ in Aredia and Zometa's clinical trials dating back to 1991 (*see id.* Vechhione Decl. Ex. 19, Petraglia Doc.), and Green's testimony that, as early as 1986, Novartis possessed a 1981 study showing ONJ in rats exposed to bisphosphonates (*see id.* Vecchione Decl. Ex. 22, Green Dep. at 125–27). Plaintiffs also point to evidence showing that defendant has acknowledged that there were at least six incidents of ONJ in its clinical trials (*see id.* Vecchione Decl. Ex. 20, Series of Emails Addressing Slides).[20] Lastly, plaintiffs note that, at the

[20] Plaintiffs note that this six-incident estimate may be inaccurate, given that an internal Novartis report referencing these clinical trials also refers to the fact that Novartis lost approximately one half of its data during this particular time period. (*See* Pls. Opp'n Vecchione Decl. Ex. 20.)

time Dr. Arcati extracted Bee's teeth in 2003, there still was no language in the warning label section of the drugs, even though Novartis had knowledge of the risk of ONJ before that time. (*Id*. at 22.)

It is undisputed that Novartis issued no explicit warnings concerning the risk of ONJ until sometime after December 2002. This is about the only point upon which the parties agree concerning the alleged adequacy of Novartis's warnings. Given the factual dispute (coupled with supporting evidence) between the parties concerning the adequacy of the information provided to the doctors in this case, the Court concludes that this is a question properly left for the jury.

Plaintiffs point to evidence indicating that Novartis had knowledge of the dangers of ONJ in patients undergoing bisphosphonate treatments, like Aredia and Zometa, well before December 2002—a time when the products' labels bore no mention of any such risk. Defendant has pointed to evidence countering this, both summarizing the steps it took to warn upon allegedly first learning of the dangers of ONJ, and indicating evidence that supports its position that there was no actual, "knowable" risk of ONJ before December 2002, whether in the medical literature or otherwise. Testimony from plaintiff's doctors raises genuine issues of material fact as to the extent of information concerning Aredia and Zometa that was available at the time relevant to this dispute. In light of these genuine issues of material fact concerning the adequacy of the warnings for Aredia and Zometa during the time when Bee was taking these drugs, the Court concludes that summary judgment cannot be appropriately granted as to this element of the failure to warn claim.

3. General Causation

In assessing proximate cause, the Court must consider whether a lack of adequate warnings contributed to plaintiff's use of the drugs, and whether plaintiff's use of the drugs constitutes a proximate cause of Bee's injury. *See Golod v. La Roche*, 964 F. Supp. 841, 856 (S.D.N.Y. 1997) ("A plaintiff suing a prescription drug manufacturer on a failure to warn theory must prove that the failure to warn was a proximate cause of the plaintiff's injury. Thus, the plaintiff must generally demonstrate that had appropriate warnings been given, the treating physicians would not have prescribed or would have discontinued use of the drug." (internal citations omitted)); *see also Lindsay*, 637 F.2d at 90–91 ("A plaintiff who seeks recovery for an injurious side effect from a properly manufactured prescription drug must prove that the drug caused her injury and that the manufacturer breached a duty to warn of the possibility that the injurious reaction might occur."). Because plaintiffs allege that Novartis failed to provide adequate warnings, and further, that this case concerns pharmaceutical drugs, the learned intermediary doctrine applies. As previously set forth, pursuant to this doctrine, "a defendant manufacturer has an obligation to inform the treating physician of the risks of a medical device" so that the physician, acting as the learned intermediary, may properly inform the patient. *Henson v. Wright Med. Tech., Inc.*, No. 12-CV-805, 2013 WL 1296388, at *3 (N.D.N.Y. Mar. 28, 2013) (citing *Glucksman*, 553 N.Y.S.2d at 726); *see also Steinman v. Spinal Concepts, Inc.*, No. 05-CV-774S, 2011 WL 4442836, at *9 (W.D.N.Y. Sept. 22, 2011) ("It is well settled with respect to prescription drugs and medical devices that a manufacturer's duty to warn is owed not [to] the patient, but to the treating physician as the 'learned intermediary.'").

Here, there is no dispute that the drugs at issue did not contain warnings or language explicitly addressing the particular risk of ONJ until sometime after December 2002. Defendant argues that Bee would have developed ONJ, even if Novartis had issued different or earlier warnings. The crux of defendant's argument is twofold: (1) Dr. Samuel still would have prescribed Aredia and/or Zometa to plaintiff, even if different warnings had issued, evidenced by the fact that Dr. Samuel continues to prescribe such drugs to patients today and was prepared to continue administering the drugs to plaintiff, even after being told of another doctor's opinion that plaintiff had bisphosphonate related ONJ; and (2) Bee would have taken Aredia and/or Zometa, even with a proper warning, because the drugs were necessary for treating his condition, and he was desperate for a cure. (*See* Def. Summ. J. Mot. at 14–19.) The Court addresses each of these arguments in turn.

a. Whether Plaintiff's Physicians' Treatment Would Have Differed

Because Novartis argues that any duty to warn here only extended to Bee's prescribing physicians (here, Dr. Samuel), it limits its arguments (that altered warnings would not have made a difference for Bee) to Dr. Samuel. In particular, defendant contends that (1) there is no evidence indicating that Dr. Samuel did not know of the association between bisphosphonates and ONJ during the time when he treated Bee (*id.* at 16); (2) Dr. Samuel testified that he had intended to continue prescribing Zometa to plaintiff, even after learning of Dr. Ruggiero's jaw necrosis diagnosis, until he observed exposed bone in plaintiff's mouth (*id.*); (3) Dr. Samuel did not rely on the product labels when deciding whether to prescribe the drugs (evidenced by plaintiff's off-label use of the drugs) (*id.*); and (4) Dr. Samuel presently prescribes both Aredia and Zometa for the off-label treatment of osteoporosis (*id.*).[21]

In essence, defendant seeks to break the causal link between the warning it issued to Dr. Samuel (via the drugs' labels), Dr. Samuel's subsequent administration of the drugs to plaintiff, plaintiff's taking of the drugs, and plaintiff's development of ONJ. It does so by relying on two principles that may act as intervening events and thereby sever causation.

The first type of intervening event that might shield Novartis from liability under a failure to warn theory occurs where "[a] treating physician[] [decides] not to inform a patient of a side effect." *Krasnopolsky*, 799 F. Supp. at 1346. Thus, if Dr. Samuel had independent knowledge concerning the correlation between Aredia and/or Zometa and the risk of ONJ, but did not inform plaintiff of such information, this would break causation. Although not specifically stated as such, defendant suggests that Dr. Samuel may have possessed such independent knowledge. (*See* Def. Summ. J. Mot. at 16 ("Plaintiffs fail to offer evidence that Dr. Samuel was unaware of the association between bisphosphonates and

[21] Novartis additionally argues that "even if Dr. Samuel had required [] Bee to have a pretreatment dental evaluation before beginning Aredia and Zometa therapy, plaintiffs have no evidence, let alone the required expert testimony, that such a warning would have avoided his subsequent dental issues." (Def. Summ. J. Mot. at 18.) Defendant points to testimony from several of plaintiff's proffered experts in support of this argument. However, as Novartis itself notes when highlighting this testimony, the experts themselves cannot say whether a pretreatment dental screening would (or would not) have made any difference had different warnings issued. Given the inconclusive state of the evidence upon which defendant relies for this point, the Court cannot say that it supports a finding of summary judgment, at least as to this particular argument.

ONJ during the entire period that he treated Mr. Bee.").) A review of Dr. Samuel's testimony reveals the following.

First, Dr. Samuel testified that he had used bisphosphonates in treating other patients before he began seeing plaintiff. (Pls. Opp'n Vecchione Decl. Ex. 2, Deposition of Dr. Edward Samuel ("Dr. Samuel Dep.") at 41, 44, 78.) Thus, bisphosphonates were not exactly new territory for Dr. Samuel when he began prescribing the medications to Bee. Second, Dr. Samuel stated that, when he began using bisphosphonates with his patients, he had "some familiarity" with the side effects and risks posed by their use. (*Id.* at 59.) He did not state, however, that ONJ was a risk of which he was aware. Dr. Samuel also did not recall Aredia's warnings being changed or the release of additional information concerning the drug's potential side effects between 1996 and 2002 (with the exception of information regarding kidney problems). (*See id.* at 144.) Regarding the extent of his knowledge pertaining to bisphosphonates, Dr. Samuel testified that he likely was aware of clinical trials concerning the use of bisphosphonates for patients with osteoporosis during those same years (*see id.* at 61), and also, that he received regular visits from Novartis representatives, which included discussions and literature concerning bisphosphonates sold by Novartis (*id.* at 55–56). But, he nowhere affirmatively states that he had knowledge concerning the risk of ONJ in these drugs before approximately November 2004, when he claims to have first heard about the association between bisphosphonates and jaw necrosis or seen a patient with such diagnosis. (*Id.* at 181, 264.)

Given this testimony, the Court cannot say that defendant has demonstrated that it is uncontroverted that Dr. Samuel held independent knowledge concerning the risk of ONJ, such that plaintiffs' causation claim cannot proceed. Stated differently, there are genuine issues regarding what Dr. Samuel might have independently known concerning bisphosphonates and ONJ during the time period relevant to this dispute. Moreover, even if defendant's argument here were sufficient to counter any disputed material fact regarding Dr. Samuel's ONJ-related knowledge, independent knowledge of an alleged risk does not necessarily mandate summary judgment on a claim. *See, e.g.*, *Fussman v. Novartis Pharm. Corp.*, No. 06-CV-149, 2010 WL 4104707, at *4 (M.D.N.C. Oct. 18, 2010) (citing *Holly v. Burroughs Wellcome Co.*, 348 S.E.2d 772, 775–77 (N.C. 1986), which denied summary judgment on proximate cause, even where treating physician testified that he was independently aware of risks, because there were genuine issues of fact as to proximate cause claim as physician relied in part on medical literature, which may have been affected by the drug manufacturer's product labeling and promotional information available at that time). Thus, the Court concludes that summary judgment on this issue is unwarranted.

The second doctrine pursuant to which defendant seeks to sever causation is the heeding doctrine. As previously set forth, a defendant may rebut the application of this presumption by pointing to specific facts indicating that the issuance of a warning would have, for all intents and purposes, been meaningless, whether because it is clear that any issued warning would not have been followed or because it is apparent that the injury would have occurred regardless of the warnings issued. *See Adesina*, 438 F. Supp. 2d at 338; *see also Hoffman-Rattet v. Ortho Pharm. Corp.*, 516 N.Y.S.2d 856, 861–62 (N.Y. Sup. Ct. 1987). Novartis's defense here may best be understood in two ways: even if a different warning had been issued, (1) Dr. Samuel

still would have prescribed Aredia and Zometa to plaintiff, and (2) plaintiff still would have taken the drugs. The Court addresses each point in turn.

Regarding Bee's physicians, Novartis turns to Dr. Samuel's direct testimony to support its position that he would have prescribed Aredia and Zometa to plaintiff, even if different warnings, indicating the association between these drugs and ONJ, had issued. (*See* Def. Summ J. Mot. at 15–16 (citing Def. 56.1 ¶¶ 101–02, 104–13).) Plaintiffs counter this defense, arguing that Novartis must show, via a physician's affirmative statement, that "even if [a physician were] adequately warned, the treatment provided would have been *virtually identical* to that actually rendered." (Pls. Opp'n at 20–21 (quoting *Hoffman-Rattet*, 516 N.Y.S.2d at 857–58) (emphasis added) (internal quotation marks omitted).) Plaintiffs assert that both the testimony of Dr. Samuel and Dr. Arcati shows that the doctors have altered their behavior since learning of the risk of ONJ, which supports the inference that these doctors might have taken different courses of treatment had different or earlier warnings issued; this raises genuine issues of material fact supporting a denial of summary judgment. (*See id.*)

The Court has reviewed the physicians' testimony.[22] Based on this review, plaintiffs have submitted sufficient evidence to create a genuine issue of fact on this question, which precludes summary judgment.

First, it is true that Dr. Samuel testified that he continues to prescribe Aredia and Zometa in present day to patients, even though he is now aware of the risks associated with such drugs. (*See* Def. 56.1 Ex. 18 at 38, 187.) Dr. Samuel also testified that he had intended to continue administering Zometa to plaintiff, even after plaintiff informed him of Dr. Ruggiero's conclusion of osteonecrosis, and that it was not until Dr. Samuel saw the exposed bone in plaintiff's mouth that he decided otherwise. (*See id.* Ex. 18 at 178–79.)

However, this testimony is not necessarily dispositive as to whether Dr. Samuel would have continued to prescribe Aredia and Zometa to Bee during his period of treatment had warnings targeting ONJ existed at that time. If different or earlier warnings had issued, Dr. Samuel might have changed plaintiff's course of treatment or altered his prescription regimen in other ways. Indeed, plaintiffs point to evidence supporting such a conclusion.

For instance, they cite to Dr. Samuel's testimony, which sets forth how his process for prescribing these same drugs has changed since he first learned of the drugs' potential ONJ-related side effects. (*See* Pls. Opp'n at 23.) Specifically, Dr. Samuel testified that he has changed his prescription process as follows: distributing handouts about Aredia and Zometa, in printed or pamphlet form, to patients (Vecchione Decl. Ex. 2, Dr. Samuel Dep. at 189); informing patients as to the benefits of the drugs for their particular condition, but also, of the risk of ONJ (*id.* at 190); providing patients with instructions for their dental care provider, to be given at the time of dental work (*id.* at 190–91); warning patients not to undergo dental work until they have stopped

[22] Although Novartis does not specifically address Dr. Arcati in its arguments (presumably because he was not the prescribing physician), plaintiffs do. This makes sense, as plaintiffs assert that the learned intermediary doctrine should not be limited to the prescriber, but to any of a plaintiff's treating physicians. Accordingly, the Court also considers Dr. Arcati's testimony when assessing whether a causation claim might lie.

taking bisphosphonate drugs for a period of time, unless it is an absolute emergency (*id.*); and advising patients to keep dental work to a minimum (*id.* at 191). The Court also notes Dr. Samuel's testimony that his practice is to discuss risks and potential adverse effects with his patients before starting them on a drug, and that while he will inform patients of the advantages and disadvantages of a given drug (as known at that time), the ultimate decision to take a drug lies with the patient. (*See id.* 118–19, 159–60, 208–09.)

This evidence raises a genuine issue of material fact as to whether Dr. Samuel would have provided different treatment and/or advice to plaintiff had different warnings been provided, given that Dr. Samuel changed his treatment advice, after Novartis altered its warning, for other patients receiving bisphosphonates (including advising patients of the risks associated with dental procedures while on these drugs, as well as the particular risks associated with these drugs in general). It reasonably can be inferred from this evidence that, had Dr. Samuel known of the risk of ONJ, he would have discussed this with plaintiff before prescribing Aredia and Zometa to him.[23]

Similar cases in other district courts, including the MDL Court, have held that even where a physician admits to continued recommendation of a drug, despite knowing of its ONJ-related risk, changes to that doctor's prescription or treatment procedures will generate triable questions of fact on the question of causation. *See, e.g.*, *Georges v. Novartis Pharm. Corp.*, No. 06-CV-5207, 2012 WL 9083365, at *5–6 (C.D. Cal. Nov. 2, 2012); *In re Aredia & Zometa Prods. Liab. Litig. (Talley)*, 3:06-MD-1670, 2010 WL 5092784, at *2 (M.D. Tenn. Dec. 7, 2010) (noting that treating physician reduced dosage of drugs on learning of correlation between bisphosphonates and ONJ); *In re Aredia & Zometa Prods. Liab. Litig. (White)*, 3:06-MD-1760, 2009 WL 2497692, at *3 (M.D. Tenn. Aug. 13, 2009) ("Plaintiff's treating oncologist . . . testified that if he had known when he prescribed Zometa to [plaintiff] what he knows today about ONJ, he would still prescribe it, but with a change in how he prepares the patients for the drug . . . . [I]t is sufficient for Plaintiff to survive summary judgment to show that one of [plaintiff's] treating physicians . . . would have behaved differently."); *In re Aredia v. Zometa Prods. Liability Litig. (Fussman)*, 3:06-MD-1760, 2009 WL 2496843, at *2 (M.D. Tenn. Aug. 13, 2009) (denying summary judgment where treating doctor testified that, if he had "known about bisphosphonates and ONJ at the time he treated [plaintiff], his treatment course for her would have definitely been different"). Thus, there is a genuine issue of fact as to whether, had different or earlier warnings issued, Dr. Samuel would have behaved identically or instead, have altered his course of treatment.

[23] Regarding Novartis's argument that the issuance of different labels also would not have made a difference in Dr. Samuel's actions here because Dr. Samuel's use of the drugs was in an off-label capacity, the Court disagrees that this is a determinative factor. The fact that Dr. Samuel used the drugs here in an off-label context does not *per se* mean that he did not look at or consider language on the drugs' labels. Indeed, Dr. Samuel's testimony makes clear that he continues to prescribe Aredia and Zometa in an off-label context, but also, that he advises his patients of the risk of ONJ, seemingly regardless of whether their use of the drugs falls into the off-label or intended use category. Accordingly, the Court does not find the fact that Dr. Samuel prescribed the drugs here in an off-label capacity to be a persuasive point requiring summary judgment in defendant's favor.

The Court next turns to Dr. Arcati. Although Dr. Arcati was plaintiff's dentist, and not a prescribing physician, the Court accepts, for purposes of this motion, that the learned intermediary doctrine may apply beyond the prescribing physician. *See Davids*, 857 F. Supp. 2d at 287 ("Although a prescribing physician's course of conduct is a relevant issue, other courts have recognized that proximate causation can be satisfied for purposes of the learned intermediary doctrine where a non-prescribing physician testifies that the physician was aware of the patient's use of a given drug and would have recommended taking the patient off of that medication if a different warning had been given." (citing *Golod v. La Roche*, 964 F. Supp. 841, 857 (S.D.N.Y. 1997)); *Hogan v. Novartis Pharm. Corp.*, No. 06-CV-0260, 2011 WL 1533467, at *9 (E.D.N.Y. April 24, 2011) (stating that "courts routinely identify the 'prescribing physician' as the learned intermediary[; b]ut 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"); *id.* at *10 ("Nor is there anything in the rationale behind the [learned intermediary] 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. 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 also Stevens v. Novartis Pharm. Corp.*, 247 P.3d 244, 260 (Mont. 2010) (describing scope of learned intermediary doctrine as applying to any healthcare professional responsible for making decisions regarding the patient's case); *McEwan v. Ortho Pharm. Corp.*, 528 P.2d 522, 529 (Or. 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."). Accordingly, the Court considers whether there are genuine issues of material fact regarding whether Dr. Arcati's treatment of plaintiff also might have varied if Novartis had administered different warnings to the medical community.

Dr. Arcati's testimony reveals that he was at least familiar with ONJ at the time he treated Bee (in 2003), but that his knowledge concerning the association between bisphosphonates and ONJ was still new and developing. (*See* Pls. Opp'n Vecchione Decl. Ex. 4 at 109–11, 217, 231–33.) Thus, construing the evidence most favorably to plaintiffs, a rational jury could find that, if different warnings had issued to plaintiff's treating physicians during the period when Dr. Arcati treated plaintiff, Dr. Arcati's treatment would have been different. Such a conclusion could be supported by Dr. Arcati's testimony, in which he states that he has since changed his patient intake forms so that patients must expressly answer whether they are taking bisphosphonates prior to any treatment. (*Id.* at 228–30.)

However, Dr. Arcati's testimony raises an additional issue. It is clear from his testimony that he was at least aware of a possible correlation between bisphosphonates and ONJ when he began

treating Bee. (*See* Pls. Opp'n Vecchione Decl., Ex. 4 at 109–11, 217, 231–33.) Moreover, Dr. Arcati specifically stated that, if he had known about Bee's bisphosphonate use in 2003, he would have changed his course of treatment for plaintiff—specifically, he would have treated Bee with root canals and capping. (*See* Pls. Opp'n Vecchione Decl. Ex. 4 at 109–11.) Thus, defendant could argue that, if Novartis had given different warnings to the medical community regarding the risk of ONJ and bisphosphonates, Dr. Arcati's testimony suggests (1) he already was aware of such a possible connection, raising a question of how great an impact any such warnings might have had, and (2) Dr. Arcati confirmed that he would have treated plaintiff differently in 2003 had he known that plaintiff was on bisphosphonates (which he did not know simply because plaintiff did not so inform him). Thus, at least as to Dr. Arcati, it is not so clear whether an intervening event might lie: plaintiff's failure to inform, the fact that Dr. Arcati already possessed knowledge concerning a link between bisphosphonates and ONJ, or both. Therefore, on the facts of this case, more than one reasonable inference could be drawn on this issue, such that summary judgment is unwarranted.

The Court concludes, on reviewing the evidence in the light most favorable to the non-moving party, that there is a genuine issue of material fact as to whether the issuance of different warnings to Dr. Arcati (or other non-prescribing treating physicians) might have led to a different result here. A rational jury could reasonably infer that different warnings would have caused Dr. Samuel to change the manner in which he treated plaintiff, including advising Bee to provide information to his dentists regarding his bisphosphonate usage prior to any dental work. There is also evidence showing that, upon Novartis's administration of different warnings, Dr. Arcati altered his intake forms. A rational jury could reasonably infer from this evidence that, had different or earlier warnings been given to the medical community, Dr. Arcati would have changed his intake forms to include specific questioning regarding a patient's possible bisphosphonate treatment and/or that plaintiff would have informed Dr. Arcati as to his drug use. Thus, although this is a closer question as to Dr. Arcati, the Court concludes that plaintiffs have shown a genuine issue of material fact as to proximate causation.

In sum, the testimony of Dr. Samuel and Dr. Arcati (if credited), could reasonably support a finding that, even if they might have continued to prescribe Aredia and Zometa to plaintiff, their course of treatment and manner of administering the drugs to plaintiff might have varied. This is sufficient, for purposes of the motion presently before the Court, to establish a genuine issue of material fact. Because the Court concludes that there is a genuine issue of material fact as to whether the issuance of different or earlier warnings addressing the risk of ONJ in these drugs might have caused plaintiff's treating physicians to have behaved differently, defendant's motion for summary judgment on this ground is denied.[24]

[24] The parties do not address Dr. Ruggiero in the particular context of whether his treatment of plaintiff might have differed upon the administration of different warnings. This makes sense, as Dr. Ruggiero's testimony confirms that he diagnosed plaintiff with ONJ in July 2004, *after* Novartis had begun taking steps to inform the medical community and issue different labels. Thus, assessment of Dr. Ruggiero's treatment of plaintiff is not informative as to whether or how his treatment might have differed, given that the medical literature and warnings already were changing at that time.

b. Whether Plaintiff's Actions Would Have Differed

Defendant's next argument against plaintiffs' causation claim is that "there is no evidence that [] Bee would not have consented to Aredia and Zometa therapy had he been warned of a risk of ONJ." (Def. Summ. J. Mot. at 17.) Stated differently, plaintiff would have accepted these drugs, regardless of whether a proper warning had been issued to him from Dr. Samuel (or otherwise). In support of this argument, Novartis notes Bee's testimony, in which he (1) stated that he was "desperate to find a solution" for his condition and "[t]o get the pain managed correctly" (Def. 56.1 Ex. 1 at 128); (2) responded affirmatively to the question of whether he would have followed Dr. Samuel's recommendation to take Aredia and/or Zometa, even if the doctor had informed him that such drugs were intended—and had been approved—to be used in the treatment of other conditions (*see id.* at 145); (3) requested to stay on prednisone, even after being warned that it might worsen his osteoporosis (Def. 56.1 ¶ 28; *see also id.* Ex. 28), further illustrating plaintiff's "willingness to take anything to avoid his skeletal pain" (Def. Summ. J. Mot. at 17); and (4) sought and received two doses of Zometa, even after Dr. Ruggiero had informed plaintiff that Zometa likely had caused his dental condition (*id.* at 17–18; *see also* Def. 56.1 ¶ 50 (citing Def. 56.1 Ex. 1 at 263)).

On reviewing the cited evidence, as well as the evidence in the record, the Court concludes that there is a genuine issue of material fact as to how plaintiff might have acted had different warnings issued. With respect to defendant's argument as to plaintiff's supposed state of distress, the extent to which plaintiff was "desperate" for a solution for his unique and painful condition is not conclusive regarding how plaintiff might have acted had altered warnings been given. Simply because plaintiff strongly wanted to end the pain and suffering he was experiencing, one cannot say that the only reasonable inference is that he would have taken *any* medication, no matter the cost or risk. Moreover, there is evidence in the record suggesting the contrary. Specifically, there is evidence showing that Bee did not blindly follow his physicians' recommendations. For example, Dr. Samuel testified that when he first recommended Aredia to plaintiff, plaintiff requested time to consider whether he wanted to begin treatment with the drug. (*See* Pls. Opp'n Vecchione Decl. Ex. 2, Dr. Samuel Dep., at 119 ("Q: Can we conclude from the fact he then started Aredia a month later that the discussions that we're talking about took place, side effects, answering questions, he agreed; is that a fair conclusion? A: Yes, it is a fair conclusion. I didn't start it when we first discussed it because I think he wanted to mull it over and think about it.").) Thus, the Court cannot determine on summary judgment how plaintiff's actions or decisions might have varied had different warnings been given to him before he commenced treatments with these drugs.

Additionally, the fact that plaintiff decided to take prednisone, despite knowing of the risk that it could worsen his osteoporosis, also is not dispositive, particularly when plaintiff's testimony is considered in context. Bee's testimony makes clear that his decision was based on his discussions with his doctor, which caused him to understand that prednisone's "side effects didn't come into play until you were taking it over an extended period of time." (Pls. Opp'n Vecchione Decl. Ex. 1 at 88.) Plaintiff, however, was only to take the drug for "[t]wo weeks." (*Id.*) Furthermore, although it is true that plaintiff had two more infusions of Zometa after learning from Dr.

Ruggiero that it likely had caused his ONJ, Bee's testimony was that he specifically asked Dr. Ruggiero if he should stop taking Zometa, and that Dr. Ruggiero's reply made clear to plaintiff that stopping the drug at that point would have been futile for purposes of preventing or helping his mouth condition. (*See id.* at 262–63 ("Q: Did you ask any questions of Dr. Ruggiero? A: I might have asked him if I should, or how long, you know, if stopping it, would it stop the infection, I believe. I believe that was one of the questions I asked him. Q: Stopping it, 'it' meaning Zometa? A: I'm sorry, stopping the Zometa . . . And from what I remember, it was no, once you have it, it's always going to be in your system. I remember him stating that as well.").)

Lastly, there is evidence in the record suggesting that once Bee was informed that his use of bisphosphonates likely had caused his ONJ, he altered his own practices with physicians, informing dental care professionals of his bisphosphonate treatments thereon out. (*See* Pls. Opp'n Vecchione Decl. Ex. 5, Keith M. Hallaian Decl. ("Hallaian Decl.") ¶¶ 4–5.)

Thus, upon considering the evidence in the record, as well as the parties' respective arguments, the Court concludes that it cannot be determined on summary judgment just how plaintiff might have acted had Dr. Samuel (or another treating physician) informed him of the risk of ONJ associated with Aredia and Zometa. Construing the evidence most favorably to plaintiff, a rational jury could find that plaintiff's decision to take the drugs might have been affected by how Dr. Samuel presented their associated risks; likewise, plaintiff's own approach to dental work might have varied, following any possible admonition against such by Dr. Samuel. For these reasons, the Court concludes that, even if warnings had issued, the evidence in the record raises a triable issue of fact as to whether plaintiff's physicians and/or plaintiff would have acted differently. Accordingly, the Court denies Novartis's motion for summary judgment on this ground.

B. Specific Causation

Novartis next argues that plaintiffs must prove, through reliable expert testimony, that Aredia and Zometa caused Bee to develop ONJ in order for plaintiffs' claims to prevail. (*See* Def. Summ. J. Mot. at 19–21.) Because defendant contends that this Court should exclude the causation opinions of plaintiffs' expert, Dr. Richard Kraut ("Dr. Kraut"), as well as the case-specific causation opinions of the treating health care providers designated by plaintiffs as non-retained experts (specifically, Drs. Arcati, O'Lear, and Ruggiero), Novartis claims that plaintiffs cannot prove specific causation. (*Id.* at 20.)[25] Alternatively, Novartis argues that plaintiffs' experts failed to rule out other conditions present in Bee's medical history, such as Fosamax and ankylosing spondylitis, which could have caused his ONJ. (*Id.* at 21.)

In order to determine whether plaintiffs can show that Aredia and Zometa were a substantial factor in causing Bee's jaw

[25] Defendant initially raised its *Daubert* motion to exclude the causation testimony of plaintiffs' experts before the MDL Court. These motions were not decided prior to the transfer to this Court. One of the grounds upon which Novartis presently moves for summary judgment is that plaintiffs cannot show that Aredia and/or Zometa substantially caused plaintiff's alleged ONJ. (*see* Def. Summ. J. Mem. at 20–21.) The evidence plaintiffs offer in support of this claim, however, is the testimony of the experts whom Novartis previously challenged before the MDL. Accordingly, the Court considers, to the extent necessary, the parties' previously submitted (but as yet undecided) *Daubert* motions solely on the question of specific causation.

condition, the Court must assess the evidence (and its corresponding admissibility) presented in support of their claim—the causation-centered testimony from plaintiffs' experts. *See Lindsay*, 637 F.2d at 90–91 ("A plaintiff who seeks recovery for an injurious side effect from a properly manufactured prescription drug must prove that the drug caused her injury and that the manufacturer breached a duty to warn of the possibility that the injurious reaction might occur.").

1. Legal Standard

In deciding whether to grant summary judgment, a district court may only consider evidence that would be admissible at trial. *Nora Beverages, Inc. v. Perrier Grp. of Am., Inc.*, 164 F.3d 736, 746 (2d Cir. 1998). Thus, as the Second Circuit has explained, it is the proper role of the district court to consider the admissibility of expert testimony to determine whether summary judgment is warranted:

> Because the purpose of summary judgment is to weed out cases in which 'there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law,' Fed. R. Civ. P. 56(c), it is appropriate for district courts to decide questions regarding the admissibility of evidence on summary judgment. Although disputes as to the validity of the underlying data go to the weight of the evidence, and are for the fact-finder to resolve, questions of admissibility are properly resolved by the court.

Raskin v. Wyatt Co., 125 F.3d 55, 66 (2d Cir. 1997) (internal citations omitted; alteration in original). In other words, "[t]he court performs the same role at the summary judgment phase as at trial; an expert's report is not a talisman against summary judgment." *Id.* at 66. Thus, if the expert testimony is excluded as inadmissible under the framework articulated in *Daubert* and its progeny, the summary judgment determination is made by the district court on a record that does not contain that evidence. *Id.* at 66–67. Such an analysis must be conducted even if precluding the expert testimony would be outcome determinative. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142–43 (1997). Accordingly, pursuant to Fed. R. Evid. 104, the court must examine the admissibility of plaintiffs' expert testimony in ruling on defendant's motion for summary judgment.

The district court must determine the admissibility of expert testimony under Rule 702 of the Federal Rules of Evidence, which provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

The proponent of the expert testimony bears the burden of establishing the admissibility of such testimony under the *Daubert* framework by a preponderance of the evidence. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10 (1993) ("These matters should be established by a preponderance of proof."

(citing *Bourjaily v. United States*, 483 U.S. 171, 175–76 (1987))); *see also* Fed. R. Evid. 702 advisory committee's note ("[T]he admissibility of all expert testimony is governed by the principles of Rule 104(a). Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence."); *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010) ("[T]he party offering the expert testimony "must show by a preponderance of the evidence both that the expert is qualified to render the opinion and that the methodology underlying his conclusions is scientifically valid." (internal citations and quotation marks omitted)); *accord Baker v. Urban Outfitters, Inc.*, 254 F. Supp. 2d 346, 353 (S.D.N.Y. 2003).

"The district court is the ultimate 'gatekeeper,'" *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007), and must ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable," *Daubert*, 509 U.S. at 589; *see Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (holding that whether the witness's area of expertise was technical, scientific, or more generally "experience-based," the court, in its "gatekeeping" function, must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"); *Nimely v. City of New York*, 414 F.3d 381, 396 (2d Cir. 2005) ("The shift under the Federal Rules to a more permissive approach to expert testimony did not represent an abdication of the screening function traditionally played by trial judges.").

Thus, under Rule 702, the district court must make several determinations before allowing expert testimony: (1) whether the witness is qualified to be an expert; (2) whether the opinion is based upon reliable data and methodology; and (3) whether the expert's testimony on a particular issue will assist the trier of fact. *See Nimely*, 414 F.3d at 396–97. Moreover, if the requirements of Rule 702 are met, the district court must also analyze the testimony under Rule 403 and may exclude the testimony "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . ." Fed. R. Evid. 403; *accord Nimely*, 414 F.3d at 397.

Under the *Daubert* standards, the district court must first determine whether the expert has sufficient qualifications to testify. *See Zaremba v. Gen. Motors Corp.*, 360 F.3d 355, 360 (2d Cir. 2004) (stating that, where the witness lacked qualifications, an analysis of the remaining *Daubert* factors "seems almost superfluous"). Specifically, under Rule 702, the Court must determine whether the expert is qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. A court should look at the totality of the witness' qualifications in making this assessment. *See, e.g.*, *Rosco, Inc. v. Mirror Lite Co.*, 506 F. Supp. 2d 137, 144–45 (E.D.N.Y. 2007) ("A court must consider the 'totality of a witness's background when evaluating the witness's qualifications to testify as an expert.'" (quoting 29 Wright & Gold, Fed. Prac. & Proc. § 6265, at 246 (1997))); *accord Arista Records LLC v. Lime Group LLC*, 06 CV 5936, 2011 WL 1674796, at *2 (S.D.N.Y. May 2, 2011). In addition, the Court must ensure that the expert will be proffering opinions on issues or subject matters that are within his or her area of expertise. *See Stagl v. Delta Air Lines, Inc.*, 117 F.3d 76, 81 (2d Cir. 1997).

With respect to reliability, "the district court should consider the indicia of reliability identified in Rule 702, namely, (1)

that the testimony is grounded on sufficient facts or data; (2) that the testimony is the product of reliable principles and methods; and (3) that the witness has applied the principles and methods reliably to the facts of the case." *Williams*, 506 F.3d at 160 (internal citation and quotation marks omitted). As the Second Circuit has explained, the *Daubert* Court "has identified a number of factors bearing on reliability that district courts may consider, such as (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) a technique's known or potential rate of error, and the existence and maintenance of standards controlling the technique's operation; and (4) whether a particular technique or theory has gained general acceptance in the relevant scientific community." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002) (internal citations and quotation marks omitted); *accord Nimely*, 414 F.3d at 396. These criteria are designed to be instructive, but do not constitute a definitive test in every case. *See Kumho*, 526 U.S. at 151; *Nimely*, 414 F.3d at 396. Moreover, in addition to these criteria for determining whether the methodology is reliable, Rule 702 also requires that there be a sufficiently reliable connection between the methodology and the expert's conclusions for such conclusions to be admissible. *See Gen. Elec. Co.*, 522 U.S. at 146 ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."); *see also Amorgianos*, 303 F.3d at 266 ("[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony.").

With respect to whether the expert's testimony will assist the trier of fact, the Second Circuit has repeatedly emphasized that "expert testimony that usurps either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it, by definition does not aid the jury in making a decision; rather, it undertakes to tell the jury what result to reach, and thus attempts to substitute the expert's judgment for the jury's." *Nimely*, 414 F.3d at 397 (internal citations, quotation marks, and alterations omitted).

2. Dr. Richard Kraut

At trial, plaintiffs seek to offer Dr. Richard Kraut's testimony that Bee had "bisphosphonate related jaw necrosis." (Pls. Causation Resp. Ex. 10, Dr. Richard Kraut Expert Report ("Ex. 10") at 6.)[26] Novartis, however, moves to exclude his causation testimony. The Court begins its analysis with a review of Dr. Kraut's background.

Dr. Kraut is a board-certified oral and maxillofacial surgeon. (Pls. Resp. to Def. *Daubert* Mot. to Exclude Expert Witnesses ("Pls. Causation Resp.") at 7; *see also id.* Ex. 10 at 3.) Upon completing his oral and maxillofacial surgery training, Dr. Kraut held various leadership positions with the United States Army. In 1988, following eight years of running the Army's Oral and Maxillofacial Surgery Residency Programs, Dr. Kraut was honorably discharged. (Pls. Causation Resp. at 7; *see also* Pls. Causation Resp. Ex. 10 at 3.) He subsequently was recruited by Montefiore Medical

[26] The pages to Dr. Kraut's report are unnumbered. The Court adopts the page numbering of ECF.

Center/Albert Einstein College of Medicine to assume the position of Director of Oral and Maxillofacial Surgery; he has held this position from 1988 through the present. (Pls. Causation Resp. at 8; *see also* Pls. Causation Resp. Ex. 10 at 3.) In 2003, Dr. Kraut became Chairman of the Department of Dentistry of Montefiore Medical Center/Albert Einstein College of Medicine, a position he continues to hold to this day. (Pls. Causation Resp. at 8; *see also* Pls. Causation Resp. Ex. 10 at 3.) He has published numerous articles in the fields of Dental Anesthesiology, Oral and Maxillofacial Surgery, and Dental Implantology. (Pls. Causation Resp. at 8; *see also* Pls. Causation Resp. Ex. 10 at 3.) He also has authored two professional papers in which he has discussed bisphosphonates. (Pls. Causation Resp. Ex. 10 at 4.) Additionally, Dr. Kraut holds editorial positions as Senior Section Editor of the Journal of Implant Dentistry, and serves as a reviewer for *Oral Surgery, Oral Medicine, and Oral Pathology*, as well as for the *Journal of Oral and Maxillofacial Surgery*; he has held these positions for over five years. (Pls. Causation Resp. at 8; *see also* Pls. Causation Resp. Ex. 10 at 3.)

At the beginning of his career (in 1973), while training at the Brook Army Medical Center, Dr. Kraut treated patients with osteoradionecrosis;[27] such experience allowed him to learn both how to diagnose the condition, and also, to treat it using surgery and hyperbaric medicine. (Pls. Causation Resp. at 8; Pls. Causation Resp. Ex. 10 at 3.) Over the years, Dr. Kraut has treated numerous cases of osteoradionecrosis. (Pls. Causation Resp. at 8; Pls. Causation Resp. Ex. 10 at 3–4.) In recent years, he also has treated numerous patients with jaw necrosis who were on Fosamax, another type of bisphosphonate. (Pls. Causation Resp. at 9; Pls. Causation Resp. Ex. 10 at 4.)

Beginning in or around 2003, Dr. Kraut observed that patients presented conditions similar to osteoradionecrosis, but upon review of their medical history, it was found that they had not undergone radiation therapy to the jaw. (Pls. Causation Resp. at 8; Pls. Causation Resp. Ex. 10 at 3); *see also Harvey v. Novartis Pharm. Corp.*, 895 F. Supp. 2d 1206, 1213 (N.D. Ala. 2012) (stating that "[a] physician can rule out osteoradionecrosis if a patient has no history of radiation exposure"). Following his attendance at the Harrigan Society Meeting at New York University's College of Dentistry in December of 2002, when Dr. Ruggiero's findings from a series of jaw necrosis cases were presented (specifically, linking jaw necrosis to the use of bisphosphonates), Dr. Kraut became aware of the association between the two. (Pls. Causation Resp. at 8; Pls. Causation Resp. Ex. 10 at 3.) He then reviewed his internal records and sent questionnaires to female patients that were over the age of forty, attempting to elicit information as to whether they had used either intravenous or oral bisphosphonates. (Pls. Causation Resp. at 9; Ex. 10 at 3–4.) The results of that study, along with an article addressing such results, were published; in the article, Dr. Kraut called for the inclusion of specific questions on health questionnaires that inquired as to a patient's use of bisphosphonates. (Pls. Causation Resp. at 8; Pls. Causation Resp. Ex. 10 at 4.)

In arriving at his determination that plaintiff has bisphosphonate related ONJ, Dr. Kraut relied on: (1) his attendance at the aforementioned Harrigan Society Meeting in

[27] Osteoradionecrosis is "a condition involving dead bone in the jaw caused by exposure to radiation." *Harvey v. Novartis Pharm. Corp.*, 895 F. Supp. 2d 1206, 1213 (N.D. Ala. 2012).

December 2002, where medical findings and corresponding literature were presented regarding bisphosphonate-caused jaw necrosis; (2) a letter to the editor by Dr. Robert Marx, which was published in the *Journal of Oral and Maxillofacial Surgery* in 2003; (3) a 2004 article published by Dr. Ruggiero; (4) a series of position papers issued by the American Association of Oral and Maxillofacial Surgeons; (5) "numerous articles" in the professional literature addressing bisphosphonate-caused jaw necrosis; and (6) his own personal experience treating patients with jaw necrosis who also had taken bisphosphonate drugs. (Pls. Causation Resp. Ex. 10 at 4.) Additionally, Dr. Kraut reviewed: (1) plaintiff's Fact Sheet and Supplemental Plaintiff's Fact Sheet; (2) the records of North Shore Hematology Oncology Associates, P.C.; (3) the records of Dr. Samuel, Dr. O'Lear, and Dr. Ruggiero, as well as the records of Dr. Laura Ferrier, Dr. Ira Brand, and Dr. Adam Maslow; (4) the records of North Shore Implant & Surgery Associates; (5) the records of Long Island Jewish Hospital; (6) the records of Healthplex; (7) specimen slides from the Long Island Jewish Medical Center; and (8) records produced by plaintiff. (Pls. Causation Resp. Ex. 10 at 5.) Dr. Kraut also physically examined plaintiff, at which time he "performed a soft tissue examination, as well as a panoramic radiographic examination of the patient." (*Id.* at 7.)

Novartis first argues that Dr. Kraut is not qualified to opine on bisphosphonate causation of ONJ. (*See* Def. Mem. in Supp. of *Daubert* Mot. to Exclude Causation Testimony of Pls. Experts ("Def. Causation Mem.") at 17 (stating that "Dr. Kraut must have the expertise both: (1) to determine that Aredia and Zometa can cause ONJ, and (2) to consider and rule out other ONJ risk factors in [] Bee's case[; h]is ability to treat ONJ does not qualify him to opine as to its cause").) This is so because, as defendant asserts, Dr. Kraut "is admittedly not an expert" on ankylosing spondylitis, cancer treatment, epidemiology, toxicology, pharmacology, hematology, chemistry, bone endocrinology, statistics, and bisphosphonates. (*Id.* (citing *id.* Exs. 55, 56, 58, & 61).) However, it is clear that if an "expert has educational and experiential qualifications in a general field closely related to the subject matter in question, the court will not exclude [an expert's] testimony solely on the ground that the witness lacks expertise in the specialized areas that are directly pertinent." *Davids*, 857 F. Supp. 2d at 277 (quoting *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007)) (internal quotation marks omitted); *see also Rupolo v. Oshkosh Truck Corp.*, 749 F. Supp. 2d 31, 37 (E.D.N.Y. 2010) ("In a product liability action, an expert witness is not strictly confined to his area of practice, but may testify concerning related applications; a lack of specialization affects the weight of the opinion, not its admissibility." (internal citation and quotation marks omitted)).

The Court finds that Dr. Kraut's admitted lack of expertise in the aforementioned fields does not disqualify him from offering an opinion as to plaintiff's ONJ. To begin with, a review of Dr. Kraut's report makes clear that he is not claiming any such expertise as the basis for his conclusions. Second, Dr. Kraut's credentials show him to be a highly experienced and qualified oral and maxillofacial surgeon; he has completed extensive training, held leadership positions, run residency programs, and authored several articles, in the oral and maxillofacial surgery fields. He also has extensive, hands-on experience treating patients with forms of jaw necrosis, including ONJ linked to oral and intravenous bisphosphonates. Additionally, Dr. Kraut has conducted his

own research, and maintained an active familiarity in the research of other leading experts, in the subject of jaw necrosis. For these reasons, the Court finds Dr. Kraut to be qualified to offer opinions concerning causation (whether general or specific) under *Daubert*. *See Davids*, 857 F. Supp. 2d at 277 (finding Dr. Kraut to be qualified for purposes of offering an expert opinion as to causation for similar reasons); *In re Fosamax Prods. Liab. Litig.*, 688 F. Supp. 2d 259, 268 (S.D.N.Y. 2010) (finding a doctor to be qualified under Rule 702 to offer expert testimony because the record showed that "[h]e has practiced dentistry for over 30 years; he specializes in oralfacial pain and maxillofacial radiology; he keeps up to date with the developments in research regarding BRONJ and has given presentations on the issue; he also has practical experience in that he has treated many patients that he believes developed ONJ from a bisphosphonate"); *cf. Harvey*, 895 F. Supp. 2d at 1211 (finding that a doctor was not qualified to testify concerning possible ONJ causation where doctor's testimony showed that he had never conducted medical or scientific research in the field of ONJ, had never researched bisphosphonates, and had not published articles or otherwise hold relevant experience concerning bisphosphonates or ONJ).

Defendant next asserts that "Dr. Kraut's general causation opinion must be excluded because it is not based on reliable data or a scientifically valid methodology." (Def. Causation Mem. at 18.) Novartis rests this argument on the fact that Dr. Kraut relied on "anecdotal information," like case reports, in forming his opinion, and that he did not utilize epidemiological studies. (*See id.* at 18–19.) The Court concludes, however, that these arguments are insufficient to establish the inadmissibility of Dr. Kraut's opinion.

Specifically, Novartis's arguments go to the weight, and not to the admissibility, of Dr. Kraut's opinion. It is true that epidemiological studies, case studies, and clinical trials are generally considered the "gold standard" of medical research. *In re Rezulin Prods. Liab. Litig.*, No. MDL 1348, 00-CV-2843, 369 F. Supp. 2d 398, 406 (S.D.N.Y. 2005). However, as Novartis itself acknowledges in its motion papers, there have been limited case trials that have produced meaningful data as to Aredia and Zometa and their link to ONJ. As previously highlighted, the Court has found the question of when, and even how many, instances of ONJ might have occurred in these drugs' clinical trials to be a disputed fact in this case. Accordingly, the fact that Dr. Kraut's opinion is not based on case studies is, while certainly relevant for purposes of a cross-examination, not sufficient for purposes of establishing his opinion's inadmissibility here.

Novartis also argues that "[a]necdotal data such as case reports do not form a reliable basis for a causal inference, because case reports do not rule out confounding factors, and, particularly as to ONJ, [intravenous] bisphosphonates are always prescribed to patients with comorbid ONJ risk factors." (Def. Causation Mem. at 19.) It is true that "[c]ausal attribution based on case studies should be viewed with caution." *See In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 184 (S.D.N.Y. 2009) (citation and internal quotation marks omitted). However, it is also true that "such studies may be carefully considered in light of other information available," *id.* (citation and internal quotation marks omitted), and that "a large number of case reports adds greater weight to the reliability of an opinion on causation" *id.* (citation and internal quotation marks omitted); *see also In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1242 (W.D.

Wash. 2003) (finding as "significant the sheer volume of case reports, case series and spontaneous reports associating PPA with hemorrhagic stroke in women"); *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002) (stating, in dicta, that reliable evidence in support of causality may include "a very large number of case reports"). As plaintiffs note, "[t]here have been hundreds of published case reports of ONJ in [intravenous] bisphosphonate users[,] in addition to a few retrospective studies finding a strong association." (Pls. Causation Resp. at 18.) In this case, the Court finds the large number of recent reports addressing the condition of ONJ—almost entirely in the context of bisphosphonate use—to be a factor supporting the reliability of Dr. Kraut's opinion, and not detracting from it. Indeed, the core of Novartis's exclusion argument here, while certainly relevant, is one best left for cross-examination, where questions concerning the accuracy or credibility of any such case reports may serve as valuable ammunition for countering Dr. Kraut's opinion, once given on the stand. They are insufficient, however, for purposes of establishing that Dr. Kraut's opinion as to causation should be deemed inadmissible altogether.

Regarding defendant's argument that Dr. Kraut relied on a scientifically invalid methodology in reaching his conclusions, (*see* Def. Causation Mem. at 18–19), the Court notes that this is not a novel question. The MDL Court has issued orders in multiple other Aredia/Zometa cases, finding that both Dr. Kraut's qualifications and his methodology satisfy the *Daubert* requirements for a specific causation expert on the precise issue of whether a plaintiff's use of Aredia or Zometa caused his or her ONJ. *See In re Aredia and Zometa Prods. Liab. Litig. (Baldwin/Winter)*, No. 3-06-MD-1760, 2010 WL 5139444, at *1–2 (M.D. Tenn. Dec. 7, 2010); *In re Aredia and Zometa Prods. Liab. Litig. (Eberhart)*, No. 3-06-MD-1760, 2010 WL 5072008, at *1–2 (M.D. Tenn. Dec. 7, 2010); *In re Aredia and Zometa Prods. Liab. Litig. (McDaniel)*, No. 3-06-MD-1760, 2010 WL 5071851, at *1–2 (M.D. Tenn. Dec. 7, 2010); *In re Aredia and Zometa Prods. Liab. Litig. (Kyle/Mahaney)*, No. 3-06-MD-1760, 2010 WL 5071063, at *1–2 (M.D. Tenn. Dec. 7, 2010).

Here, Dr. Kraut performed a differential diagnosis for plaintiff to ultimately determine whether Zometa caused plaintiff's ONJ. "A differential diagnosis is a patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes." *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) (citations and internal quotation marks omitted); *see also Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 260 (6th Cir. 2001) (describing a differential diagnoses as "the method by which a physician determines what disease process caused a patient's symptoms[; t]he physician considers all relevant potential causes of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and a thorough case history" (alteration, citation, and internal quotation marks omitted)). Generally, courts have held that "[a] medical expert's opinion based upon differential diagnosis normally should not be excluded because the expert has failed to rule out every possible alternative cause of a plaintiff's illness." *Davids*, 857 F. Supp. 2d at 278 (quoting *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001)). That being said, while "an expert need not rule out every potential cause in order to satisfy *Daubert*, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant." *Deutsch*

v. Novartis Pharm. Corp., 768 F. Supp. 2d 420, 474 (E.D.N.Y. 2011) (quoting *Israel v. Spring Indus., Inc.*, 98-CV-5106, 2006 WL 3196956, at *5 (E.D.N.Y. Nov. 3, 2006)).

Defendant's arguments against Dr. Kraut's differential diagnosis methodology are as follows: he (1) was not reliable, (2) failed to consider (i) factors like "bisphosphonates, osteomyelitis, malignancy, oral pathology, chemical trauma, physical trauma, corticosteroids and osteoporosis," (Def. Causation Mem. at 20), or (ii) that "there are many conditions that may cause exposed necrotic bone in bisphosphonate patients" (*id.*), and (3) did not "scientifically consider and rule out critical facts in [] Bee's history regarding other possible causes of his ONJ," like Bee's taking of Fosamax (*id.*). The Court, however, again concludes in this case that these issues go to the weight of his testimony, not its admissibility.

A review of Dr. Kraut's expert report shows that Dr. Kraut, after his own independent research, review of pertinent research concerning ONJ and bisphosphonates, a review of plaintiff's medical history, and his own examination of plaintiff (including a soft tissue examination and a panoramic radiographic examination), specifically "considered the possibility of other etiologic factors" when assessing the possible cause of plaintiff's condition. (Pls. Causation Resp. Ex. 10, at 7.) In particular, Dr. Kraut expressly states that he recognized the potential effect of Fosamax on plaintiff's condition. (*See id.* (stating that Dr. Kraut "considered the relative potency and exposure to Fosamax" that Bee underwent, as well as his "aware[ness] that Zometa is 10,000 times as potent as Fosamax with a potency of 500").) Further, Dr. Kraut examined "critical facts" in plaintiff's history that could have impacted Bee's development of ONJ; he specifically notes that Bee "has not had chemotherapy nor radiation therapy," that Bee "had both maxillary and mandibular exposed bone," and that he "did not go on to develop classic symptoms of osteomyelitis at either of those two sites." (*Id.*) Dr. Kraut also considered plaintiff's course of medical treatment, which he details in the report, as well as plaintiff's drug history and clinical course following his teeth extractions in October and November of 2003. (*Id.* at 6.) Dr. Kraut nowhere dismisses as irrelevant the fact that plaintiff previously took Fosamax, that he had teeth extractions performed, or that he was diagnosed with ankylosing spondylitis. Regarding the latter point, Dr. Kraut acknowledges plaintiff's condition (*see id.* ("Mr. Bee's underlying medical problem of ankylosing spondylitis requires that he be maintained on large doses of Oxycontin and other pain medications."), and he notes that "[i]t is remarkable that with the background of Oxycontin in his system that he would still report jaw pain" (*id.*; *see also id.* ("It should be noted that during the course of his bisphosphonate related jaw necrosis, the patient reported jaw pain, which is significant in view of the fact that he was taking Oxycontin in significant dosage to deal with his ankylosing spondylitis.")). Based on all of these considerations, Dr. Kraut arrived at his ultimate conclusion that plaintiff developed "bisphosphonate related jaw necrosis." (*Id.*) This methodology is sufficient to satisfy *Daubert*.

As noted above, to the extent Novartis argues that Dr. Kraut failed to adequately rule out other factors, or that his diagnoses at this point regarding bisphosphonate-treated patients who have developed ONJ are but a "foregone conclusion" (*see* Def. Causation Mem. at 21; *see also id.* at 20 ("Dr. Kraut has diagnosed every bisphosphonate patient who has presented with ONJ with bisphosphonate-related ONJ . . . and never attributed cause to

anything else")), these are all points that go to the weight, and not to the admissibility, of Dr. Kraut's opinion. Defendant is free to highlight any such flaws or weaknesses in Dr. Kraut's opinion on cross-examination, but these are not sufficient grounds upon which to reject Dr. Kraut's opinion under *Daubert*.

For these reasons, the Court denies Novartis's *Daubert* motion to exclude the specific causation testimony of Dr. Kraut.

3. Plaintiff's Treating Physicians' Testimony (Drs. Arcati, Lear, and Ruggiero)

Defendant also challenges the opinions of plaintiffs' non-retained experts (who also served as Bee's treating physicians) on the issue of specific causation. These non-retained experts include Drs. Arcati, O'Lear, and Ruggiero. Because the Court has already determined that Dr. Kraut's testimony is admissible for purposes of assessing causation, it is clear that plaintiffs have evidence directly addressing the question of causation that is sufficient to preclude summary judgment on that issue (as discussed below). Accordingly, the Court will defer ruling on Novartis's *Daubert* challenges to plaintiffs' remaining, non-retained experts at this time.

4. Whether Aredia and/or Zometa Substantially Caused Plaintiff's ONJ

Novartis argues that plaintiffs' claims fail because they cannot establish a required element of all their claims: specific causation. *See Heckstall v. Pincus*, 797 N.Y.S.2d 445, 447 (N.Y. App. Div. 2005). As previously set forth, defendant's first argument is that plaintiffs do not carry their evidentiary burden as to specific causation on summary judgment because plaintiffs' proffered expert opinions are inadmissible under *Daubert*. However, the Court already has concluded that at least Dr. Kraut's testimony is admissible as to the question of causation. It thus proceeds to Novartis's next argument, which challenges whether plaintiffs can show that Aredia and/or Zometa were a substantial factor in Bee's development of ONJ.

Novartis asserts that in order for a plaintiff to successfully establish a negligence claim, the plaintiff must show that "defendant['s] conduct was a substantial causative factor in the sequence of events that led to [plaintiff's] injury." *Nallan v. Helmsley-Spear, Inc.*, 50 N.Y.2d 507, 520 (1980); *see also Galioto v. Lakeside Hosp.*, 506 N.Y.S.2d 725, 726 (N.Y. App. Div. 1986). Because "[p]laintiffs cannot show that Aredia and Zometa were a substantial factor in [] Bee's jaw condition," defendant contends that summary judgment should be granted in its favor. (Def. Summ. J. Mot. at 21.) The Court, upon reviewing the evidence in the record, concludes that there is sufficient evidence from which a rational jury would find that Novartis's drugs were a substantial causative factor in Bee's development of ONJ. Specifically, plaintiffs offer their expert, Dr. Kraut (along with the testimony of their other non-retained experts, Drs. Arcati, Ruggiero, and O'Lear). Dr. Kraut's expert report raises a genuine issue of material fact as to whether Aredia and/or Zometa were a substantial factor in plaintiff's development of ONJ. Although Novartis asserts otherwise, contending that Dr. Kraut failed to conduct a valid differential diagnosis to consider the impact of plaintiff's other risk factors on the development of his ONJ, thereby making it impossible to establish that Aredia and/or Zometa could have been a substantial factor in plaintiff's jaw condition, a rational jury could credit Dr. Kraut's testimony. As detailed *supra*, review of Dr. Kraut's expert report suggests that he did, in fact, examine other potential factors when drawing his

conclusions that plaintiff's ONJ development was attributable to bisphosphonates. Indeed, Dr. Kraut explicitly states in his report that he "considered the possibility of other etiologic factors" (Pls. Causation Resp. Ex. 10, at 7), that he was aware of the potential effect of Fosamax on plaintiff's condition (*id.*), and that he took into account other "critical facts" in plaintiff's medical history that could have impacted his development of ONJ, including the fact that Bee had not had chemotherapy or radiation treatment (*id.*), and that he had been diagnosed with ankylosing spondylitis (*id.* at 6). Even after considering all such factors, Dr. Kraut concluded that, based on plaintiff's drug history (with Aredia and Zometa), as well as Bee's clinical course following his teeth extractions, his jaw necrosis was bisphosphonate related. (*See* Pls. Causation Resp. Ex. 10 at 6.)

Moreover, the fact that Dr. Kraut did not expressly rule these other factors out does not mean his opinion would not be credited by the jury and relied upon to rationally find specific causation. Although Novartis argues otherwise, asserting that Dr. Kraut's report is not sufficient evidence upon which plaintiffs can rely to establish specific causation because he did not "*eliminate* [plaintiff's] other risk factors, such as Fosamax and ankylosing spondylitis" when conducting his differential diagnosis (Def. Summ. J. Mot. at 21 (emphasis added)), the law is not so rigid. As the case law to which Novartis cites makes clear, while a plaintiff must show that a defendant's alleged negligence was a substantial causal factor in bringing about a plaintiff's claimed injury, it "need not be the *sole* cause of the injury." *Galioto*, 506 N.Y.S.2d at 726 (emphasis added). That is, where a case concerns other potential causes of an alleged harm, a plaintiff "need not positively exclude every other possible cause"; however, "the proof must render those other causes sufficiently remote or technical" such that the logical inference that may be drawn from the evidence is that "it was 'more likely' or 'more reasonable' that the alleged injury was caused by the defendant's negligence." *Gayle v. City of New York*, 92 N.Y.2d 936, 937 (1998) (citations and internal quotation marks omitted). The Court concludes that plaintiff's evidence, including Dr. Kraut's expert report, creates a genuine issue of material fact as to whether Aredia and/or Zometa were the "most likely" or "more reasonable" causes of plaintiff's jaw necrosis. Indeed, it is well-settled that "[w]here a defendant raises alternative causes to avoid liability for a product's failure," a plaintiff may successfully counter this by "rais[ing] a triable question of fact [via] . . . competent evidence which, if credited by the jury, is sufficient to rebut defendant's alternative cause evidence." *Steinman v. Spinal Concepts, Inc.*, No. 05-CV-774S, 2011 WL 4442836, at *7 (W.D.N.Y. Sept. 22, 2011) (citations and internal quotation marks omitted). Plaintiffs have done just that, and a rational jury could credit such evidence. The role that other factors may have played in Bee's ONJ development is, at this juncture, a matter inappropriate for summary judgment. Thus, the Court must step aside to allow the jury to perform its appropriate role, which at this point, will require a probing of the facts and a weighing of the expert's credibility to determine whether Novartis's drugs were a substantial factor in plaintiff's subsequent ONJ development. For these reasons, the Court denies Novartis's motion for summary judgment as to specific causation.

C. Implied Warranty

As Novartis acknowledges, plaintiffs' implied warranty claim is also based on an alleged failure to warn and its corresponding evidence. (*See* Def. Summ. J. Mot. at 23–24

("Bee's claims for breach of warranty are subsumed under his failure to warn claim . . . . Therefore, plaintiffs must rely on the same evidence and allegations for their breach of implied warranty claim as they do for their tort claims, and, thus, is subject to the same analysis as those claims.").) For the same reasons that the Court denies summary judgment as to plaintiffs' strict liability and negligent failure to warn claims, the Court concludes that there are genuine issues of material fact precluding summary judgment on plaintiffs' breach of implied warranty claim. It therefore denies Novartis's motion for summary judgment as to plaintiffs' implied warranty claim.

D. Loss of Consortium

D. Bee's loss of consortium claim is derivative of, and dependent upon, plaintiffs' other claims. *See Smith v. Herman Miller, Inc.*, 03-CV-5358, 2005 WL 3501883, at *3 (E.D.N.Y. Dec. 21, 2005) ("A loss of consortium claim is a derivative claim"). Accordingly, the Court denies defendant's motion for summary judgment on this claim. *See In re Aredia & Zometa Prods. Liab. Litig. (Deutsch)*, No. 3:07-Md-1760, 2009 WL 2496891, at *4 (M.D. Tenn. Aug. 13, 2009) (denying summary judgment on loss of consortium claim on the grounds that it derived from plaintiff's other claims, for which court also had denied summary judgment).

V. CONCLUSION

For the reasons set forth herein, the Court denies Novartis's motion for summary judgment in its entirety, and denies Novartis's *Daubert* motion to exclude the specific causation testimony of Dr. Kraut.

SO ORDERED.

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JOSEPH F. BIANCO
United States District Judge

Dated: May 9, 2014
Central Islip, New York

* * *

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