UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
NORTHERN DIVISION
(at Covington)

IN RE: DARVOCET, DARVON AND PROPOXYPHENE PRODUCTS LIABILITY LITIGATION	)	Master File No. 2: 11-md-2226-DCR MDL Docket No. 2226
Williams v. Eli Lilly and Company,	)	Civil Action No. 2: 12-270-DCR
	)	**MEMORANDUM OPINION AND ORDER**

*** *** *** ***

Plaintiff Burneva Williams, Administratrix for the Estate of Marion Williams a/k/a Marion T. Williams, filed this action on November 30, 2012, in the United States District Court for the Western District of New York. [Record No. 1] This case, along with dozens of similar cases, was later transferred to this Court for consolidated pre-trial proceedings. [Record Nos. 3, 4] This matter is currently pending for consideration of Defendant Eli Lilly and Company's ("Lilly") motion for summary judgment. [Record No. 56] For the reasons outlined below, the Court will grant the defendant's motion.

I.

In 1957, the federal Food and Drug Administration (FDA) approved a New Drug Application (NDA) for Darvon, a propoxyphene-containing drug used to treat mild to moderate pain that was developed by Lilly. The FDA approved Lilly's NDA for Darvocet, which contained propoxyphene and acetaminophen, in 1973. Lilly retained all the rights to

these propoxyphene-containing drugs until February 2002, when it sold its NDA to NeoSan Pharmaceuticals Inc. Xanodyne, in turn, purchased the rights from NeoSan on July 25, 2005.

In 2009, the FDA Advisory Committee voted to suspend the marketing of propoxyphene-containing drugs. The FDA ordered Xanodyne to conduct clinical trials to assess the dangers of cardiotoxicity from propoxyphene. The study confirmed that propoxyphene can cause "significant changes to the electrical activity of the heart." News Release, U.S. Food & Drug Admin., Xanodyne Agrees to Withdraw Propoxyphene from the U.S. Market (Nov. 19, 2010). As a result, Xanodyne agreed to stop marketing propoxyphene products in the United States, and generic manufacturers of the drug were asked to do the same.

The current case concerns the death of Marion Williams ("Mr. Williams"). In May 1999, Mr. Williams began seeing Dr. Nady Shehata in Buffalo, New York, regarding heart issues. [Record No. 56-2, p. 16] Dr. Shehata prescribed Mr. Williams Darvocet-N 100, a prescription medicine containing propoxyphene. At that time, the defendant was manufacturing the drug. A prescription for the drug was filled from May 1999 through March 2000 at a local Rite Aid Store in Buffalo, New York. [Record No. 56-3] While taking the drug, Mr. Williams received inpatient and outpatient treatment from Sisters of Charity Hospital in Buffalo, New York, for continuing heart issues. [Record No. 56-2, p. 18] On March 8, 2000, Mr. Williams died of a heart attack.

On November 30, 2012, the plaintiff brought suit in the United States District Court for the Western District of New York alleging claims of products liability, personal injury, and violation of the False Claims Act, as a result of the death of Mr. Williams. [Record No.

1, p. 1] The suit was transferred to this Court, together with numerous others, for consolidated pre-trail proceedings on December 27, 2012. [Record Nos. 3, 4] The defendant contends that summary judgment is appropriate regarding all claims presented.[1] [Record No. 56]

II.

Summary judgment is appropriate when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Chao v. Hall Holding Co.*, 285 F.3d 415, 424 (6th Cir. 2002). A dispute over a material fact is not "genuine" unless a reasonable jury could return a verdict for the nonmoving party. That is, the determination must be "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251–52 (1986).

The party moving for summary judgment bears the burden of showing conclusively that no genuine issue of material fact exists. *CenTra, Inc. v. Estrin*, 538 F.3d 402, 412 (6th Cir. 2008). Once the moving party has met its burden of production, the party opposing summary judgment must "'do more than simply show that there is some metaphysical doubt as to the material facts.'" *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)).

1 On May 18, 2015, the Court granted the plaintiff's motion for leave to supplement the Response to the defendant's motion for summary judgment. [Record Nos. 66, 67] Therefore, in ruling on the current motion, the Court has considered the plaintiff's previously stricken filing captioned "Supplemental Brief in Response to Motion to Dismiss by Eli Lilly and Company Inc." [Record No. 63]

Instead, the nonmoving party must present "significant probative evidence" of a genuine dispute in order to defeat the motion for summary judgment. *Chao v. Hall Holding Co.*, 285 F.3d 415, 424 (6th Cir. 2002). In deciding whether to grant summary judgment, the Court views all the facts and inferences drawn from the evidence in the light most favorable to the nonmoving party. *Matsushita*, 475 U.S. at 587.

III.

A federal district court, sitting in diversity, must apply "the law, including the choice of law rules, of the forum state." *Westfield Ins. Co. v. Tech Dry, Inc.*, 336 F.3d 503, 506 (6th Cir. 2003); *see Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). In a MDL proceeding, "the forum state is typically the state in which the action was initially filed before being transferred to the MDL court." *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 454 (E.D. La. 2006). The above-captioned action was filed in the United States District Court for the Western District of New York. [Record No. 1] Thus, the Court must "determine which state's law applies by applying the choice of law rules of [New York]." *In re Volkswagen & Audi Warranty Extension Litig.*, 692 F.3d 4, 14 (1st Cir. 2012). New York courts engage in an "interest analysis" in determining which law applies. Under this analysis, the Court looks to the parties' domicile and the locus of the injury. *AroChem Int'l, Inc. v. Buirkle*, 968 F.2d 266, 270 (2d Cir. 1992).

The Complaint states that Mr. Williams resided in New York until death. [Record No. 1, p. 1] He also was prescribed propoxyphene-containing drugs, filled prescriptions, began experiencing symptoms allegedly caused by the drugs, and was treated, in New York. [Record No. 59, pp. 1–2] Further, the plaintiff's response to Lilly's motion does not contend

that the law of any other state should apply in this action. [*See id.*] Accordingly, the Court will apply New York law when analyzing the plaintiff's products liability and personal injury claims.

IV.

A. Products Liability and Personal Injury

The defendant asserts that the plaintiff's products liability and personal injury claims are barred by the applicable statute of limitations. [Record No. 56-1, pp. 6–8] Under New York law, an action to recover damages for personal injury must be brought within three years, except as provided by section 214-c.[2] N.Y. C.P.L.R § 214(5). Section 214-c covers actions resulting from "direct or indirect exposure by absorption, contact, ingestion, inhalation, implantation, or injection." N.Y. C.P.L.R. § 214-c(1). The parties agree that the current action is covered by this statutory section.

Section 214-c(2) states:

> [T]he three year period within which an action to recover damages for personal injury . . . caused by the latent effects of exposure to any substance or combination of substances, in any form, upon or within the body . . . must be commenced shall be computed from the date of discovery of the injury by the plaintiff or from the date when through the exercise of reasonable diligence such injury should have been discovered by the plaintiff, whichever is earlier.

2 Exceptions are also included under section 214-b ("Action to recover damages for personal injury caused by contact or exposure to phenoxy herbicides") and section 215 (stating that actions against: (1) a sheriff, coroner or constable; (2) for escape of a prisoner; (3) for assault, battery, false imprisonment, malicious prosecution, libel, slander, or violation of the right of privacy; (4) for penalty given to informer; (5) an action upon an arbitration award; (6) recovery of an overcharge of interest; or (7) a tenant action, must be commenced within one year). N.Y. C.P.L.R. §§ 214-b and 215. However, these sections are not applicable to the current action.

N.Y. C.P.L.R. § 214-c(2). The purpose of this provision is to "provide relief to injured New Yorkers whose claims would otherwise be dismissed for untimeliness simply because they were unaware of the latent injuries until after the limitation period had expired." *Jensen v. Gen. Elec. Co.*, 623 N.E.2d 547, 549 (N.Y. 1993) (internal quotations omitted).

The New York Court of Appeals has determined that the limitations period begins to run under section 214-c(2) at the time of "discovery of the physical condition and not . . . the more complex concept of discovery of both the condition and the nonorganic etiology of that condition." *Wetherill v. Eli Lilly & Co.*, 678 N.E.2d 474, 478 (N.Y. 1997). In other words, "[t]he three year limitations period runs from the date when plaintiff first noticed symptoms, rather than when a physician first diagnosed those symptoms." *Galletta v. Stryker Corp.*, 283 F. Supp. 2d 914, 917 (S.D.N.Y 2003). Based on the allegations in the plaintiff's Complaint, the limitations period under section 214-c(2) began to run, at the latest, with the death of Mr. Williams on March 8, 2000.[3] Therefore, the plaintiff had until March 8, 2003, in which to file claims resulting from Mr. Williams' death. However, the plaintiff did not file suit until November 30, 2012, more than nine years later. Thus, the plaintiff's claims cannot be properly brought pursuant to section 214-c(2).

However, New York law includes a safety provision under section 214-c(4) for certain claims "in which the plaintiff was aware of the 'injury' itself but there was a delay in the discovery of its 'cause.'" *Wetherill*, 678 N.E.2d at 477. The provision states:

3 The Court notes that the Plaintiff Fact Sheet alludes to the fact that Mr. Williams began experiencing symptoms prior to his death. [Record No. 56-2, pp. 35–36] However, an exact date is not alleged.

> [W]here the discovery of the cause of the injury is alleged to have occurred less than five years after discovery of the injury or when with reasonable diligence such injury should have been discovered, whichever is earlier, an action may be commenced or a claim filed within one year of such discovery of the cause of the injury; provided, however, if any such action is commenced or claim filed after the period in which it would otherwise have been authorized pursuant to subdivision two or three of this section the plaintiff or claimant shall be required to allege and prove that technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injury had not been discovered, identified or determined prior to the expiration of the period within which the action or claim would have been authorized and that he has otherwise satisfied the requirement of subdivisions two and three of this section.

N.Y. C.P.L.R. § 214-c(4).

The plaintiff asserts that it was "not until 2011 that anyone could have determined that there was a causal relationship between the heart attack that brought about the illness of Mr. Williams and his ultimate death." [Record No. 59, p. 9] Thus, the plaintiff contends that the limitations period could not have started until 2011, allowing the claims brought on November 30, 2012, to be timely.

However, the plaintiff misreads the statutory provision. The plain language of the statute provides that any extension of the limitations period requires that "the discovery of the cause of the injury" be "alleged to have occurred less than five years after discovery of the injury." N.Y. C.P.L.R. § 214-c(4). Therefore, the plaintiff was required to allege that prior to March 8, 2005, five years from the date of Mr. Williams' death, it was discovered that the drug caused his injury. However, the plaintiff asserts that discovery of the cause of Mr. Williams' injury did not occur until November 2011. [Record No. 59, p. 10] Therefore, the plaintiff does not allege to have discovered the cause of the injury within the time provided under the statute. *See Freier v. Westinghouse Elec. Corp.*, 303 F.3d 176, 184 (2d

Cir. 2002) ("[Section] 214-c(4) gives the plaintiff five years after the discovery (actual or constructive) of the injury to ascertain its cause. If [the plaintiff] does not (or cannot) discover the etiology within five years, then [the plaintiff] is barred by the statute of limitations.") (internal citation and quotation marks omitted).

The plaintiff cites *Giordano v. Market America, Inc.*, 15 N.Y.3d 590 (N.Y. 2010), and asserts that its holding "affirmatively rejected [the] six year limitation" in such cases. [Record No. 59, p. 9] However, the plaintiff misreads the court's decision. In *Giordano*, the United States Court of Appeals for the Second Circuit certified three questions to the New York State Court of Appeals. Among the questions was whether "an effect that appears within a matter of hours [could] be considered 'latent'" under section 214-c. *Id.* at 598–600. During discussion of the question, the court summarized the extension included in subdivision (4) by stating that it extends the limitations period to "five years from the discovery of the injury to the discovery of its cause, plus another year to sue or file a claim." *Id.* at 600. The court further stated that "for plaintiffs like the present one [whose injuries are discovered recently after exposure], subdivision (4) would replace the three-year tort statute of limitations with at most a six-year statute—an extension less generous to plaintiffs, and risking less hardship to defendants, than the indefinite extensions that can result from long-term latency." *Id.* Here, as stated earlier, Mr. Williams' injuries were discoverable, at the latest, at the time of his death on March 8, 2000. Therefore, the plaintiff had five years to discover the cause of the injury and another year to bring the cause of action. However, the plaintiff waited more than twelve years following Mr. Williams' death to file the claims.

Thus, the plaintiff's claims of products liability and personal injury are not timely under section 214-c(4).

The plaintiff further argues that equitable estoppel and equitable tolling are applicable to these claims. [Record No. 63] "Under New York law, the doctrines of equitable tolling or equitable estoppel may be invoked to defeat a statute of limitations defense when the plaintiff was induced by fraud, misrepresentations or deception to refrain from filing a timely action." *Abbas v. Dixon*, 480 F.3d 636, 646 (2d Cir. 2007); *see also Marshall v. Hyundai Motor Am.*, 51 F. Supp. 3d 451, 462 (S.D.N.Y. 2014). To establish equitable tolling, a plaintiff must show that "the defendant wrongfully concealed material facts," which "prevented plaintiff's discovery of the nature of the claim, and that "plaintiff exercised due diligence in pursuing the discovery of the claim during the period plaintiff seeks to have tolled." *Koch v. Christie's Int'l PLC*, 699 F.3d 141, 157 (2d Cir. 2012). On the other hand, "[t]o invoke equitable estoppel, a plaintiff must show that: (1) the defendant made a definite misrepresentation of fact, and had reason to believe that the plaintiff would rely on it; and (2) the plaintiff reasonably relied on that misrepresentation to [their] detriment." *Tardd v. Brookhaven Nat'l Lab.*, 407 F. Supp. 2d 404, 416 (E.D.N.Y. 2006) (internal quotation marks omitted). "Typically, [equitable estoppel] is invoked in cases in which [a defendant] has made misrepresentations concerning the statute of limitations or lulled the plaintiff into believing that it was not necessary for [them] to commence litigation." *Id.*

The plaintiff specifically asserts that "it appears that there was an intentional concealment of the hazards that one would be exposed to from the use of Darvon and Darvocet" and "Lilly spent great sums of money to conceal from the public the very hazard

of death and heart attacks" that use of these drugs could cause before being "forced to take its drug off the market by the [FDA] in November of 2010." [Record No. 63, p. 5] However, Lilly ceased manufacturing propoxyphene-containing drugs in February 2002, over ten years before the plaintiff brought suit. And the plaintiff has provided absolutely no evidence that Lilly spent great sums of money to conceal possible hazards caused by use of the drugs prior to selling its manufacturing rights. Therefore, the plaintiff has not offered any support for the claim that the defendant concealed material facts or made misrepresentations of fact resulting in the plaintiff's detriment. Thus, equitable estoppel and equitable tolling are not proper under the circumstances presented and summary judgment is appropriate for the defendant on the plaintiff's products liability and personal injury claims.

B. False Claims Act

The plaintiff also asserts a violation of the False Claims Act ("FCA"). [Record No. 1, pp. 3–4] Under the procedures set out in 31 U.S.C. § 3730(b) for Actions by Private Persons, the plaintiff must bring suit "in the name of the Government," and

> [a] copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

31 U.S.C. § 3730(b)(1)–(2) (footnote omitted).

In the present case, the plaintiff failed to abide by any of the statutory procedures. The action was brought exclusively as "Mrs. Burneva Williams – Administratrix for the Estate of Marion Williams a/k/a Marion T. Williams," without naming the government.

[Record No. 1, p. 1] Further, there is no indication that the Complaint was served upon the government, filed in camera, or placed under seal for at least 60 days. The United States Court of Appeals for the Sixth Circuit has determined that summary judgment is appropriate for claims under the FCA where a plaintiff "complied with none of the requirements for filing a *qui tam* claim." *Hackett v. Martin Marietta Corp.*, 98 F.3d 1341 (table), 1996 WL 577628, at *1 (6th Cir. Oct. 7, 1996) (citing *United States ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995, 997–1000 (2d Cir. 1995)); *see also U.S. ex rel. Summers v. LHC Group, Inc.*, 623 F.3d 287, 296–98 (6th Cir. 2010). Thus, because the plaintiff failed to abide by the statutory provisions governing claims brought under the FCA, summary judgment is appropriate with respect to this claim.

Additionally, this claim is time barred. Under 31 U.S.C. § 3731(b)(2), an action under section 3730 may not be brought

> (1) more than 6 years after the date on which the violation of section 3729 is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed.

31 U.S.C. § 3731(b).

Here, the plaintiff's Complaint alleges that the acts violating the FCA occurred on March 8, 2000. [Record No. 1, pp. 3–4] In response to the motion for summary judgment, the plaintiff attempts to revise the allegations by stating that the false claims continued past Mr. Williams' death until November 2010. [Record No. 59, pp. 14–15] However, the plaintiff has not identified the asserted false claims with any specificity or provided evidence

supporting that they occurred. The plaintiff did not bring her claim under the FCA until November 30, 2012, over twelve years after the actions alleged in the Complaint. [*Id.*, p. 1] Thus, the plaintiff's claim was brought more than 10 years after the date on which the violation was alleged to be committed. As a result, the claim is time barred.

However, the plaintiff again argues that equitable tolling and/or equitable estoppel are appropriate. [Record No. 63, pp. 1–4] To demonstrate equitable tolling as a result of fraudulent concealment, a plaintiff must prove the following: "(1) wrongful concealment of their actions by the defendants; (2) failure of the plaintiff to discover the operative facts that are the basis of [the] cause of action within the limitations period; and (3) plaintiff's due diligence until discovery of the facts." *Hill v. U.S. Dep't of Labor*, 65 F.3d 1331, 1335 (6th Cir. 1995) (internal quotation marks omitted). A party relying on equitable tolling through fraudulent concealment has the burden of proof. *Id.* Additionally, to demonstrate equitable estoppel a plaintiff must show: "(1) misrepresentations by the party against whom estoppel is asserted; (2) reasonable reliance on the misrepresentation by the party asserting estoppel; and (3) detriment to the party asserting estoppel." *Mich. Exp., Inc. v. United States*, 374 F.3d 424, 427 (6th Cir.2004) (citation omitted).

Here, similar to the plaintiff's earlier arguments relating to the products liability and personal injury claims, the plaintiff contends that through lobbying and legal efforts Lilly was able to keep Darvocet and Darvon on the market despite "[knowing] that their drug[s] [were] causing heart problems around the world." The plaintiff also contends that Lilly "deliberately marketed [the drugs] knowing that [they] caused problems" because "the profits were so great." [Record No. 63, p. 2] However, as stated earlier, the plaintiff has

provided no evidence supporting these allegations but, instead, makes general assertions regarding events which purportedly took place well after the defendant ceased manufacturing the drugs in question. Thus, the plaintiff has failed to demonstrate that equitable tolling or equitable estoppel is proper regarding the claims brought under the FCA.

Further, the plaintiff's Complaint is too broad to satisfy the heightened pleading requirements for fraud under Federal Rule of Civil Procedure 9(b). A complaint alleging a violation under the FCA must assert the circumstances surrounding the fraud in compliance with Rule 9(b). *See Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 972 (6th Cir. 2005). Rule 9(b) requires a party alleging fraud to "state with particularity the circumstances constituting fraud or mistake," while "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." FED. R. CIV. P. 9(b). Additionally, Rule 9(b) must be read "in conjunction with" the notice pleading requirement of Federal Rule of Civil Procedure 8, requiring "'a short and plain statement of the claim.'" *See U.S. ex rel. Bledsoe v. Comm. Health Sys., Inc.*, 501 F.3d 493, 503 (6th Cir. 2007) (quoting FED. R. CIV. P. 8); *see also Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 876 (6th Cir. 2006). When the two rules are read together, "it is clear that the purpose of Rule 9 is not to reintroduce formalities to pleading, but is instead to provide defendants with a more specific notice" regarding the particularities of the fraud claim. *Bledsoe*, 501 F.3d at 503.

To comply with Rule 9(b) in the context of the FCA, the Sixth Circuit has further stated that a plaintiff must allege "the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendant[]; and the injury resulting from the fraud." *Id.* at 504. Therefore, under the

FCA, a claim must be pled with sufficient particularity to, at a minimum, state "the who, what, when, where, and how of the alleged fraud." *Sanderson*, 447 F.3d at 877 (internal quotations omitted).

The plaintiff contends that the pleading "suggests that [Lilly] failed to state if combined with other medication approved by the FDA that Darvocet could be lethal and toxic to the heart" and "intimates reckless disregard for the safety of the public." [Record No. 59, p. 14] Further, the plaintiff states that "[t]o my mind, the pro se complaint articulates a false claim under the False Claims Act," but concedes that the claim brought under the FCA is "imperfectly articulated" and "imperfectly stated." [*Id.*] Here, as the plaintiff admits, the claim brought under the FCA has not been pled with the required specificity to satisfy Rule 9(b). As stated by the Sixth Circuit, "pleading an actual false claim with particularity is an indispensable element of a complaint that alleges a FCA violation in compliance with Rule 9(b)." *Bledsoe*, 501 F.3d at 504. The plaintiff has not sufficiently identified the who, what, when, where, and how of the alleged fraud or provided evidence supporting the claim. Instead, the plaintiff only provides broad assertions that do not allege fraud with the specificity required by the Federal Rules of Civil Procedure.

The plaintiff further requests leave to re-plead the claim under the FCA in the event that the Court finds the pleading inadequate. [Record No. 63, p. 6] The Court declines the plaintiff's request. The Complaint was filed well over two years ago and the plaintiff has provided no evidence that the opportunity to re-plead the claim will result in a pleading sufficiently specific to satisfy Rule 9(b).

V.

For the foregoing reasons, summary judgment for the defendant is proper regarding all of the plaintiff's claims. Accordingly, it is hereby

ORDERED as follows:

1. The defendant's motion for summary judgment [Record No. 56] is **GRANTED**.

2. All claims having been resolved, this action is **DISMISSED** and **STRICKEN** from the Court's docket.

3. A final and appealable Judgment shall be entered this date.

This 21st day of May, 2015.

Signed By:
Danny C. Reeves DCR
United States District Judge