Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ANDREW NELSON, *Plaintiff,* v. BIOGEN IDEC INC. AND ELAN PHARMACEUTICALS, INC., *Defendants.*	Civil Action No. 12-7317 **OPINION**

John Michael Vazquez, U.S.D.J.

The present matter comes before the Court on Defendants' Biogen Idec Inc. ("Biogen") and Elan Pharmaceuticals, Inc.'s ("Elan") (collectively, "Defendants") joint objection to the Magistrate Judge's order granting Plaintiff leave to file a Fourth Amended Complaint ("FAC") or, in the alternative, Defendants' joint motion to dismiss the negligent undertaking claim in the FAC for failure to state a claim under Rule 12(b)(6).[1] Plaintiff opposes the motions. The negligent undertaking claim alleges that Biogen acted negligently in failing to bring to market sooner a medical test that could have screened Plaintiff for the presence of an antibody. The motions were decided without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil

[1] Defendants' motion will be referred to hereinafter as "Def. Br." (D.E. 144), Plaintiff's opposition to Defendants' motion will be referred to hereinafter as "Pl. Opp'n" (D.E. 148), and Defendants' reply brief in support of its motion will be referred to hereinafter as "Def. R.Br." (D.E. 149).

Rule 78.1. The Court has considered the parties' submissions and grants Defendants' motion to dismiss. Defendants' appeal of Judge Falk's Order is therefore moot.

I. BACKGROUND & PROCEDURAL HISTORY

The following facts are derived from the FAC. D.E. 142.[2] In May 2004, Biogen and Elan submitted a Biologics License Application ("BLA") to the United States Food and Drug Administration ("FDA") for approval of Tysabri for treatment of Multiple Sclerosis ("MS"). *Id.* ¶ 14. Tysabri is the trade name for the immunosuppressant natalizumab. *Id.* ¶ 1. In November 2004, the FDA approved the drug for treatment of remitting and relapsing MS. *Id.* ¶ 15. On or about November 24, 2004, Defendants began to market and distribute Tysabri in the United States. *Id.*

In February 2005, three months after gaining FDA approval, Defendants withdrew Tysabri from the market and put all clinical trials on hold because two patients receiving Tysabri developed Progressive Multifocal Leukoencephalopathy ("PML"). *Id.* ¶ 26. PML is an aggressive brain infection caused by the immunosuppressive effects of Tysabri. *Id.* ¶ 18. Specifically, PML is caused by the JC virus. *Id.* PML is a typically fatal brain disease that usually results in death within one to four months of the onset of the disease. *Id.*

In 2006, after no additional cases of PML were reported, the FDA permitted Tysabri to return to the market, with additional restrictions. *Id.* ¶ 26. Nonetheless, MS patients receiving Tysabri continued to develop PML. *See id.* ¶¶ 32–34. By July 2008, Tysabri had caused PML in fourteen patients, and by July 2009, the number grew to more than twenty. *Id.* ¶¶ 32–33, 36.

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[2] When reviewing a motion to dismiss, the Court accepts as true all well-pleaded facts in the complaint. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009).

In 2010, Defendants revised the U.S. label for Tysabri to reflect an increased risk of developing PML with longer treatment duration. *Id.* ¶ 42. Then, in 2011, the FDA issued a drug safety communication stating that "patients who took an immune system suppressing medication prior to taking Tysabri[] have been shown to be at an increased risk for developing PML." *Id.* ¶ 48. In January of 2012, the FDA issued another drug safety communication, which stated that "testing positive for anti-JC Virus antibodies has been identified as a risk factor for PML." *Id.* ¶ 51. Plaintiff contends that because of this, "Defendants undoubtedly knew [that] patients whose blood tested positive for JC virus antibodies would be at a higher risk of developing PML." *Id.* ¶ 90.

Plaintiff was diagnosed with MS in October 2002 and commenced Tysabri infusions in January of 2007. *Id.* ¶¶ 54–55. Plaintiff received monthly Tysabri infusions for the next three years without any warning of increased risk of developing PML. *Id.* ¶ 56. Throughout the time Plaintiff was receiving treatment, the drug's labeling contained no warnings regarding risk factors associated with taking Tysabri. *Id.* ¶¶ 61–64. In November 2010, Plaintiff was admitted to the hospital with worsening symptoms and a brain biopsy confirmed a PML diagnosis. *Id.* ¶ 65. Nelson was severely debilitated as a result of the PML and has since undergone steroid treatment and extensive physical therapy. *Id.* ¶ 66.

Plaintiff filed his initial Complaint on November 28, 2012, which he amended shortly thereafter. D.E. 1, 4. The initial and First Amended Complaint included a negligence claim that was dismissed pursuant to Rule 12(b)(6) for failure to state a claim. D.E. 34 at 3. In dismissing Plaintiff's negligence claim, Judge Linares held that the New Jersey Products Liability Act ("NJPLA") is the sole remedy for products liability claims, and under the NJPLA there are only three available causes of action: manufacturing defect, failure to warn, and design defect. *Id.*

On May 22, 2013, Plaintiff filed a Second Amended Complaint, including two counts under the PLA: (1) design defect; and (2) failure to warn. D.E. 37. Defendants moved to dismiss the design defect claim, alleging that federal law preempted it because Defendants are prohibited from marketing Tysabri with any design other than that approved by the FDA. D.E. 51. Plaintiff subsequently withdrew his design defect claim before the motion to dismiss was decided. Def. Br. at 6. Plaintiff's Third Amended Complaint, filed on September 20, 2013, asserted a single cause of action pursuant to the PLA – failure to warn. D.E. 52. The parties then engaged in over two years of discovery. *Id.*

On September 28, 2015, Plaintiff alleges that Defendants produced, for the first time, a Biological Materials License Agreement (the "Agreement") dated October 19, 2006 between the National Institute of Health ("NIH") and Biogen. D.E. 148-1. The Agreement licensed Biogen to use NIH's JC virus antibody assay "for the purpose of developing this assay for commercial use." FAC ¶ 92. Since "testing positive for anti-JC [v]irus antibodies has been identified as a risk factor for PML," the assay (if developed) would test for these antibodies to determine whether a patient faced a greater risk of contracting PML. *Id.* ¶¶ 51, 90. Biogen did not release a JC virus antibody assay until January 2012, more than five years after it executed the Agreement. *Id.* ¶ 92. Plaintiff alleges that the Agreement demonstrates Defendants' negligence in bringing the assay to market in a timely manner and forms the basis of his negligent undertaking claim. Plaintiff further alleges that in developing its own assay, the Stratify Assay, Biogen also sought a financial benefit in addition to incurring the further delay. *Id.* ¶ 94.

Thereafter, Plaintiff sought leave to amend his Third Amended Complaint, adding a claim for negligent undertaking. D.E. 121. Defendants opposed Plaintiff's motion. D.E. 124. On June 7, 2016, Judge Falk granted that motion, finding that although Plaintiff's negligent undertaking

claim is "enterprising" and "adventurous," but not "frivolous on its face." D.E. 140. Judge Falk further found that the claim was not clearly futile and, while acknowledging the similarities between a motion to amend and a motion dismiss, also determined that a motion to amend does not contemplate the substantive motion practice associated with a motion to dismiss. *Id.* Subsequently, Plaintiff filed the FAC. D.E. 142. Currently pending before the Court is Defendants' appeal from Judge Falk's decision, and, in the alternative, their motion to dismiss the negligent undertaking claim. Plaintiff opposes this motion.

II. STANDARD OF REVIEW[3]

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a defendant to move to dismiss a count for "failure to state a claim upon which relief can be granted[.]" To withstand a motion to dismiss under Rule 12(b)(6), a plaintiff must allege "enough facts to state a claim to relief that is *plausible on its face*." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (emphasis added). A complaint is plausible on its face when there is enough factual content "that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Although the plausibility standard "does not impose a probability requirement, it does require a pleading to show more than a sheer possibility that a defendant has acted unlawfully." *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 786 (3d Cir. 2016)

[3] Because the Court is not ruling on the substance of Defendant's appeal, it will not address the standard of review of a magistrate judge's decision granting a motion to amend. The Court does note that Judge Falk undertook a careful review of the record in rendering his decision. For example, the Court agrees with Judge Falk that the MLA was disclosed *after* the scheduling order's time to amend had expired, that Plaintiff's expert did *not* know the details of the MLA when he referenced it briefly in his report, that Plaintiff's expert provided cogent ethical and professional reasons for not discussing his limited knowledge of the agreement with Plaintiff's counsel (specifically, concerns about Defendants' prior attempts to disqualify him as an expert), and that Plaintiff's counsel acted in a prudent manner when they determined that they first needed to review the actual MLA before making the motion to amend (regardless of the amount of detail from the MLA that was included in the FCA).

(internal quotation marks and citations omitted). As a result, a plaintiff must "allege sufficient facts to raise a reasonable expectation that discovery will uncover proof of [his] claims." *Id.* at 789.

In evaluating the sufficiency of a complaint, a district court must accept all factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff. *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). A court, however, is "not compelled to accept unwarranted inferences, unsupported conclusions or legal conclusions disguised as factual allegations." *Baraka v. Syneevey*, 481 F.3d 187, 211 (3d Cir. 2007). If, after viewing the allegations in the complaint most favorable to the plaintiff, it appears that no relief could be granted under any set of facts consistent with the allegations, a court may dismiss the complaint for failure to state a claim. *DeFazio v. Leading Edge Recovery Sols.*, No. 10-2945, 2010 WL 5146765, at *1 (D.N.J. Dec. 13, 2010).

III. DISCUSSION

In Plaintiff's negligent undertaking claim, he alleges that "Defendants voluntarily assumed the duty to develop and commercialize a JC virus antibody assay for use with Tysabri." FAC ¶ 91. Plaintiff alleges that Biogen acquired the assay from NIH through the MLA, a 2006 licensing agreement, in which it promised to "develop[] this assay for commercial use." *Id.* ¶ 92. By not releasing a JC virus antibody assay until 2012, Plaintiff alleges that "Defendants failed to act reasonably in developing the NIH assay for commercial use" and "fail[ed] to dedicate adequate time and resources to the Assay's development [] caus[ing] unreasonably delay in its commercialization." *Id.* ¶ 93. If Defendants had acted reasonably, alleges Plaintiff, then he would have had the assay available to him, he would have been tested, he would have tested positive, he would have discontinued Tysabri, and he would not have developed PML. *Id.* ¶¶ 95-96.

Defendants submit two main arguments in support of their motion to dismiss. First, Defendants argue that the NJPLA preempts claims for negligence and therefore Plaintiff's negligent undertaking claim is preempted as a matter of law. Def. Br. at 15-16, 20. Second, Defendants argue that Plaintiff fails to plausibly plead negligent undertaking. *Id.* at 20-24.[4]

Plaintiff responds that "[the NJPLA] does not preclude Plaintiff's negligent undertaking claim." Pl. Opp'n at 10. Plaintiff argues that the NJPLA is "wholly premised on preexisting legal duties," and since negligent undertaking is not based on a preexisting duty, it is not subsumed by the NJPLA. *Id.* Additionally, Plaintiff argues that he has sufficiently pled his negligent undertaking claim. *Id.* at 16-19.

First, as to the preemption argument, the NJPLA subsumes any cause of action "for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. § 2A:58C–1(b)(3). The NJPLA, as a result, "establishe[s] the sole method to prosecute a product liability action[.]" *Tirrell v. Navistar Int'l, Inc.*, 248 N.J. Super. 390, 398–99 (App. Div. 1991). "The language chosen by the Legislature in enacting the [NJ]PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint Litig.*, 191 N.J. 405, 436–37 (2007). Thus, New Jersey law "no longer recognizes . . . negligence . . . as [a] viable separate claim[] for harm deriving from a defective product." *Id.*; *see also Koruba v. Am. Honda Motor Co., Inc.*, 396 N.J. Super. 517, 531 (App. Div. 2007) ("[The PLA no longer

[4] Additionally, Defendants argue that the claim for negligent undertaking is "incompatible with prior rulings of this Court." Def. Br. at 20. Specifically, Defendants contends that Judge Linares's Order dismissing Plaintiff's prior negligence claim precludes Plaintiff from pursuing a claim for negligent undertaking. *Id.* at 14. The Court disagrees. Judge Linares' ruling was based on a different cause of action (negligence as opposed to negligent undertaking), and therefore does not automatically preclude Plaintiff from bringing a claim for negligent undertaking. That being said, the Court does find Judge Linares' analysis to be relevant to the current issue.

recognizes negligence . . . as a viable separate claim for harm [] caused by a defective product or an inadequate warning.") (internal quotation marks omitted).

The NJPLA is therefore broadly construed to include virtually all common-law claims that are based on a defective product. *See Kury v. Abbott Labs., Inc.*, No. 11-803, 2012 WL 124026, at *4 (D.N.J. Jan. 17, 2012) (finding that the NJPLA "encompasses virtually all possible causes of action relating to harms caused by consumer and other products"). Here, Plaintiff alleges that Defendants' failure to bring the assay to market was negligent. This argument is premised on the same defective product – Tysabri – as Plaintiff's failure to warn claim. Thus, Plaintiff's negligent undertaking claim is subsumed (and therefore precluded) by the NJPLA.

Plaintiff attempts to distinguish his negligent undertaking claim by arguing that, unlike many if not all negligence actions, it is not based on a preexisting duty. The Court finds two issues with this argument. First, Plaintiff provides absolutely no New Jersey authority to support his position. In fact, Plaintiff fails to cite any analogous decision from another jurisdiction. Second, the Court agrees with Defendants that the application of the NJPLA is not premised on the timing of the duties incurred. *See* Def. R.Br. at 3. As a practical matter, most duties are at some point voluntarily assumed. For example, before Defendants decided to develop, market, and sell Tysabri, they had no duty to do so. Once Defendants voluntarily decided to produce Tysabri, they then had a duty to act with reasonable care in doing so. Similarly, before a person decides to drive a car, she owes no duty to other motorists or pedestrians. However, once she voluntarily decides to operate a motor vehicle, she then has a duty to use reasonable care while driving. More importantly, Plaintiff does not point to any case or section of the NJPLA to support his novel argument. And the Court has found none. Plaintiff's negligent undertaking claim is dismissed because it is precluded by the NJPLA.

Moreover, even if the NJPLA did not preclude Plaintiff's claim, Plaintiff fails to plausibly plead a claim for negligent undertaking. Defendants argue that Plaintiff fails to plead: (1) that Defendants undertook "to render services to another," (2) reliance by Plaintiff; or (3) increased risk of harm to Plaintiff. Def. Br. at 22-25.

Plaintiff responds that he must prove that *either* "[Defendant's] failure to exercise such care increases the risk of harm [to Plaintiff]," *or* "the harm is sufferance because of [Plaintiff's] reliance upon the undertaking." Pl. Opp'n at 17. Thus, Plaintiff argues that Defendants are incorrect that he needs to show each of these elements, and "Plaintiff specifically pleads that Defendants' failure to act reasonably increased the risk of harm to Plaintiff." *Id.* at 17-18.

Section 323 of the *Restatement (Second) of Torts* provides:

> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other 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.

Restatement (Second) of Torts § 323 (1965). Two threshold issues are necessary to plead a claim for negligent undertaking under New Jersey Law: (1) "the 'undertaking' was performed negligently;" and (2) "reliance on the part of the insured." *Daraio v. Carey Canada, Inc.*, 309 F. Supp. 2d 706, 710 (E.D. Pa. 2004) (citing *Jackson v. N.J. Mfrs. Ins. Co., P.E.*, 166 N.J. Super. 448, 458 (1979)). Additionally, "the defendant's negligent performance must somehow put the plaintiff in a worse situation than if the defendant had never begun the performance." *Sabric v. Lockheed Martin*, 532 F. App'x 286, 293 (3d Cir. 2013).

At the outset, the Court notes that neither party cites to a case in which a party who agrees to a license was held liable for negligent undertaking. In fact, Defendants strenuously assert that this lack of precedent is not coincidental and instead reflects the weakness of Plaintiff's argument. The Court has significant policy concerns about extending the doctrine of negligent undertaking to such circumstances. Taken to its logical extreme, any licensing agreement (and perhaps any contract) could then be a basis for a negligent undertaking claim, with the claim being made by a third person who is not a party to the agreement. The Court believes that the better course would be for the agreement to address any such concerns by the parties. For example, here the NIH licensed the assay to Biogen. The NIH, as part of the United States Department of Health and Human Services, is essentially America's medical research agency. If the NIH thought that Biogen could develop the assay within a certain period of time, it could have certainly included such a condition in a license. The NIH could have easily inserted into the license a requirement that Biogen had a specific time to commercialize the assay and, if Biogen did not, the license was revoked.

In addition, the decisions relied upon by Plaintiff are readily distinguishable. The only two cases Plaintiff cites in support of his position are *Callahan v. Stanley Works*, 306 N.J. Super. 488 (Law. Div. 1997) and *Velazquez ex rel. Velazquez v. Jiminez*, 172 N.J. 240 (2002). However, neither of these cases analyzes of a claim for negligent undertaking in any detail, let alone one in the circumstances presented here. The overarching issue in each case was not one of negligent undertaking.

In *Callahan*, the court addressed whether the plaintiff could bring a claim for negligent spoliation of evidence.[5] 306 N.J. Super. at 494. There, the court referred to Section 323 of the Restatement of Torts only by analogy, stating that "a jury could conclude that [defendant] gratuitously undertook a duty to preserve the [evidence] and failed to perform that duty." *Id.* at 497. However, even then, the *Callahan* court also noted that the facts of the case produced "special circumstances" to support a finding of a duty as opposed to actual reliance by the plaintiff. *Id.* (noting that defendant took steps to preserve the evidence and imposed a lien on damages to the evidence). The court in *Callahan* did not perform any extensive analysis of the tort of negligent undertaking.

Similarly, in *Velazquez*, the issue presented concerned the reach of New Jersey's Good Samaritan Act, specifically whether it applied to emergency care provided in a hospital setting. 172 N.J. at 257-58. The New Jersey Supreme Court in *Velasquez* concluded that a hospital did not fall under the purview of the Good Samaritan Act. *Id.* The Court's analysis relied in large part on the principles of statutory interpretation. *Id.* at 256-62. The *Velasquez* Court merely made a passing observation as to negligent undertaking. *Id.* at 262.

In short, there is nothing in the facts or analysis of *Callahan* or *Velasquez* to support Plaintiff's claim other than that both refer to the tort of negligent undertaking.

Even if the Court were to apply the doctrine of negligent undertaking to the current case, Plaintiff fails to allege a necessary element – reliance. *See Fackelman v. Lac d'Amiante du Quebec*, 398 N.J. Super. 474, 482 (App. Div. 2008) ("[R]eliance . . . is a basic and necessary prerequisite to the imposition of liability."). Plaintiff was not a party to the licensing agreement.

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[5] New Jersey had previously recognized a cause of action for the *intentional* spoliation of evidence. 306 N.J. Super. at 493-94 (citing *Viviano v. CBS, Inc.*, 251 N.J. Super. 113 (App. Div. 1991)).

The agreement was between NIH and Biogen. Plaintiff is, in essence, claiming that he is a third party beneficiary to the agreement. However, Plaintiff has provided no authority indicating that a third party can satisfy the reliance element of negligent undertaking, and the Court declines to extend the reach of the tort. If the courts of New Jersey belief that such an extension is appropriate, then they are in a better position to expand their own common law in the first instance.[6] *See* Nat'l Mfg. Co. v. Citizens Ins. Co. of Am., No. 13-0314, 2015 WL 1735423, at *3 (D.N.J. Apr. 15, 2015) ("When possible, United States District Courts sitting in diversity should not wade into the waters of creating new state law.").

Therefore, the Court grants Defendants' motion to dismiss with prejudice. Because the Court finds Defendants' motion to dismiss dispositive, it will not address Defendants' appeal of Judge Falk's decision. Thus, that motion is dismissed as moot.

[6] Plaintiff's factual allegations are also largely conclusory. *See, e.g.*, FAC ¶ 93 ("After voluntarily assuming the duty to develop a JC virus antibody assay, Defendants failed to act reasonably in developing the NIH assay for commercial use because they failed to dedicate adequate time and resources to the Assay's development and caused unreasonable delay in its commercialization."). Thus, while Plaintiff concludes that Defendants did not expend adequate time and resources in developing the assay, he does not plausibly indicate how much time and resources would have been sufficient, or when the assay should have been appropriately commercialized. If the Court were dismissing this claim solely due to factual inadequacies, then the Court would dismiss it without prejudice. However, the Court finds that the negligent undertaking claim as asserted is not legally viable and therefore dismisses with prejudice.

IV. CONCLUSION

In sum, the Court the Court **GRANTS WITH PREJUDICE** Defendants' motion to dismiss and Defendants' appeal of Magistrate Judge Falk's decision is **DENIED AS MOOT.** An appropriate Order accompanies this Opinion.

Date: April 17, 2017

JOHN MICHAEL VAZQUEZ
UNITED STATES DISTRICT JUDGE