CLERK'S NOTICE	DOCKET NUMBER 1381CV04461	Trial Court of Massachusetts The Superior Court

CASE NAME:
Angela Cleary et al vs. Biogen Inc. et al

Michael A. Sullivan, Clerk of Court
Middlesex County

TO:
Brian Dunphy, Esq.
Mintz Levin Cohn Ferris Glovsky & Popeo PC
One Financial Center
Boston, MA 02111

COURT NAME & ADDRESS
Middlesex County Superior Court - Woburn
200 Trade Center
Woburn, MA 01801

You are hereby notified that on 09/13/2017 the following entry was made on the above referenced docket:

MEMORANDUM & ORDER:

MEMORANDUM AND ORDER ON DEFENDANTS' OMNIBUS MOTION FOR SUMMARY JUDGMENT: ORDER: Defendants' Omnibus Joint Motion for Summary Judgment is ALLOWED. Judgment for defendants in each of these six cases shall enter accordingly. Dated: September 8, 2017

DATE ISSUED	ASSOCIATE JUSTICE/ ASSISTANT CLERK	SESSION PHONE#
09/13/2017	**Hon. Peter B Krupp**	

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COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, SS. **SUPERIOR COURT**
Civil No. 13-4461

ANGELA CLEARY & another[1]
Plaintiff

vs.

BIOGEN IDEC INC. & another[2]
Defendants
(and consolidated cases[3])

MEMORANDUM AND ORDER ON DEFENDANTS' OMNIBUS MOTION FOR SUMMARY JUDGMENT

The plaintiffs in these six cases sued Biogen Idec, Inc. ("Biogen") and Elan Pharmaceuticals, Inc. ("Elan") to recover money damages after patients developed a rare viral brain infection after receiving infusions of Tysabri, a drug the defendants developed and sold to treat relapsing forms of multiple sclerosis ("MS"). I previously allowed a defense motion for summary judgment in a similar case. Gentile v. Biogen Idec, Inc. ("Gentile"), 33 Mass. L. Rptr. 607, 2016 WL 4168942 (Mass. Super. July 28, 2016). Two federal courts have since issued similar rulings. See Amos v. Biogen Idec Inc. ("Amos"), ___ F. Supp. 3d ___, 2017 WL 1316968 (W.D.N.Y. Apr. 10, 2017); Christison v. Biogen Idec, Inc. ("Christison"), 199 F. Supp.

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1 Keith Cleary.

2 Elan Pharmaceuticals, LLC.

3 Jerilyn Erichson and Georg Erichson v. Biogen Inc. and Elan Pharmaceuticals, LLC, No. 14-6541; Joanne B. Friedmeyer, as Trustee of the Bankruptcy Estate of Marla Fair, and Terry Fair v. Biogen Idec Inc. and Elan Pharmaceuticals, LLC, No. 14-6807; David Glisson, as Power of Attorney for Pamela Glisson v. Biogen Inc. and Elan Pharmaceuticals, LLC, No. 15-3765; Susan Speigel and Barry Speigel v. Biogen Idec Inc. and Elan Pharmaceuticals, LLC, No. 14-488; Kimberly A. Yout v. Biogen Idec Inc., Elan Pharmaceuticals, LLC, Bharanidharan Padmanabhan, M.D., Ph.D., and Scleroplex, Inc., No. 13-3917.

3d 1315 (D. Utah 2016). The six remaining cases are now before me on defendants' omnibus motion for summary judgment. For the following reasons, the motion for summary judgment is **ALLOWED**.

BACKGROUND

This decision assumes familiarity with my decision in Gentile, including the history of approval of Tysabri by the U.S. Food and Drug Administration ("FDA"); discovery of a link among Tysabri, antibodies to the John Cunningham Virus ("JCV"), and the development of progressive multifocal leukoencephalopathy ("PML"); and FDA's requirements before Tysabri was allowed back on the market in 2006. See Gentile, 2016 WL 4168942 at ** 1-4.

The summary judgment record, viewed most favorably to plaintiffs, contains the following facts material to this motion:

Angela Cleary, a resident of Connecticut, was diagnosed with MS. Dr. Peter Calabresi prescribed Tysabri to control the progression of her disease. Ms. Cleary received approximately 22 infusions in Maryland between January 2009 and October 2010. She was diagnosed with PML in October 2010.

Jerilyn Erichson, a resident of Utah, was diagnosed with MS. Dr. John Foley prescribed Tysabri to control the disease. Ms. Erichson received monthly infusions from June 2007 until approximately August 2012. She was diagnosed with PML in October 2012.

Marla Fair,[4] a resident of Indiana, was diagnosed with MS in 2002. Dr. Caryn Vogel prescribed Tysabri to control the disease. Ms. Fair received approximately 24 infusions between July 2007 and May 2009. She was diagnosed with PML in May 2009.

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[4] The United States Bankruptcy Court for the Southern District of Indiana appointed Joanne Friedmeyer as the Trustee of the Bankruptcy Estate of Marla Fair. Ms. Friedmeyer brought this claim in her capacity as the bankruptcy trustee.

Pamela Glisson, a resident of Nebraska, was diagnosed with MS in approximately 1989. Dr. Jan Weber prescribed Tysabri. Ms. Glisson received more than 50 infusions between January 2007 and June 2011. She was diagnosed with PML in June 2011.

Susan Speigel, a resident of Illinois, was diagnosed with MS in approximately 1998. Dr. George Katsamakis prescribed Tysabri. Ms. Speigel received more than 50 infusions between June 2007 and February 2012. She was diagnosed with PML in March 2012.

Kimberly Yout, a resident of Massachusetts, was diagnosed with MS in approximately 1997. Drs. Bharanidharan Padmanabhan and Salvatore Napoli prescribed Tysabri. Ms. Yout received more than 50 infusions from approximately 2006 until August 2012. She was diagnosed with PML in August 2012.

DISCUSSION

I. The Summary Judgment Standard

Summary judgment is appropriate when "there is no genuine issue as to any material fact and [ ] the moving party is entitled to a judgment as a matter of law." Mass. R. Civ. P. 56(c). See Bulwer v. Mount Auburn Hosp., 473 Mass. 672, 680 (2016); Kourouvacilis v. General Motors Corp., 410 Mass. 706, 712-716 (1991). A party may succeed on summary judgment by demonstrating that the nonmoving party has no reasonable expectation of proving an essential element at trial. Flesner v. Technical Commc'ns Corp., 410 Mass. 805, 809 (1991); Kourouvacilis, 410 Mass. at 716. Once the moving party establishes the absence of a triable issue, the opposing party must respond with specific facts showing a genuine issue of material fact. Mass. R. Civ. P. 56(e). The nonmoving party may not merely rest on assertions of dispute, but must show the existence of actual disputes of fact. LaLonde v. Eissner, 405 Mass. 207, 209

(1989). I must resolve doubts about the existence of a genuine issue of material fact against the moving party. Parent v. Stone & Webster Eng'g Corp., 408 Mass. 108, 112 (1990).

Defendants move for summary judgment on plaintiffs' failure to warn claims and argue that the preemption ruling in Gentile should apply with equal force to the claims brought in these cases. Defendants also argue that there are no factual or legal differences between these cases and Gentile that would lead to a different result. Before addressing these arguments, I must address a threshold issue raised by plaintiffs.

II. Plaintiff's Rule 56(f) Motion

Relying on Mass. R. Civ. P. 56(f), plaintiffs contend summary judgment is premature and that they should first be permitted additional discovery. Plaintiffs seek production of Biogen's entire regulatory file regarding Tysabri; all documents and communications between defendants and FDA regarding development of a JCV antibody assay; and all of defendants' internal communications and documents regarding JCV antibodies and the potential use of an antibody assay in conjunction with Tysabri. Plaintiffs assert that because Tysabri was reintroduced to the market in 2006 and warnings mentioning JCV antibodies were not approved until 2012, there must have been communications in the interim that have not yet been produced.

Rule 56(f) allows a party opposing summary judgment to show "it cannot, without further discovery, 'present by affidavits facts essential to justify [its] opposition.'" Commonwealth v. Fall River Motor Sales, Inc., 409 Mass. 302, 307 (1991), quoting Mass. R. Civ. P. 56(f). "[T]he nonmoving party [ ] must show that 'the information sought would have raised a material factual question.'" Alphas Co., Inc. v. Kilduff, 72 Mass. App. Ct. 104, 109 (2008), quoting Blake Bros. Corp. v. Roche, 12 Mass. App. Ct. 556, 560 (1981).

In analyzing a Rule 56(f) claim, I must consider five factors: "authoritativeness, timeliness, good cause, utility, and materiality." See Resolution Trust Corp. v. North Bridge Assocs., Inc., 22 F.3d 1198, 1203 (1st Cir. 1994). As the Appeals Court has explained, quoting Resolution Trust, 22 F.3d at 1203:

> the request for relief under rule 56(f), after meeting the preliminary requirements that the request be timely and that it be accompanied by an authoritative affidavit based on firsthand knowledge, "should show good cause for the failure to have discovered the facts sooner; it should set forth a plausible basis for believing that specified facts, susceptible of collection within a reasonable time frame, probably exist; and it should indicate how the emergent facts, if adduced, will influence the outcome of the pending summary judgment motion."

Alphas, 72 Mass. App. Ct. at 110. The trial court "enjoys considerable discretion" in deciding whether to grant a continuance under Rule 56(f). Id. at 111.

Defendants have already produced voluminous documents. In producing Biogen's regulatory file, its counsel initially indicated that only "portions" had been produced. From this statement, plaintiffs construe that other documents have been withheld. Plaintiffs also argue that five out of the six of the patients in these cases were diagnosed with PML after Ms. Gentile received her diagnosis, so the same preemption analysis may not necessarily apply here and other documents bearing on Biogen's knowledge and conduct may be relevant.

In response, defendants contend that plaintiffs cannot show "a plausible basis for a belief that discoverable materials exist that would likely suffice to raise a genuine issue of material fact and, thus, defeat summary judgment." Resolution Trust, 22 F.3d at 1206. They argue that because this claim pertains specifically to the issue of federal preemption, plaintiffs are not entitled to a continuance because the current record demonstrates that FDA would not have approved a labeling change prior to 2012. Defendants also state -- and plaintiffs offer nothing to

the contrary -- that Biogen's entire Tysabri regulatory file through April 2013 as may be potentially relevant[5] has already been produced, as have communications between defendants and FDA before January 2012 regarding JCV antibodies.

As a preliminary matter, I note that plaintiffs made a timely request for relief under Rule 56(f). Attorney Clinton's affidavit is made with firsthand knowledge of the obstacles to conducting discovery and demonstrates good cause for plaintiffs' inability to complete discovery before the filing of the omnibus motion for summary judgment. See Alphas, 72 Mass. App. Ct. at 111.

As to the requirements of materiality and utility, plaintiffs' contention that additional documents actually exist or would be material does not amount to more than mere speculation. See Resolution Trust, 22 F.3d at 1206 ("Rule 56(f) proffer need not be presented in a form suitable for admission as evidence at trial, so long as it rises sufficiently above mere speculation."). Plaintiffs rely on a phrase included in a cover letter attached to a production of documents, stating that the documents comprise "portions" of Tysabri's regulatory filings. Besides the single occurrence of this term, plaintiffs have not alleged that in reviewing the current record, they have identified specific deficiencies or omissions of documents. Rather,

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[5] Defendants assert that the only portion of the regulatory file that has not been produced is from after April 2013. The parties agreed that this later period is not relevant. In addition, a "module" pertaining to Tysabri's composition and manufacturing was not produced as the parties apparently agreed it was not relevant to Tysabri's labeling. At a hearing on a motion to stay the summary judgment briefing, defendants represented that the entire relevant regulatory file through at least January 2012 had already been produced. See Transcript (Jan. 27, 2017) at 9 ("Everything having to do with the labeling of Tysabri we have produced."), 15-16 ("They have the entire supplemental biologics license application concerning the assay. They have everything that the FDA relied upon . . . [t]hrough 2012."), 18 ("we produced the entire SBLA, the supplemental biologics license application, to FDA, upon which FDA relied in allowing [Biogen] to change the label. . . . So they have everything [ ] through 2012 that has any relevance whatsoever to the labeling of this drug.").

they simply surmise that further communications beyond those already produced must have taken place during the six years between Tysabri's second release to the market and FDA's eventual approval of warnings identifying the drug's interaction with JCV antibodies. See Plaintiffs' Memorandum in Opposition to Defendants' Omnibus Joint Motion for Summary Judgment in the Remaining Specially Assigned Cases ("Plaintiffs' Opp.") at 16 ("Defendants must have generated some form of information . . . related to JCV antibodies up until January 2012 when FDA approved the label update.").

Defendants clearly continued to work with FDA after it denied a label change in 2010. These communications were produced in discovery. There is no indication that any additional material documents were withheld from production. Plaintiffs are not entitled to "'fish' for evidence on which to base their complaint 'in hopes of somehow finding something helpful to their case in the course of the discovery procedure.'" E.A. Miller, Inc. v. South Shore Bank, 405 Mass. 95, 102 (1989), quoting Charbonnier v. Amico, 367 Mass. 146, 153 (1975). See, e.g., Alphas, 72 Mass. App. Ct. at 114 (plaintiffs' claims "far too speculative to meet even the minimal threshold to warrant further discovery under rule 56(f).").

Voluminous records have already been produced in these cases. There is no reason to believe that anything material has been withheld. Plaintiffs have not justified delaying consideration of defendants' omnibus motion for summary judgment.

III. Preemption

A. Biogen

Defendants argue that plaintiffs' state law claims are preempted by federal law, as I found in Gentile and as the federal courts found in Christison and Amos. Because this argument is based on federal law it applies to each of these six cases with equal force, regardless of which

state's law controls the underlying claims. In Gentile, I summarized the applicable law as follows:

> When state and federal law directly conflict, federal law triumphs under the Supremacy Clause of the United States Constitution. PLIVA, Inc. v. Mensing, 564 U.S. 604, 617-618 (2011). In the context of drug labels, state law is preempted where "it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." Id. at 618. The FDA must approve a manufacturer's proposed changes to a prescription drug's labeling "to reflect newly acquired information," including "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction." 21 C.F.R. §§ 314.70(c)(1), (c)(6)(iii). "If the agency disapproves the supplemental application, it may order the manufacturer to cease distribution of the drug product(s) made with the manufacturing change." 21 C.F.R. § 314.70(c)(7).

Gentile, 2016 WL 4168942 at * 10. Accord Christison, 199 F. Supp. 3d at 1347 ("if there is 'clear evidence that the FDA would not have approved a change' to the label, the manufacturer is under no obligation to make any change to the label."). In Gentile, I concluded that "FDA's decision to reject the proposed modifications regarding risks associated with providing Tysabri to patients with the JCV antibody demonstrates that prior to Mrs. Gentile's diagnosis, defendants could not have strengthened their warnings to comply with state law without violating the FDA's decision." 2016 WL 4168942 at * 10.

The two federal courts that have considered the Tysabri labeling and regulatory history have reached the same conclusion, albeit in cases presenting slightly different relevant timeframes. In Christison, the injured plaintiff's last Tysabri infusion was in June 2009. She was diagnosed with PML in July 2009 and died in August 2009. 199 F. Supp. 3d at 1330. In that case, based on "'clear evidence' that the FDA would not have approved a change to the Tysabri label regarding JCV antibodies before 2012," the court found the state law claims were preempted by federal law. Id. at 1347-1348 (emphasis added). In Amos, the plaintiff's last

Tysabri infusions were in June 2011. She was diagnosed with PML in mid-July 2011 and died in September 2011. 2017 WL 1316968 at * 3. In Amos, the court found "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." Id. at * 6. The court in Amos concluded that "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." Id. at * 7 (emphasis added).

Plaintiffs argue that preemption of failure to warn claims is typically disfavored and that the "clear evidence" exception is extremely narrow, citing Wyeth v. Levine, 555 U.S. 555, 571 (2009). They argue that the patients in Gentile and Christison were diagnosed with PML *before* FDA rejected the proposed label change in September 2010; and that five out of six of the patients in the cases now before me were diagnosed after that date in 2010. Plaintiffs further claim that the holding in Gentile was based in large part on FDA finding insufficient data to justify a label change in 2010, which constituted "clear evidence" that the agency would have rejected a change with less data before 2010. Because five patients here were diagnosed after September 2010, plaintiffs contend my ruling in Gentile does not fully answer the preemption question because defendants could have continued to develop more scientific evidence in the months following the rejection, resulting in the addition of a warning mentioning JCV antibodies at some point before FDA eventually approved the change in January 2012.

The factual record does not permit a different conclusion on the preemption issue given the undisputed events between September 2010 and the label change approved in January 2012. After FDA rejected proposed changes to the Tysabri label in September 2010, defendants continued to try to persuade FDA to alter the drug label by providing additional information

about the increased risk of patients developing PML if the patients received Tysabri after developing JCV antibodies. Cf. Aaron v. Wyeth, 2010 WL 653984 at * 6 (W.D. Pa. Feb. 19, 2010) ("Though the FDA disagreed with certain [labeling] changes . . . , [drug maker] did not press its position, it instead acquiesced to the requests made by the FDA."). It bears reciting the chronology after September 2010.

On September 8, 2010, FDA found that it was "too early in the analysis of this methodology [a proposed JCV antibody assay] to determine the value of this marker as a PML risk stratification tool," and that "the proposed data package is [in]sufficient to demonstrate clinical utility of the anti-JCV antibody assay." It concluded that proposed changes to the Tysabri label relating to an individual's JCV antibody status were not then scientifically justified.

Defendants met with FDA representatives on November 18, 2010 to present and discuss additional supporting data. FDA did not "agree that the clinical utility of the [JCV antibody] assay ha[d] been established" because "[t]he information provided [did] not allow [FDA] to determine the clinical utility for the intended use claims." Although FDA agreed that "the evaluation of the anti-JCV antibodies pre-, at, and post-PML diagnosis suggests the association of anti-JCV antibody detection with the development of PML, especially, since all PML patients tested positive for anti-JCV" antibodies, it found "the utility" of using a JCV antibody assay was "not established." FDA recommended further scientific study.

Based on the discussions at these two prior meetings, Biogen submitted a supplemental licensing application for Tysabri on December 21, 2010, relating specifically to the inclusion of language in the approved Tysabri label and in documents directed at patients describing the clinical utility of the JCV antibody assay for PML risk stratification. Biogen stated that "[r]esults of the anti-JCV antibody assay demonstrate that patients who are positive for anti-JCV

antibodies are at higher risk for development of PML than the overall Tysabri treated population, while patients who are negative for anti-JCV antibody are at significantly lower risk than those who are positive." Biogen asked that its application be given "priority review."

In mid-February 2011, FDA asked for additional data relating to the JCV antibody assay. Biogen responded on April 15, 2011 with the results of certain tests, and supplemented its response on April 29, 2011 with additional information.

FDA and defendants held a teleconference on May 5, 2011 to discuss FDA's requests for data, defendants' recent responses, and the pending supplemental licensing application related to Tysabri and the JCV antibody assay. A letter from Biogen on May 13, 2011 provided additional data underlying Biogen's assumptions and calculations in the supplemental application. In its letter, Biogen stated that "[s]amples from 5,896 MS patients, collected and archived from completed or ongoing clinical trials and an MS registry, were tested for anti-JCV antibody status to establish the antibody prevalence in the MS population (55%)"; and that, as of November 2, 2010, only 19 patients that had been treated with Tysabri and had later been diagnosed with PML had blood samples taken before their PML diagnosis, but that all 19 of these patients tested positive for JCV antibodies. Biogen concluded that "the anti-JCV antibody assay provides physicians and patients with a risk stratification tool, to be used in conjunction with other known risk factors including Tysabri treatment duration and prior IS use, when making benefit-risk decisions with respect to Tysabri therapy."

On May 27, 2011, Biogen provided FDA with evaluations pertaining to the JCV antibody assay for cross-reactivity, interference by endogenous agents and concomitant medications, and precision at the limits of detection.

FDA provided comments to Biogen on September 23, 2011. Biogen then revised its Tysabri label in accordance with FDA's comments and sent its revised proposed draft to FDA on October 5, 2011. Pertinent additions included statements that "[p]atients who are anti-JCV antibody positive have a higher risk for developing PML"; "[a]nti-JCV antibody testing should not be used to diagnose PML"; and "[w]hen assessed, anti-JCV antibody status should be determined using an analytically and clinically validated immunoassay." Biogen also provided estimates of the number of PML cases in patients who had the JCV antibody based on data updated as of September 1, 2011.

On November 4, 2011, FDA requested more information regarding the 159 known PML cases in Tysabri-treated patients. Biogen responded the same day with a spreadsheet containing a dataset with demographic variables for each such patient.

FDA and Biogen had a conference call on November 29, 2011 to discuss the proposed labeling. On or about December 9, 2011, Biogen memorialized this call in a letter and proposed a further labeling change based on feedback on its proposed label after consultation "with a number of practicing physicians in the community."

On December 13, 2011, Biogen wrote to FDA with additional labeling concerns after "additional research with a panel of MS experts."

Despite these communications, FDA did not conclude that there was enough supporting data to mention JCV antibodies on the Tysabri label until January 20, 2012. This chronology amounts to "clear evidence," as the courts in Christison and Amos found, that FDA would not

have approved a labeling change earlier. Any state law claims for failing to alter the label sooner are preempted.[6]

B. Elan

Plaintiffs argue their failure to warn claims against Elan are not preempted by federal law based on an interpretation of PLIVA, Inc. v. Mensing, 564 U.S. 604, 613 (2011), which held that "[a] brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label." Plaintiffs argue that some courts applying this case have declined to find that claims against distributors were preempted. See Freitas v. McKesson Corp., 889 F. Supp. 2d 931, 937-938 (E.D. Ky. 2012); In re Plavix Prod. Liab. & Mktg. Litig., 2014 WL 4954654 at * 8 (D.N.J. Oct. 1, 2014).

Federal law, however, only allows the holder of the original, approved application for a drug to modify, or seek approval to modify, its label. See 21 C.F.R. § 314.70(1)(i) ("the applicant must notify FDA about each change in each condition established in an approved [new drug application]"). Biogen is the holder of the Tysabri application. Therefore, Elan, as the distributor, did not have the ability to modify the warnings present on the label, or to add new warnings. See Gentile, 2016 WL 4168942 at * 11, citing In re Fosamax Prods. Liab. Litig., 2012 WL 181411 at * 3 (D.N.J. Jan. 17, 2012). The failure to warn claims against Elan are preempted by federal law.

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[6] There is no merit to plaintiffs' contentions that even without FDA's approval, defendants could have proactively added different types of warnings about JCV antibodies in a different location or could have warned of the risk with alternative language. As discussed above, there is clear evidence FDA would not have allowed such a change to the label without further supporting data, which did not exist until January 2012.

IV. State Law Claims

Plaintiffs assert various state law claims from their respective jurisdictions. Although my conclusion on the preemption issue is conclusive, I address the state law claims seriatim.

A. Angela Cleary

Ms. Cleary, whose action is governed by Massachusetts law,[7] presents claims for negligence (Count I), failure to warn (Count II), fraud (Count III), breach of the implied warranty of merchantability and fitness for particular use (Count IV), G.L. c. 93A (Count V), negligent undertaking (Count VI), and loss of consortium (Count VII).

1. Failure to Warn

To the extent her claims are premised on an allegation that defendants failed adequately to warn of the dangers associated with Tysabri use, her arguments are unavailing. Massachusetts subscribes to the "learned intermediary rule" with respect to failure to warn claims. MacDonald v. Ortho Pharmaceutical Corp., 394 Mass. 131, 136 (1985). This means that "a drug manufacturer's duty to warn is generally discharged by providing physicians with an adequate warning about any risks associated with its prescription drug products." Niedner v. Ortho-McNeil Pharm., Inc., 90 Mass. App. Ct. 306, 309 (2016). A warning is considered adequate if it "not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk." MacDonald, 394 Mass. at 141. This includes providing "written warnings conveying reasonable notice of the nature, gravity, and likelihood of known or knowable side effects." Id. at 148. Although "judicial intrusion into jury

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[7] In 2014, the Court (Lauriat, J.) ruled that Massachusetts law applies to the Cleary claim. I previously refused to revisit that ruling, see Memorandum and Order on Defendants' Motion to Dismiss and Strike Allegations in Plaintiffs' Complaints at 15-16 (Nov. 17, 2015) (Docket #28 in Cleary v. Biogen Idec Inc., Civil No. 13-4461), and see no reason to do so now.

decision making in negligence cases is exceedingly rare," a "court may, as a matter of law, determine 'whether the defendant has conformed to that standard, in any case in which the jury may not reasonably come to a different conclusion.'" Id. at 140, quoting Restatement (Second) of Torts § 328B(d) and comment g (1965).

Defendants' duty was to warn Ms. Cleary's treating physician of the risks of contracting PML after treatment with Tysabri. It is undisputed that a black box warning was present on the Tysabri packaging prior to Ms. Cleary's first Tysabri infusion in January 2009. The black box warning informed Ms. Cleary's treating physician that a small number of MS patients treated with Tysabri had been diagnosed with PML, but that other factors associated with this relationship were yet unknown. It also explained that PML is "an opportunistic viral infection of the brain that usually leads to death or severe disability." It therefore conveyed "a fair indication of the nature of the dangers involved," i.e., the risk of developing PML. Because the black box warning is considered "the strongest warning required or permitted by FDA," Christison, 199 F. Supp. 3d at 1343-1344, it warned the reader with "the degree of intensity demanded by the nature of the risk." See MacDonald, 394 Mass. at 141. This is precisely what is required by law. Gentile, 2016 WL 4168942 at * 6 ("The black box warning . . . explicitly warned against the precise risk (developing PML) that Mrs. Gentile ultimately suffered, and fully disclosed the serious consequences of that disease."); Christison, 199 F. Supp. 3d at 1343-1345; Amos, 2017 WL 1316968 at * 6 ("warnings were adequate as a matter of law").[8] A reasonable jury could not come to a contrary conclusion.

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[8] There is no merit to Cleary's contention that the label was inadequate because it did not include an "exact quantification of risk." Indeed, there was insufficient extant data to establish such an exact number.

2. Negligent Undertaking

Ms. Cleary's negligent undertaking claim also falls short. The theory underlying this count is that through institution of the TOUCH program, which was intended "to assess the risk of [PML] associated with [Tysabri], minimize the risk of PML, minimize death and disability due to PML, and promote informed risk-benefit decisions regarding TYSABRI use," see Gentile, 2016 WL 4168942 at ** 1-2, defendants voluntarily assumed a duty directly to warn patients, including Ms. Cleary, of the dangers of Tysabri. See Cottam v. CVS Pharmacy, 436 Mass. 316, 323-324 (2002). "If a person voluntarily assumes a duty or undertakes to render services to another that should have been seen as necessary for her protection, that person may be liable for harm caused because of the negligent performance of his undertaking." Thorson v. Mandell, 402 Mass. 744, 748 (1988).

As discussed above, because the learned intermediary rule applies here, the only conclusion I need reach is that defendants adequately informed Ms. Cleary's treating physician of the risks of contracting PML. As I held in Gentile, Ms. Cleary "cannot prove that defendants voluntarily assumed a duty to warn [her] by providing her with information directly, and not through her doctor." See Gentile, 2016 WL 4168942 at * 9. Additionally, as the warning was adequate as a matter of law, even if defendants had assumed such a duty, Ms. Cleary could not prove that this duty had been breached. Defendants are accordingly entitled to judgment as a matter of law on the negligent undertaking claim.

3. Remaining State Law Claims

There is little to distinguish Ms. Cleary's remaining claims for negligence, fraud, breach of an implied warranty, and violation of G.L. c 93A, from the claims discussed above. Because the warning was adequate as a matter of law, Ms. Cleary cannot demonstrate that the Tysabri

warning was defective for her negligence or implied warranty claims. Nor is there any fraudulent statement or misrepresentation of fact upon which to rest her fraud claim. Finally, because Ms. Cleary has failed "to demonstrate that the [warning] was inaccurate, false, or deceptive," her claim under G.L. c. 93A also fails. See Niedner, 90 Mass. App. Ct. at 313. Therefore, summary judgment must be granted in favor of defendants on Count I and III-V.

B. Jerilyn Erichson

Ms. Erichson's complaint, which is governed by Utah law, contains the following counts: negligence (Count I), failure to warn (Count II), negligent misrepresentation (Count III), fraud (Count IV), breach of the implied warranty of merchantability and fitness for particular use (Count V), negligent undertaking (Count VI), and loss of consortium (Count VII).

1. Failure to Warn

The learned intermediary doctrine applies in Utah. Schaerrer v. Stewart's Plaza Pharm., Inc., 79 P.3d 922, 928 (Utah 2003) ("[M]anufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient."). Therefore, defendants had a duty to provide an adequate warnings to Ms. Erichson's prescribing physician of the risks of prescribing Tysabri. Christison, 199 F. Supp. 3d at 1320 ("[U]nder Utah law, a drug manufacturer's duty is to give timely, adequate, complete, and appropriate warnings to the prescribing physician such that the physician can understand possible side effects and prepare a suitable prescription program for a patient.").

The facts underlying Erichson's claim are not sufficiently dissimilar from those at issue in Christison to allow the court here to arrive at a different conclusion. The court in Christison determined that, regardless of which test applied under Utah law, the Tysabri labeling was adequate as a matter of law. 199 F. Supp. 3d at 1342-1344. Under the Model Utah Jury

Instructions, defendants "provided an adequate warning because the FDA controlled what warnings could be given with respect to Tysabri." Id. at 1343. See, supra, at 8-9. Alternatively, under the articulation supplied in House v. Armour of America, Inc., 886 P.2d 542, 551 (Utah App. 1994), aff'd, 929 P.2d 430 (Utah 1996), the Tysabri labeling prior to 2012 was adequate because it "(1) was designed so it could reasonably be expected to catch the attention of the consumer; (2) was comprehensible and gave a fair indication of the specific risks involved with Tysabri; and (3) was of an intensity justified by the magnitude of the risk." Christison, 199 F. Supp. 3d at 1343.

Contrary to her protestation that disputed material facts exist to prevent entry of summary judgment on the failure to warn claim, Ms. Erichson presents no facts or inferences from facts that would allow a reasonable jury to conclude that the black box warning was anything other than accurate, clear and unambiguous. Defendants are entitled to judgment as a matter of law on the failure to warn claim.

2. Negligent Undertaking

Ms. Erichson's negligent undertaking claim alleges that "[i]f Biogen had made reasonable efforts toward developing and commercializing the [JCV] antibody assay after voluntarily undertaking the duty to do so, [she] would have had the assay available to her before her PML diagnosis" and would have discontinued Tysabri. See Plaintiffs' Opp. At 36.

According to Utah law,

> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other's person or things, is subject to liability to the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking, if (a) his failure to exercise such care increases the risk of such harm, or (b) the harm is suffered because of the other's reliance upon the undertaking.

Instructions, defendants "provided an adequate warning because the FDA controlled what warnings could be given with respect to Tysabri." Id. at 1343. See, supra, at 8-9. Alternatively, under the articulation supplied in House v. Armour of America, Inc., 886 P.2d 542, 551 (Utah App. 1994), aff'd, 929 P.2d 430 (Utah 1996), the Tysabri labeling prior to 2012 was adequate because it "(1) was designed so it could reasonably be expected to catch the attention of the consumer; (2) was comprehensible and gave a fair indication of the specific risks involved with Tysabri; and (3) was of an intensity justified by the magnitude of the risk." Christison, 199 F. Supp. 3d at 1343.

Contrary to her protestation that disputed material facts exist to prevent entry of summary judgment on the failure to warn claim, Ms. Erichson presents no facts or inferences from facts that would allow a reasonable jury to conclude that the black box warning was anything other than accurate, clear and unambiguous. Defendants are entitled to judgment as a matter of law on the failure to warn claim.

2. Negligent Undertaking

Ms. Erichson's negligent undertaking claim alleges that "[i]f Biogen had made reasonable efforts toward developing and commercializing the [JCV] antibody assay after voluntarily undertaking the duty to do so, [she] would have had the assay available to her before her PML diagnosis" and would have discontinued Tysabri. See Plaintiffs' Opp. At 36.

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MacGregor v. Walker, 322 P.3d 706, 709 (Utah 2014), quoting Restatement (Second) of Torts § 323. Even assuming that Erichson could establish that defendants had voluntarily undertaken such a duty,[9] she will be unable to prove that the failure to exercise reasonable care in performing that duty increased the risk of harm or that she relied on this undertaking and subsequently suffered harm. See Id. at 710 ("A mere failure 'to facilitate the prevention of harm that occurred through other causes' is insufficient.").

Ms. Erichson also argues that her prescribing physician has not yet been deposed. However, having the benefit of his testimony would still be insufficient to entitle this case to advance past the summary judgment stage where I have already determined the warning was adequate as a matter of law.

3. Remaining State Law Claims

Ms. Erichson's remaining state law claims for negligence, negligent misrepresentation, fraud, and breach of the implied warranty of merchantability and fitness for particular use are also unavailing. First, the negligence and negligent misrepresentation claims must fail because the black box warning was adequate. Accord Christison, 199 F. Supp. 3d at 1346 & n.194. Her breach of implied warranty claim must be dismissed for the same reason. Finally, as Ms. Erichson has not presented a fraudulent statement or misrepresentation of fact by defendants, the fraud count must be dismissed.

C. Marla Fair

The substantive law of Indiana governs Ms. Friedmeyer's complaint brought on behalf of Ms. Fair's bankruptcy estate. It asserts claims for negligence (Count I), failure to warn under the

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[9] In Gentile, I denied a request to amend to include a similar claim where plaintiff cited "no case to suggest the viability of such a novel cause of action." See Gentile, 2016 WL 4168942 at * 11. Ms. Erichson presents nothing more.

Indiana Product Liability Act ("IPLA") § 34-20-4-2 (Count II), violation of IPLA § 34-20-4-1 (Count III), fraud (Count IV), breach of the implied warranty of merchantability and fitness for particular use (Count V), negligent undertaking (Count VI), and loss of consortium (Count VII).

1. Failure to Warn

The learned intermediary doctrine applies to failure to warn claims in Indiana. See Ortho Pharmaceutical Corp. v. Chapman, 388 N.E.2d 541, 548 (Ind. App. 1979) ("Since [certain] drugs are available only by prescription, a manufacturers duty to warn extends only to the medical profession, and not the ultimate users."). Under Indiana law, defendants therefore had a duty to warn Ms. Fair's prescribing physician adequately of the risk of a patient developing PML following treatment with Tysabri. "To be adequate, a warning must be reasonable under the circumstances." Id. at 60. See also Tucker v. SmithKline Beecham Corp., 701 F. Supp. 2d 1040, 1066 (S.D. Ind. 2010) ("Where the manufacturer warns of the precise adverse effect of which the plaintiff complains, the warning may be deemed adequate as a matter of law."). Given the risk of death or severe disability that could result from being diagnosed with PML, the Tysabri warnings had to convey in a particularly forceful and effective manner the seriousness of the possible side effects in order to be found reasonable.

As discussed above in further detail, the black box warnings were the strongest warnings authorized by FDA. The warnings were sufficient to inform Ms. Fair's prescribing physician of "the precise adverse effect of which the plaintiff complains," id., namely PML. Contrary to Ms. Fair's assertion that the warning was inadequate because it made no mention of JCV antibodies, reasonable minds could not disagree about the label's adequacy according to Indiana law.

2. Negligent Undertaking

As with Ms. Erichson, Ms. Friedmeyer alleges that defendants voluntarily assumed a duty to develop a JCV antibody assay for use in conjunction with Tysabri, and that they breached this duty by failing to develop the assay quickly enough. "Indiana recognizes that a duty of care may arise where one would not otherwise exist if a party gratuitously or voluntarily assumes such a duty by affirmative, deliberate conduct." Gochenour v. CSX Transp., Inc., 44 N.E.3d 794, 807 (Ind. App. 2015). However, under Indiana law, "[w]hether the law recognizes any obligation on the part of a particular defendant to conform his conduct to a certain standard for the benefit of the plaintiff is a question of law exclusively for the court." Hooks SuperX v. McLaughlin, 642 N.E.2d 514, 517 (Ind. 1994).

Also like Ms. Erichson, Ms. Friedmeyer has failed to present any case from Indiana or elsewhere that suggests any viability for a negligent undertaking theory in the context of a business developing a product of questionable viability that would have to be approved by FDA. Courts have not traditionally imposed such a duty on drug manufacturers, and I decline to find such a duty (or a cause of action for breach of such a duty) here. There being no other disputed material facts in the record, Ms. Friedmeyer's negligent undertaking claim necessarily fails.

3. Remaining State Law Claims

Ms. Friedmeyer's remaining state law claims include counts for negligence, violation of IPLA § 34-20-4-1, fraud, and breach of implied warranties. IPLA "governs actions by users or consumers against manufacturers or sellers for physical harm caused by products." Stegemoller v. ACandS, Inc., 767 N.E.2d 974, 975 (Ind. 2002). It "subsumes, governs, and controls any claim brought by a consumer or user against a manufacturer or seller for injuries caused by the product." Gasser Chair Co. v. Nordengreen, 69 N.E.3d 954, 2016 WL 7426735 at * 4 (Ind. App.

Dec. 22, 2016) (emphasis in original). See also Ridgley v. Ethicon, Inc., 2017 WL 525854 at * 2 (S.D. W. Va. Feb. 8, 2017) ("IPLA requires all of the plaintiffs' causes of action [including claims for negligence, failure to warn, fraud, and breach of implied warranty] to be consolidated into one claim for [plaintiff's] alleged personal injuries, 'regardless of the substantive legal theory or theories upon which the action is brought,'" quoting Ind. Code § 34-20-1-1). Accordingly, Ms. Friedmeyer's claims are merged into IPLA. Based on my ruling regarding the adequacy of the Tysabri warning label, this claim necessarily fails.

D. Pamela Glisson

Ms. Glisson's claims are controlled by Nebraska law. Her complaint states claims for negligence (Count I), failure to warn (Count II), negligent undertaking (Count III), fraud (Count IV), breach of the implied warranty of merchantability and fitness for particular use (Count V), and negligent misrepresentation (Count VI).

1. Failure to Warn

Nebraska has adopted the learned intermediary doctrine. Freeman v. Hoffman-LaRoche, Inc., 618 N.W.2d 827, 841-842 (Neb. 2000). Defendants therefore had a duty to give "reasonable instructions or warnings regarding foreseeable risks of harm" from prescribing Tysabri, and to provide them to Ms. Glisson's prescribing physician, who was "in a position to reduce the risks of harm in accordance with the instructions or warnings." Freeman, 618 N.W.2d at 842, quoting Restatement (Third) of Torts: Products Liability § 6(d) at 145 (1997). As the parties acknowledge, "[t]he Nebraska Supreme Court has not addressed the adequacy of specific warnings in the context of pharmaceutical products." Vallejo v. Amgen, Inc., 2014 WL 4922901 at * 3 (D. Neb. Sept. 29, 2014). Looking to other jurisdictions, however, the court in Vallejo reasonably applied the general test that "[t]o find a warning adequate as a matter of law, the label

must accurately and unambiguously convey the scope and nature of the risk, with sufficient specificity given the particular . . . risk at issue." Id., quoting Rowland v. Novartis Pharms. Corp., 34 F. Supp. 3d 556, 572 (W.D. Pa. 2014) (internal quotations omitted).

This standard does not materially differ from the standards applied to the Tysabri cases decided to date. See Gentile, 2016 WL 4168942 at * 6; Christison, 199 F. Supp. 3d at 1342-1344; Amos, 2017 WL 1316968 at ** 5-6. As discussed above, the Tysabri warning label "accurately and unambiguously convey[ed] the scope and nature of the risk," including language specifically referring to the risk of developing PML. See Vallejo, 2014 WL 4922901 at * 3. Ms. Glisson's physician was therefore reasonably informed of the risks of prescribing Tysabri to Ms. Glisson and the warning was adequate as a matter of law.

2. Negligent Undertaking

Ms. Glisson concedes that Nebraska law does not support a negligent undertaking theory outside the area of contracts and therefore agrees to dismissal of her negligent undertaking claim. See Plaintiffs' Opp. at 45.

3. Remaining State Law Claims

Ms. Glisson's remaining state claims are for negligence, fraud, breach of implied warranty, and negligent misrepresentation. Ms. Glisson attempts to distinguish these counts from the failure to warn claim by referring to the various analyses that apply to each cause of action. However, as the Tysabri warning is adequate as a matter of law, Ms. Glisson lacks a factual predicate for these additional claims. For instance, defendants did not breach a duty for the purposes of a negligence claim; there is no fraudulent or misleading statement in the record; there was no breach of an implied warranty; and there has not been a negligent misrepresentation of fact. Therefore, defendants are entitled to judgment on these remaining claims.

E. Susan Speigel

Illinois law applies to Ms. Speigel's complaint, which asserts the following claims: negligence (Count I), failure to warn (Count II), negligent misrepresentation (Count III), fraud (Count IV), breach of the implied warranty of merchantability and fitness for particular use (Count V), violation of 815 ILCS 510/2 Uniform Deceptive Trade Practices Act (Count VI), and negligent undertaking (Count VII).

1. Failure to Warn

Illinois applies the learned intermediary doctrine to failure to warn claims. As the Illinois Supreme Court stated:

> [M]anufacturers of prescription drugs have a duty to warn prescribing physicians of the drugs' known dangerous propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients. . . . The doctor, functioning as a learned intermediary between the prescription drug manufacturer and the patient, decides which available drug best fits the patient's needs and chooses which facts from the various warnings should be conveyed to the patient, and the extent of disclosure is a matter of medical judgment.

Kirk v. Michael Reese Hosp. & Med. Ctr., 513 N.E.2d 387, 392-393 (Ill. 1987). "[W]here the warning is being communicated to a physician who acts as a learned intermediary," Illinois law assesses the adequacy of a warning based on "whether it sufficiently appraises the prescribing physician of the risk associated with the use of the drug." Northern Trust Co. v. Upjohn Co., 572 N.E.2d 1030, 1036 (Ill. App. 1991). Although the sufficiency of the warning is typically a question of fact, it "can become a question of law where the warning is clear, accurate and unambiguous." Hernandez v. Schering Corp., 958 N.E.2d 447, 455 (Ill. App. 2011). Therefore, under Illinois law, like the law in other jurisdictions described above, the question on summary

judgment is whether the warning in question was clear, accurate and unambiguous and therefore adequate to warn Ms. Speigel's doctor of the potential dangers of treating with Tysabri.

I have found the Tysabri warning label was clear, accurate and unambiguous because it warned of the risk of contracting PML, the precise adverse effect that Ms. Speigel eventually experienced. The label sufficiently conveyed, in necessarily intense language, the seriousness of this risk, and what was known about PML's association with Tysabri.

Ms. Speigel's contention that the case law requires the presentation of expert testimony to determine the adequacy of the warnings is unconvincing here. See Northern Trust, 572 N.E.2d at 1036 ("[E]xpert testimony shall be necessary and proper in a case . . . where a drug manufacturer's liability for a prescription drug is based upon its failure to provide adequate warnings"). The court in Northern Trust noted that its decision was "limited to those instances where the inadequacy of the warning is not so obvious that a lay person could not readily understand the insufficiency of the warning." Id. The black box warning on the Tysabri label stated, in no uncertain terms, that users risked developing PML, and that this side effect was potentially fatal. This warning was sufficiently obvious, clear and unambiguous that no expert testimony is necessary. Ms. Speigel's treating physician was adequately warned of the potential risk of prescribing Tysabri to Ms. Speigel.

2. Negligent Undertaking

Ms. Speigel's negligent undertaking claim alleges that defendants assumed a duty to inform her directly of the risks associated with Tysabri through the TOUCH program. See Frye v. Medicare-Glaser Corp., 605 N.E.2d 557, 560 (Ill. 1992) ("Pursuant to the voluntary undertaking theory of liability, one who gratuitously or for consideration renders services to another is subject to liability for bodily harm caused to the other by one's failure to exercise due

care or 'such competence and skill as [one] possesses.'"). Ms. Speigel argues that because "the duty of care to be imposed upon a defendant is limited to the extent of its undertaking," see id., the court need only find that defendants bypassed her physician and opted to warn her directly, and that they did so negligently. As in Ms. Cleary's case, see, supra, at 16, this argument is unavailing for the reasons stated in Gentile, 2016 WL 4168942 at * 5. Defendants are entitled to summary judgment on this claim.

3. Remaining State Law Claims

Ms. Speigel's complaint asserts additional claims for negligence, negligent misrepresentation, fraud, breach of an implied warranty, and a violation of 815 ILCS 510/2 Uniform Deceptive Trade Practices Act. These claims all necessarily fail where the Tysabri warning has been found adequate as a matter of law. There is no indication in the record that defendants acted negligently or otherwise made a material misrepresentation to Ms. Speigel. Judgment will enter on these remaining claims in defendants' favor.

F. Kimberly Yout

Ms. Yout's claims for negligence (Count I), failure to warn (count II), negligent undertaking (Count III), breach of implied warranty of merchantability and fitness for particular use (Count V), and violation G.L. c. 93A (Count VI), are controlled by Massachusetts law.

1. Failure to Warn

The analysis I applied to Ms. Cleary's claim applies with equal force here, as the two are governed by Massachusetts law. See, supra, at 14-15. For the same reasons, defendants are entitled to summary judgment on Ms. Yout's failure to warn claim.

2. Negligent Undertaking

Ms. Yout's negligent undertaking claim, like those asserted by Ms. Cleary and Ms. Speigel, is based on the theory that defendants voluntarily assumed a duty to warn her directly by requiring her to acknowledge certain documents associated with the TOUCH program. For the reasons set out in Gentile, 2016 WL 4168942 at * 5, defendants are entitled to summary judgment on Ms. Yout's negligent undertaking claim.

3. Remaining State Law Claims

Ms. Yout's remaining state law claims, including claims for negligence, breach of implied warranty, and violations G.L. c. 93A, also cannot survive. See, supra, at 16-17.

ORDER

Defendants' Omnibus Joint Motion for Summary Judgment is **ALLOWED**. Judgment for defendants in each of these six cases shall enter accordingly.

Dated: September 8, 2017

Peter B. Krupp
Justice of the Superior Court