UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

GREGORY A. AMOS, in his capacity as Administrator of the Estate of ANDREA R. AMOS, Deceased,

Plaintiff,

v.

BIOGEN IDEC INC. and ELAN PHARMACEUTICALS, INC.,

Defendants.

13-CV-6375 T

DECISION and ORDER

INTRODUCTION

Plaintiff Gregory A. Amos ("plaintiff"), the widower of Andrea R. Amos ("Mrs. Amos") and administrator of her estate, brings this wrongful death action against defendants Biogen Idec Inc., ("Biogen") and Elan Pharmaceuticals, Inc. ("Elan") (collectively "defendants"), alleging that Mrs. Amos died as the direct result of taking the prescription drug Tysabri, which was developed, marketed, and sold by the defendants. Specifically, plaintiff claims that Mrs. Amos' use of Tysabri caused her to develop a fatal infection in her brain, and that the warnings included with Tysabri failed to adequately warn of this risk.

Defendants deny any liability and move pursuant to Rule 56 of the Federal Rules of Civil Procedure for summary judgment against the plaintiff. Defendants contend that: (1) Tysabri's warnings were adequate as a matter of law; (2) plaintiff has not produced competent evidence that the label warnings were inadequate; (3) plaintiff cannot establish proximate cause; and (4) plaintiff's claims are preempted by federal law. In addition, defendants have

moved *in limine* to preclude certain testimony by plaintiff's expert, Eugene O. Major, Ph.D. ("Dr. Major"). Plaintiff opposes both of defendants' motions.

For the reasons set forth below, the Court grants defendants' motion for summary judgment. Defendants' motion to preclude Dr. Major's testimony is denied as moot.

BACKGROUND

The following facts are taken from the respective statements of fact, affidavits, and exhibits submitted by plaintiff and defendant.

I. Multiple Sclerosis and Tysabri

Multiple sclerosis ("MS") is a chronic, progressive, and disabling autoimmune disease, in which white blood cells enter the central nervous system ("CNS") and attack myelin, a fatty substance that surrounds nerve cells and assists in the transmission of signals to and from the brain. MS gradually destroys myelin (a process known as "demyelination"), resulting in nerve damage throughout the brain and spinal cord. The damage caused by demyelination may result in brain atrophy, cognitive impairment, limited mobility, and shortened life expectancy. There are multiple types of MS, including "relapsing-remitting MS," wherein specific attacks are followed by remission, and "secondary progressive MS," wherein the disease continually worsens without identifiable periods of remission. There is no known cure for MS and all current treatments have side effects.

Tysabri is the brand name for natalizumab, a humanized monoclonal antibody that inhibits the ability of inflammatory white blood cells to enter the CNS and thereby protects against demyelination. Tysabri decreases relapses in individuals with MS and can reduce and delay nerve damage. The Food and Drug Administration (the "FDA") first approved Tysabri in November 2004 for treatment of relapsing forms of MS. Defendant Biogen is the FDA license holder for Tysabri.

II. Tysabri and Progressive Multifocal Leukoencephalopathy

Progressive multifocal leukoencephalopathy ("PML") is an opportunistic viral infection of the brain caused by the JC virus. The JC virus is carried by the majority of adults and is usually harmless. There are no known treatments or cures for PML.

In February 2005, defendants received reports that two patients involved in ongoing clinical trials for Tysabri used in combination with Avonex, another medication used to treat MS, had developed PML. This was the first time that PML was associated with Tysabri or MS. Biogen voluntarily withdrew Tysabri from the market on February 28, 2005, and suspended its use in clinical trials. Defendants then undertook steps to analyze the reported PML cases and to assess and quantify the risk associated with Tysabri. In April 2005, Biogen announced that a third case of PML had been identified, this time in a patient from a clinical trial studying the use of Tysabri in patients with Crohn's Disease.

Prior to returning Tysabri to the market, the FDA requested that Biogen conduct an assessment for the presence of JC virus

antibodies at baseline in patients entering clinical trials. Biogen did so and, on March 2, 2006, submitted a report to the FDA regarding the results of antibody testing. The antibody testing had been performed at a laboratory at the National Institute of Health (the "NIH") led by plaintiff's expert, Dr. Major. The report concluded that there was no consensus on a clinically relevant cut off for JC virus antibody detection.

On June 5, 2006, the FDA re-approved Tysabri as a treatment of relapsing forms of MS, subject to new conditions and requirements regarding the risk of PML. Specifically, the FDA required that the prescribing information for Tysabri contain a "black box" warning (a warning printed inside a black box on the first page of drug labeling) stating that Tysabri use increases the risk for PML. A black box warning is the strongest type of warning allowed in drug labeling, and to ensure their significance is undiluted, use of a black box warning is permitted only where specifically required by the FDA. The prescribing information for Tysabri further informed treating physicians that because of the increased risk of PML associated with Tysabri usage, it is generally recommended only for patients who had an inadequate response to other MS treatments. As a further condition of re-approval, the FDA required that a medication guide be provided to physicians and specially trained infusion nurses, and limited prescription of Tysabri to prescribers registered in the Tysabri Outreach: Unified Commitment to Health ("TOUCH") Prescribing Program, a special restricted distribution program. The TOUCH Prescribing Program requires that prior to

prescribing Tysabri a physician both acknowledge in writing that he or she understands the PML risk and obtain a written acknowledgment from the patient that the patient understands the PML risk.

III. Tysabri Labeling Changes

When Tysabri returned to the market in June 2006, defendants and the FDA thought it was possible that PML risk might be associated with duration of treatment, but determined that there was insufficient data to support that conclusion. The black box warning required by the FDA thus stated that the relationship between the risk of PML and the duration of treatment was unknown. Based on additional confirmed Tysabri-related cases of PML in 2008 and 2009, in November 2009, the FDA approved an update to the label to state that in patients treated with Tysabri, the risk of PML increases with longer treatment duration. In July 2010, the FDA approved another label update, this one stating that the risk of PML is increased in patients who have been treated with immunosuppressants prior to receiving Tysabri.

IV. JC Virus Antibody Testing

After Tysabri was removed from the market, defendants researched the use of polymerase chain reaction ("PCR") assay testing to detect the presence of JC virus DNA in the blood. PCR assay testing was considered by some to be the most likely risk stratification tool because a person must be infected with the JC virus in order to develop PML. However, in 2010, PCR assay testing was determined to be unlikely to be useful in stratifying the risk for PML.

Defendants also conducted research on the use of JC virus antibody testing as a risk stratification tool. Plaintiff maintains that technology existed to test for and detect the presence of JC virus antibodies in humans in 2005, while Defendants argue that the test in question had not been validated. The parties agree that by late 2009, Biogen scientists had developed an analytically validated assay to reliably detect JC virus antibodies in the blood. Biogen subsequently convened an advisory board of MS experts and regulatory experts to discuss the data it had collected regarding testing for JC virus antibodies. Summary notes from a December 9, 2009 advisory board meeting indicate that the regulatory experts believed the data were too preliminary to be of predictive value regarding PML at that time. However, most of the medical experts on the advisory board agreed that research in this area should continue and that it was possible that JC virus antibody testing could be of use in risk stratification.

On September 8, 2010, defendants met with the FDA to discuss Biogen's JC virus antibody testing and related proposed changes to the Tysabri label. Specifically, Biogen proposed changing the Tysabri label to inform prescribing physicians that individual JC virus antibody status should be considered in determining the benefits and risks of Tysabri, that screening for serum JC virus antibodies should be performed prior to initiating Tysabri therapy and annually thereafter, and that there is an increased risk for PML in JC virus antibody positive patients. The FDA rejected Biogen's proposal on the basis that there was currently

insufficient information to support the clinical utility of the JC virus antibody assay in determining the risk for PML.

On November 18, 2010, defendants again met with the FDA, this time to discuss a Biogen proposal to make its JC virus antibody assay available to Tysabri prescribers. The FDA rejected this proposal as well, reiterating its conclusion that the usefulness of the test had not been established.

Subsequent to these FDA rejections and throughout 2011, Biogen continued to sponsor clinical trials regarding its JC virus antibody assay and to work with the FDA to demonstrate the assay's usefulness in the clinical setting. In October 2011, in light of the additional evidence it had collected, Biogen again asked the FDA to permit amendment of the Tysabri label to include information regarding testing for JC virus antibodies. On January 12, 2012, the FDA cleared Biogen's JC virus antibody assay and approved associated changes to Tysabri's labeling.

V. Mrs. Amos' Use of Tysabri and Subsequent PML

Mrs. Amos first developed symptoms of MS in 1992. Dr. David Smith, her treating physician from March 2005 to May 2011, diagnosed her with MS in April 2005. In March 2006, Mrs. Amos suffered an MS relapse. By July 2006, Mrs. Amos had reported two MS attacks since her diagnosis, and expressed a desire for aggressive therapy. Due to the severity of Mrs. Amos' MS, Dr. Smith determined that four drugs often used to treat MS (Avonex, Betaseron, Copaxon, and Rebif, the so-called "ABCR" drugs) would not be the most effective treatment options. Instead, on

July 28, 2006, he prescribed Tysabri. Dr. Smith testified at deposition that he reviewed the Tysabri informed consent information with Mrs. Amos and that there was no question she was aware of the risk of PML. Dr. Smith was enrolled in the TOUCH Prescribing Program and appreciated the significance of black box warnings. Dr. Smith was aware that PML was a risk of Tysabri use and that PML is caused by the JC virus. Mrs. Amos received her first monthly Tysabri infusion in September 2006. She continued to receive Tysabri infusions under Dr. Smith's care until May 2011, during which time she tolerated the drug well, her MS symptoms were stable, and periodic MRI exams showed no MS progression.

In May 2011, Mrs. Amos began seeing neurologist Dr. Louis Medved. Dr. Medved continued to prescribe Tysabri to Mrs. Amos due to the aggressiveness of her MS and because Tysabri had controlled the progression of her disease. Dr. Medved testified at deposition that he discussed the risk of PML with Mrs. Amos relative to the risk of her MS getting worse without treatment. Mrs. Amos received two additional Tysabri infusions in June 2011. In mid-July 2011, Mrs. Amos was diagnosed with PML. She died on September 20, 2011.

VI. <u>Procedural History</u>

Plaintiff commenced the instant action on July 19, 2013. Docket No. 1. On October 7, 2013, defendants filed a motion seeking dismissal of counts II, III, V, VI, and VIII of the complaint. Docket No. 16. The Court entered a Decision and Order on June 25, 2014, granting defendants motion in part and denying

defendants motion in part. Docket No. 29. In particular, the Court granted defendants' motion to dismiss plaintiff's design defect, New York General Business Law, and fraud claims, and denied defendants' motion to dismiss plaintiff's strict liability and negligent misrepresentation claims. *Id.* Following completion of discovery, defendants filed their motion for summary judgment on January 18, 2017. Docket No. 56.

DISCUSSION

I. Standard of Review

Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure, the Court will grant summary judgment if the moving party demonstrates that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. When considering a motion for summary judgment, all genuinely disputed facts must be resolved in favor of the party against whom summary judgment is sought. *See Tolan v. Cotton*, 134 S.Ct. 1861, 1863 (2014). If, after considering the evidence in the light most favorable to the nonmoving party, the court finds that no rational jury could find in favor of that party, a grant of summary judgment is appropriate. *See Scott v. Harris*, 550 U.S. 372, 380 (2007), citing *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-587 (1986).

II. Plaintiff's Claims Turn on the Sufficiency of the Warnings

In support of their motion for summary judgment, defendants argue that all of plaintiff's claims rise or fall based on the

adequacy of the warnings for Tysabri. Plaintiff disagrees, maintaining that his claims for negligence, negligent misrepresentation, strict liability, and breach of implied warranty may proceed independent of his failure to warn claim. The Court therefore must determine as a threshold issue whether a failure of proof with respect to failure to warn is determinative of all plaintiff's claims.

Under New York law, which the parties agree governs this case, "the adequacy of the warnings, as a matter of law, precludes any related claims for negligence, strict liability, breach of warranties, or fraud." *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 410 (S.D.N.Y. 2014) (internal quotation omitted); *see also In re Accutane Prod. Liab.*, 2012 WL 3194954, at *6 (M.D. Fla. July 24, 2012) ("[U]nder New York law, the adequacy of the warnings, as a matter of law, precludes any related claims for negligence, strict liability, breach of warranties, or fraud."); *Gentile v. Biogen Idec, Inc.*, 2016 WL 4168942, at *9 (Mass. Super. July 28, 2016) ("under New York law, where a failure to warn claim cannot succeed, the court must dismiss any related claims for negligence, strict liability, breach of warranties, or fraud"). Plaintiff has identified no cases holding to the contrary, nor has he proffered a viable explanation how his claims, all of which involve in some fashion the adequacy of the warnings, can survive if the warnings were adequate as a matter of law.

In addition, plaintiff's claim for negligent misrepresentation is barred by New York's "learned intermediary" rule, pursuant to

which "[w]arnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects," and "the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." *Martin v. Hacker*, 83 N.Y.2d 1, 9 (1993). A plaintiff alleging negligent misrepresentation "must establish reliance upon a false statement or material misrepresentation or omission," and the learned intermediary rule eliminates the possibility of any such reliance. *See Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 447 (W.D.N.Y. 2001).

As a result of the foregoing, it is clear that all of plaintiff's claims in this matter rise or fall upon the adequacy of defendants' warnings. As a result, and because (as set forth in detail in below) the Court finds that the warnings were adequate as a matter of law, defendants are entitled to judgment in their favor on all plaintiff's claims.

III. The warnings were adequate as a matter of law

As discussed above, New York follows the learned intermediary rule, pursuant to which a drug manufacturer's duty to warn is fulfilled by providing adequate warning of potential side effects to a treating physician. *See Martin*, 83 N.Y.2d at 9. "A warning

is adequate as a matter of law if it provides specific detailed information on the risks of the drug." *McDowell*, 58 F. Supp. 3d at 403 (internal quotation omitted). In assessing a warning, the Court must evaluate it as a whole, and "not through the nitpicking prism of an interested legal advocate after the fact." *Id.* The Court considers factors "including whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk involved in taking the drug." *Id.* (internal quotation omitted). Additionally, "[i]t has long been the law in New York that prescription medicine warnings are adequate when . . information regarding 'the precise malady incurred' was communicated in the prescribing information." *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009) (quoting *Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 60 (4th Dep't 1979). As a result, "when a plaintiff claims to be injured in a manner that is addressed by warnings provided to his physician, summary judgment is granted on failure to warn claims." *Id.*

In the instant case, there is no dispute that at the time Mrs. Amos was prescribed Tysabri, its label specifically warned treating physicians of an increased risk of PML. Indeed, Tysabri's label contained this information in a black box warning, the strongest warning available. Moreover, Dr. Smith testified at deposition that he was fully aware that PML was a risk of Tysabri use, further

supporting the conclusion that the warnings were adequate. *See Gentile*, 2016 WL 4168942, at *7 (treating physician's "testimony that she was aware that Tysabri increased a patient's risk of developing PML further demonstrates the adequacy of the warning").

Plaintiff maintains that Tysabri's warnings were inadequate because they did not include information regarding the correlation between JC virus antibodies and PML, nor did they inform physicians of the risks associated with duration of treatment and prior treatment with immunosuppressant. The *Gentile* court rejected these precise arguments in a matter also involving claims by a widower whose wife developed PML and died after Tysabri treatment. In granting summary judgment to defendants, the *Gentile* court concluded that Tysabri's warnings were adequate as a matter of law under New York law because "even without [the details regarding specific risk factors], when read as a whole, the warnings unmistakably conveyed the seriousness of PML and its association with Tysabri treatment." *Id.* The *Gentile* court further noted that New York law does not require drug manufacturers to include specific information regarding the frequency of adverse events, and that Tysabri's packaging "unambiguously assumed that anyone who took Tysabri increased their risk of developing PML." *Id.* The Court agrees with the reasoning in *Gentile*. Even without additional information regarding specific risk factors, the

warnings for Tysabri clearly, directly, and unequivocally informed treating physicians of the increased risk for PML and the seriousness of that condition. *See Christison v. Biogen Idec Inc.*, 199 F. Supp. 3d 1315, 1345 (D. Utah 2016) ("The Tysabri label clearly conveys a warning that taking Tysabri would increase the risk of PML, and that due to the preliminary nature of the research in 2006, there was no reliable correlation between length of treatment, use with other immunosuppressant drugs, or a positive indication of JC Virus antibodies. [Plaintiff's] request that that information be placed on the label is aided by hindsight rather than the scientific information *available at the time*.") (emphasis in original). Under these circumstances, the Court finds that the warnings were adequate as a matter of law.

III. Plaintiff's Claims are Preempted by Federal Law

Defendants also argue that plaintiff's claims are preempted by federal law. It is well-established that, pursuant to the Supremacy Clause of th United States Constitution (U.S. Const., Art. VI, Cl. 2), federal law preempts conflicting state law. In the specific context of drug manufacturing, the Supreme Court has held that while the Food, Drug, and Cosmetics Act and its associated regulations do not expressly preempt state tort law, where a plaintiff's theory of the case requires a drug manufacturer to have taken an action that it could not lawfully take under federal law, conflict preemption bars that particular claim. *See*

Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2477, 186 L. Ed. 2d 607 (2013) (state law design-defect cause of action based on warning was preempted with respect to FDA-approved drugs sold in interstate commerce because it was impossible for drug manufacturer to comply with both state and federal law).

"Impossibility pre-emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). In the context of claims against drug manufacturers for allegedly inadequate warnings, a drug manufacturer may show preemption in two ways: (1) by showing that it was prohibited by federal law from modifying the FDA-approved labeling; or (2) by presenting clear evidence that the FDA would not have approved a change to the drug's label. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 619 (2011); *Wyeth*, 555 U.S. at 571. In this case, defendants have demonstrated both that they could not have unilaterally added the warning plaintiff argues was required and that the FDA would have rejected the proposed change to Tysabri's label. Because plaintiff has failed to adduce any evidence to contradict this showing, no reasonable jury could find in plaintiff's favor, and summary judgment is required.

First, with respect to defendants' ability to unilaterally change Tysabri's label, pursuant to certain FDA regulations known as Changes Being Effected or "CBE" regulations, a drug manufacturer may change a product label without prior FDA approval if the change in question (1) reflects newly acquired information and

(2) accomplishes one of five specific objectives set forth in the regulations. *See* 21 C.F.R. § 314.70(c)(6)(iii). However, a drug manufacturer cannot add or change a black box warning without permission from the FDA, because the FDA determines the contents of such warnings. *See Schedin v. Ortho-McNeil-Janssen Pharm., Inc.*, 776 F. Supp. 2d 907, 912 (D. Minn. 2011); *Rheinfrank v. Abbott Labs.*, Inc., No. 1:13-CV-144, 2015 WL 5258858, at *2 (S.D. Ohio Sept. 10, 2015). In this case, the FDA-approved labeling included a black box warning regarding the increased risk of PML that made no mention of testing for the presence of JC virus antibodies. *See* Defendants' Ex. 5, Docket No. 56-5 at 77. Plaintiffs have not proffered any explanation how defendants could have lawfully modified the black box warning absent approval from the FDA.

Second, the evidence of record leads inescapably to the conclusion that the FDA would not have approved a change to Tysabri's label prior to 2012. In deciding a motion for summary judgment with respect to the preemption defense, the Court "compare[s] the evidence presented with the evidence in *Wyeth*, to determine whether it is more or less compelling," and "[a] trial by jury [is] only . . . necessary in those cases where the evidence presented is more compelling than that in *Wyeth* but no 'smoking gun' rejection letter from the FDA is available." *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, __ F.3d __, 2017 WL 1075047, at *18 (3d Cir. Mar. 22, 2017). "{T]he question for

summary judgment purposes is . . . whether a reasonable juror could find that it is highly probable that the FDA would have rejected the warning." *Id*. at *19. In this case, there exists not one but two "smoking gun" rejections from the FDA. It is undisputed that on September 8, 2010, Biogen proposed to the FDA that Tysabri's labeling be modified to state that: (1) individual JC virus antibody should be considered in determining the risk/benefit of Tysabri; (2) screening for serum JC virus antibody should be performed prior to initiating therapy and annually thereafter,; and (3) there is an increased risk for PML in JC virus antibody positive patients. It is further undisputed that the FDA rejected that proposal, stating that it did not believe that there was currently sufficient information to support the clinical utility of testing for JC virus antibodies. Plaintiff also does not dispute that on November 18, 2010, Biogen proposed making its JC virus antibody assay available to Tysabri prescribers, and that the FDA again rejected Biogen's proposal on the basis that the utility of the test had not been established. It was not until February 2012, after completion of additional clinical trials and testing, and as a result of ongoing communications between Biogen and the FDA, that the FDA finally agreed to approve a Tysabri labeling change. On this record, no reasonable jury could conclude that the FDA would have approved a labeling change for Tysabri prior to Mrs. Amos' death. This is not a case where there was a mere quibble over

language (*see In re Fosamax*, 2017 WL 1075047 at *21) - to the contrary, the record is clear that the FDA did not believe that the data sufficiently established the utility of testing for JC virus antibodies.

A federal court in the District of Utah recently reached a similar conclusion in a factually analogous case. *See Christison*, 199 F. Supp. at 1347. As in this case, the plaintiff in *Christison* was the widower of an individual who died of PML after being treated for MS with Tysabri. *Id*. at 1319. Also like the plaintiff in this case, the *Christison* plaintiff argued the Biogen and Elan should have updated the Tysabri label to warn about the increased risk of developing PML for patients who had tested positive for JC virus antibodies. *Id*. The court in *Christison*, on the same administrative record as in the instant matter, concluded that the plaintiff's claims were preempted because the FDA expressly rejected Biogen's request to change Tysabri's label in September and November 2010. *Id*. at 1347. As a result, the court concluded that there was "'clear evidence' that the FDA would not have approved a change to the Tysabri label regarding JCV antibodies before 2012." *Id*.

Gentile, which is discussed at length above, is another factually analogous case in which a court determined that the plaintiff's claims were preempted by federal law. In *Gentile*, as in the instant case and *Christison*, the plaintiff's wife developed

PML and died after treatment with Tysabri. *Id.* at *3. The Massachusetts Superior Court granted summary judgment to Biogen and Elan, explaining that plaintiff's claims were preempted because "[Biogen and Elan] continued to research the JCV antibody correlation until the FDA finally approved the modified warning" and that "[the] FDA rejected defendants' proposed change in the warning not because of the language used, but because the supporting data was not yet sufficiently persuasive." *Id.* at *10. For the reasons set forth above, the Court agrees with the holdings in *Christison* and *Gentile*.

The Court also holds that plaintiff's claims against Elan are preempted because Elan is not the holder of the approved application for Tysabri in the United States. "A distributor, even of a brand name drug, has no power to change. . . labeling. That power lies with the applicant who filed the New Drug Application (NDA)." *Brazil v. Janssen Research & Dev. LLC*, 196 F. Supp. 3d 1351, 1365 (N.D. Ga. 2016) (internal quotation omitted). In *Mensing*, the Supreme Court held that claims against a manufacturer of generic drugs were preempted because such a manufacturer has no authority under federal regulations to modify labeling. 564 U.S. at 618-19. The same reasoning compels the Court to find preemption here. Federal regulations do not permit Elan, as a distributor, to change labeling. Any claim that state law compelled it to do so is therefore preempted. *See Gentile*, 2016 WL 4168942, at * 11

(finding claims against Elan preempted because "Elan could not have sought modifications of the label").

IV. The Court Need not Reach Defendants' Remaining Arguments

Defendants have also argued that Dr. Major's testimony is unrelated to the adequacy of Tysabri's warnings and that plaintiff cannot show proximate cause. Because the Court has determined that defendants are entitled to summary judgment for the reasons set forth above, it need not and does not reach these arguments.

The Court's decision also renders moot defendants' request that Dr. Major be precluded from testifying as to certain subjects. As a result, defendants' motion *in limine* is denied as moot.

CONCLUSION

For the reasons set forth above, the Court grants defendants' motion for summary judgment (Docket No. 56) and denies defendants' motion *in limine* (Docket No. 55) as moot. The Clerk of the Court is instructed to enter judgment in favor of defendants and to close the case.

ALL OF THE ABOVE IS SO ORDERED.

S/ Michael A. Telesca

MICHAEL A. TELESCA
United States District Judge

DATED: Rochester, New York
April 10, 2017