UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re: CELEXA AND LEXAPRO MARKETING AND SALES PRACTICES LITIGATION	MDL No. 2067 Master Docket No. 09-md-2067-NMG Judge Nathaniel M. Gorton
THIS DOCUMENT RELATES TO: ALLIED SERVICES DIVISION WELFARE FUND, *et. al*, v. FOREST LABORATORIES, INC., *et al.*	Case No. 1:14-cv-10784 (NMG)

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE *ALLIED SERVICES* COMPLAINT

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Plaintiffs Allied Services Division Welfare Fund ("ASD") and New Mexico UFCW Union's and Employers' Health and Welfare Trust Fund ("NM UFCW") (collectively, "Plaintiffs"), respectfully submit this memorandum of law in opposition to Defendants' Motion to Dismiss the complaint with prejudice. For the reasons set forth below, Defendants' motion should be denied.

PRELIMINARY STATEMENT

This case presents yet another example of a pharmaceutical company putting profits over safety and waging a massive marketing and promotional campaign to mislead the healthcare community and public about the true risks and benefits of a prescription drug. Specifically, Defendants misrepresented the safety and efficacy of Celexa/Lexapro for use in the pediatric population.[1] Defendants perpetrated a carefully orchestrated scheme to wrongfully market and promote Celexa/Lexapro for "off-label" pediatric use – *i.e.*, an indication not approved by the Food and Drug Administration ("FDA") – for which the safety and efficacy of the drugs had not been established.[2] As part of their illegal scheme, Defendants: (1) actively suppressed and failed to timely disclose negative data and study results of the drugs;[3] (2) engaged in selective dissemination of medical articles and publications in an effort to mislead and misinform physicians, patients, parents and purchasers of the safety and efficacy of Celexa/Lexapro for use in pediatric patients;[4] (3) knowingly made false and misleading statements through national advertising and promotional and marketing materials regarding the true risks and benefits of Celexa/Lexapro for pediatric use;[5] (4) trained its employees in various methods designed to

[1] *See* Compl. ¶¶ 3, 4.
[2] *Id.* ¶ 5.
[3] *Id.* ¶¶ 54, 85, 146.
[4] *Id.* ¶¶ 100, 106, 107.
[5] *Id.* ¶¶ 97, 101, 102, 104.

detail and target pediatric specialists and promote "off-label" use of Celexa/Lexapro;[6] (5) developed a campaign to increase sales of Celexa/Lexapro while at the same time misrepresenting the safety and efficacy of the drugs;[7] and (6) induced physicians to prescribe Celexa/Lexapro through a system of kickbacks, such as paid promotional speeches, honoraria, lavish gifts and entertainment and research grants.[8] Following the U.S. Government's investigation into allegations of false claims and misbranding, Defendants agreed to pay $313 million to resolve criminal charges and civil claims under the False Claims Act for engaging in the off-label promotion of Celexa/Lexapro for pediatric use. For the sake of brevity we will not repeat each and every one of the detailed factual allegations in the complaint.

Plaintiffs are third party payors ("TPPs") that have incurred significant losses to the extent they paid for Celexa/Lexapro for use by a minor that they would not have but for Defendants conduct.[9] Plaintiffs and their agents reasonably and justifiably relied on Defendants false and misleading representations to their detriment.[10] As a direct result of Defendants' illegal promotion of Celexa/Lexapro for pediatric use and the suppression of material information as alleged in the complaint, Plaintiffs and other similarly situated TPPs were denied the opportunity to make fully informed decisions about whether and how to include Celexa/Lexapro on their formularies.[11] This caused TPPs to pay for more Celexa/Lexapro prescriptions than they otherwise would have paid absent Defendants' unlawful conduct.[12]

At this stage of the proceedings, Plaintiffs have sufficiently pled facts, which must be taken as true, that plausibly support claims under the federal Racketeer Influenced and Corrupt

[6] *See* Compl. ¶¶ 113, 115.
[7] *Id.* ¶¶ 6, 7, 87, 88, 112.
[8] *Id.* ¶¶ 117, 119, 132, 134, 138.
[9] *Id.* ¶¶ 7, 140.
[10] *Id.* ¶¶ 4, 92, 93, 95, 107.
[11] *Id.* ¶¶ 7, 87, 146, 147.
[12] *Id.* ¶¶ 7, 98, 140, 148, 149, 174.

Organizations Act (RICO), under state consumer protection laws and for unjust enrichment on behalf of a nationwide class. Therefore, Defendants' Motion to Dismiss should be denied.

BACKGROUND

Plaintiffs acknowledge and accept Defendants' recitation of the procedural history in this action; however, the procedural history, prior motion practice and rulings in the *Jaeckel, Palumbo,* and *Wilcox* actions[13] are relevant and critical to the legal analysis presented herein. On March 12, 2009, Plaintiff NM UFCW filed a complaint in the Eastern District of New York against Defendants asserting RICO, consumer fraud, and unjust enrichment claims on behalf of a nationwide class of third party payors[14] and on March 23, 2009, Plaintiff ASD was added.[15] On March 20, 2009, plaintiffs in *Jaeckel, et al., v. Forest Pharmaceuticals, Inc. et al.,*[16] instituted an action in the Eastern District of Missouri that included similar factual allegations and causes of action on behalf of a consumer class and third party payor class defined as:

> "All entities in the United States and its territories (other than state governmental entitles) that, for purposes other than resale, purchased, reimbursed and/or paid for all or part of the cost of Celexa or Lexapro from 1998, through the present (the "Class Period") for use by a minor."

On September 15, 2009, plaintiffs in *Palumbo, et al. v. Forest Pharmaceuticals, et al*.,[17] filed an action in the Southern District of New York. These actions along with several others were transferred to this Court for consolidated pretrial proceedings in September 2009.[18] On January 19, 2010, plaintiffs in the *Jaeckel* and *Palumbo* actions filed their first amended class action

[13] *Palumbo et al v. Forest Laboratories Inc. et al.,* No. 1:09-cv-11532 (NMG)(D. Mass. 2009); *Angela Jaeckel, et al., v. Forest Pharmaceuticals, Inc. et al.,* No. 1:09-cv-11518 (NMG)(D. Mass. 2009); *Wilcox v. Forest Laboratories, Inc. et al., No*. 1:10-cv-10154 (NMG)(D. Mass. 2010).
[14] *New Mexico UFCW and Employers' Health & Welfare Trust Fund v. Forest Labs., Inc*., et al, No. 09-cv-11524 (NMG)(D. Mass. Mar. 12, 2009)(Dkt. 1).
[15] *Id.* (Dkt. 2).
[16] *Id.* at n.12
[17] *Id.*
[18] See Transfer Order, *In re Celexa & Lexapro Mktg., & Sales Practices Litig.*, MDL No. 2067 (JPMDL. Aug. 19, 2009)(Dkt. 1).

complaints in this MDL.[19] On June 23, 2010, Plaintiffs and Defendants stipulated to a voluntary dismissal without prejudice pursuant to Fed.R.Civ.P. 41(A)(1)(a)(ii).[20] On March 13, 2014, Plaintiffs filed the present complaint asserting claims under federal RICO law, state consumer protection laws, and for unjust enrichment on behalf of a nationwide class. Under the *American Pipe* doctrine, the relevant statutes of limitations were tolled because a class action that included Plaintiffs in the proposed class was commenced timely and class certification was not denied until recently. As a result, Plaintiffs' present complaint is timely.

STANDARD OF REVIEW

To survive a motion to dismiss, a complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face."[21] The Court may look only to the facts alleged in the pleadings, documents attached as exhibits or incorporated by reference in the complaint and matters of which judicial notice can be taken.[22] Furthermore, the Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor.[23]

To survive a Rule 12(b)(6) motion, the claim first must comply with Rule 8(a) by providing "a short and plain statement of the claim showing that the pleader is entitled to relief,"[24] such that the defendant is given "fair notice of what the claim is and the grounds upon which it rests."[25] Second, the factual allegations in the claim must be sufficient to raise the possibility of relief above the "speculative level."[26] Under Rule 9(b) "all averments of fraud or

[19] *In Re: Celexa and Lexapro Marketing and Sales Practices Litig.*, No. 09-md-02067 (NMG)(D. Mass.)(Dkt. 23).
[20] *Id.*(Dkt. 49).
[21] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).
[22] *Nollet v. Justices of the Trial Court of Mass*., 83 F. Supp. 2d 204, 208 (D. Mass. 2000) *aff'd*, 248 F.3d 1127 (1st Cir. 2000).
[23] *Langadinos v. Am. Airlines, Inc*., 199 F.3d 68, 69 (1st Cir. 2000).
[24] Fed.R.Civ.P. 8(a)(2).
[25] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).
[26] *E.E.O.C. v. Concentra Health Srvs.*, 496 F.3d 773, 776 (7th Cir. 2007)(quoting *Twombly*, 550 U.S. at 555).

mistake, the circumstances constituting fraud or mistake shall be stated with particularity."[27] A plaintiff must generally allege the "who, what, where, and when of the alleged fraud."[28] However, the particularity requirement of Rule 9(b) may be relaxed when it is shown the details are within the defendants' exclusive knowledge.[29]

ARGUMENT

Defendants' Motion to Dismiss should be denied for three principle reasons. First, Defendants' statutes of limitation arguments are not relevant to the case at hand and fail to acknowledge, much less apply, the well-established principle of tolling in the *American Pipe* doctrine which governs the timeliness of Plaintiffs' claims. Second, Plaintiffs have adequately pled claims under RICO and any arguments to contrary disregard the law of this Circuit. Third, Defendants ignore the stage of the proceedings by arguing what Plaintiffs must ultimately prove under Illinois and New Mexico law versus what Plaintiffs must plead to survive a Rule 12(b)(6) motion.

I. *Plaintiffs' Claims are Not Time-Barred*

Dismissing a complaint as untimely at the motion to dismiss stage is "an unusual step"[30] and "often inappropriate" because the application of the affirmative defense of the statute of limitations "most typically depends on factual determinations."[31]

Defendants claim the relevant statutes of limitation began to run in 2005 when Plaintiffs were allegedly put on inquiry notice that they may have been defrauded[32] and/or should have

[27] Fed.R.Civ.P. 9(b).
[28] *Ackerman v. Northwestern Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir.1999).
[29] *North Bridge Assoc., Inc. v. Boldt*, 274 F.3d 38, 44 (1st Cir. 2001).
[30] *The Cancer Foundation, Inc. v. Cerberus Capital Management, LP*, 559 F.3d 671, 674 (7th Cir. 2009).
[31] *Johnson Controls, Inc. v. Exide Corp*., 129 F.Supp 2d 1137, 1142 (N.D. Ill 2001).
[32] As many courts have held, in a fraud case, "inquiry notice" does not occur, and the statute of limitations does not begin to run, until "circumstances suggest to a person that he may have been *defrauded . . . ." Blue Cross v. SmithKline Beecham Clinical Labs, Inc.*, 108 F. Supp. 2d 116, 122 (D. Conn. 2000)(emphasis added). *See also, McLntyre v. United States*, 367 F.3d 38, 52 (1st Cir. 2004)(Once a duty to inquire is established, the plaintiff is

exercised reasonable diligence[33] in discovering their alleged injury. (Def. Br. at 6-7). Plaintiffs submit that issues of inquiry notice and due diligence are highly factual and are not proper grounds for dismissal under Rule 12(b)(6). Rather the Court need not look any further than the application of *American Pipe*[34] and procedural history of this MDL to determine that Plaintiffs' claims are timely.

A. Plaintiffs' Claims Were Tolled Under the American Pipe Doctrine

Plaintiffs' claims were timely filed in March 2009 as were the claims filed in the *Jaeckel*, *Palumbo* and *Wilcox* actions.[35] Under *American Pipe*, the "commencement of a class action suspends the applicable statute of limitations as to all asserted members of the class who would have been parties had the suit been permitted to continue as a class action."[36] The statute of limitations is tolled as to all potential class members because to hold otherwise would lead class members to file unnecessary anticipatory suits for fear that class certification would be denied.[37]

In addition, "[o]nce the statute of limitations has been tolled, it remains tolled for all members of the class until class certification is denied."[38] The Supreme Court further explained

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charged with the knowledge of *what he or she would have uncovered through a reasonably diligent investigation*. The next question is whether the plaintiff, if armed with the results of that investigation, would have known enough to permit a reasonable person to believe that she had been injured and that there is a causal connection between the [defendant] and her injury…*This inquiry is highly fact- and case-specific* …)(emphasis added); *See also, In re Celexa & Lexpro Mktg. & Sales Practices Litig.*, 769 F.Supp.2d 11, 14 (D. Mass. Jan. 11, 2011).

[33] *Am. Jur. Proof of Facts 3d* 129 § 10 (2004)(citation omitted)(Any questions surrounding plaintiffs' due diligence is a question for the trier of fact. It is "black letter law" that "[e]ven though a plaintiff might have inquiry notice of a potential claim, it does not follow that reasonable diligence will discover sufficient facts to support a legal action. Where such is the case, the failure to file suit on the basis of such information does not necessarily show a lack of due diligence.)

[34] *Arivella v. Lucent Technologies, Inc.*, 623 F.Supp.2d 164, 174 (D. Mass. 2009)("*American Pipe*, which is a tool for judicial economy, promotes the goals of Rule 23, and rests on the notice provided to defendants by filing a class action, has nothing to do with fairness; the duration of its extension of the statute of limitations thus cannot hinge on concepts of *reasonableness* or *diligence*.")(emphasis added).

[35] Defendants belated arguments that 2005 is the appropriate "trigger" date for statute of limitation purposes fails to acknowledge that this Court has not affirmatively dismissed with prejudice a single plaintiff whose complaint was filed in 2009.

[36] *American Pipe & Construction Co*., 414 U.S. 538, 554 (1974).

[37] *Crown, Cork & Seal Co., Inc. v. Parker*, 462 U.S. 345, 354 (1983).

[38] *Id.* at 353-354. The Supreme Court's decisions in *American Pipe* and *Crown, Cork, & Seal Co.* was not based on judge-made equitable tolling, but rather on the Court's conclusion that Rule 23's goal of efficiency would be

that its' holding was not limited to class members who had deliberately relied on the class action to advance their claims. The ruling extends to allow class members to benefit passively from the suit's tolling effect.[39] It is clear from *American Pipe* and *Crown, Cork & Seal* that the filing of a class action tolls the statute of limitations as of the date the litigation is commenced.[40] Most courts, including the First Circuit, also agree that tolling ceases only upon entry of an order denying class certification in the trial court.[41]

Beyond class membership, each of the plaintiff's particular claims must be sufficiently similar, although not necessarily identical, to toll the statute of limitations under *American Pipe*.[42] The salient question is whether the claims "share a common factual basis and legal nexus so that the defendant would rely on the same evidence and witnesses in his defense."[43]

In the case at hand, the *American Pipe* doctrine applies in full force to toll the statute of limitations because the *Jaeckel* class action complaint – that included Plaintiffs in the proposed class – was commenced on March 20, 2009 and class certification was not denied until February 5, 2013.

Even though Plaintiffs instituted an earlier action, the parties stipulated to a voluntary dismissal without prejudice pursuant to Fed.R.Civ.P. 41(A)(1)(a)(ii).[44] (Dkt. 49) As numerous

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frustrated if the commencement of a putative class action did not toll the statute of limitations for putative class members, *i.e.*, each class member would otherwise need to commence litigation prior to the expiration of that class member's own limitations period. *Arctic Slope Native Association, Ltd. v. Sebelius*, 583 F.3d 785, 791-92 (Fed. Cir. 2009).

[39] *Crown, Cork & Seal Co.*, 462 U.S. at 552.

[40] *Id.* at 354; *See also, Arivella v. Lucent Technologies, Inc.*, 623 F.Supp.2d 164, 174 (D. Mass. 2009).

[41] *Arivella v. Lucent Technologies, Inc.*, 623 F.Supp.2d at174.

[42] *Id.* at 180.

[43] *Id.* (quoting *In re Enron Corp. Sec*., 465 F. Supp. 2d 687, 718 (S.D. Tex. 2006) (tolling applied where the failed class action which alleged exactly the types of breach claimed by the subject plaintiff plainly put the defendant on notice of the potential claims it might have to defend, the factual bases for those claims and the potential witnesses who might be called); *See also, City Select Auto Sales, Inc. v. David Randall Associates, Inc.*, 2012 WL 426267, *3 (D.N.J. 2012)("Generally speaking, there is sufficient connection between the actions when the claims brought in a subsequent suit share a common factual and legal nexus with those brought in the prior class action sufficient to notify the defendants and thereby satisfy the policy goals of the statute of limitations.").

[44] *Id.* at n.20

federal courts have made clear, a voluntary dismissal without prejudice under Rule 41(a) leaves the situation as if the action never had been filed.[45] Accordingly, the running of the statute of limitations as it relates to Plaintiffs claims was tolled by the filing of the class action complaint in both *Jaeckel* and *Palumbo*. Plaintiffs fall squarely within this class definition.[46] In addition, Plaintiffs' complaint in the instant action and the claims raised in this MDL are sufficiently similar.

In September 2012, the plaintiffs in the *Jaeckel* and *Palumbo* actions moved to certify two national consumer classes of individuals and entities who purchased, reimbursed or paid for Celexa or Lexapro for use by a minor. (Dkt. 109). After a hearing, the Court denied motion for class certification on February 5, 2013. (Dkt. 174) In its ruling, the Court held that the *Jaeckel* and *Palumbo* plaintiffs could not satisfy Fed.R.Civ.P 23(b)(3), because they failed to meet the superiority requirement.[47] Following the Court's order denying class certification, tolling of Plaintiffs claims under *American Pipe* ceased.

It is well settled that once a court has decided that a federal statute is tolled, the time in which to sue after the clock restarts is calculated by subtracting from the full limitations period whatever time ran while the period was not tolled.[48] In *Adorno v. Crowley Towing & Transport Co.*, the First Circuit, considering a class certification circumstance, held that the time to sue

[45] *Sandstrom v. Chemlawn Corp.*, 904 F.2d 83, 86 (1st Cir. 1990)(a voluntary dismissal under Fed.R.Civ.P. 41(a) wipes the slate clean, making any future lawsuit based on the same claim an entirely new lawsuit unrelated to the earlier (dismissed) action); *See, e.g., Commercial Space Mgmt. Co. v. Boeing Co.,* 193 F.3d 1074, 1078 (9th Cir. 1999) ("it is beyond debate that [under] a dismissal under Rule 41(a)(1) ... the parties are left as though no action had been brought"); Such a dismissal "leaves the situation as if the action never had been filed." 9 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2367, at 321 (2d ed.1995).
[46] Defendants have not raised or disputed that Plaintiffs were not covered by the class definition in *Jaeckel.*
[47] *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 291 F.R.D. 13, 19 (D. Mass. Feb. 5, 2013).
[48] *United States v. Ibarra*, 502 U.S. 1, 4 (1991).

after the clock restarts is measured against the statutory period, not against a subjective "reasonable" time period.[49]

To determine if Plaintiffs' claims were timely filed, the Court must address when the clock started to run. Because the *Jaeckel* and *Palumbo* actions were filed timely, the Court need not address whether Plaintiffs' initial March 2009 complaint was timely. The relevant statutes of limitations did not begin to run until February 13, 2009, when the U.S. government *qui tam* complaints were unsealed.[50] Under *American Pipe* tolling, the relevant periods of limitations run as follows:

- February 13, 2009 to the date the *Jaeckel* complaint was filed, March 20, 2009. The statute of limitations had run, at most, 37 days.
- The relevant limitations periods were tolled from March 20, 2009 until February 5, 2013, the date that the Court denied plaintiffs' motion for class certification.
- The statutes of limitations then began running again and ran for an additional 401 days until March 13, 2014, when Plaintiffs filed the instant action.
- The total period during which the statutes of limitations was running was thus, at most, 438 days (or approximately 1.2 years), well within the limitations period for each cause of action.[51]

Defendants have not pointed to any facts that would negate Plaintiffs' allegation that they acted timely. Nor does Defendants' motion raise or dispute that the *Jaeckel, Palumbo,* and *Wilcox* actions were timely filed.

II. *Plaintiffs Adequately Allege Claims under RICO*[52]

[49] *Adorno v. Crowley Towing & Transport Co.,* 443 F.3d 122, 126 (1st Cir. 2006); *See also, Owens v. United States,* 236 F.Supp. 2d 122, 129 (D. Mass. 2002)(*American Pipe* tolling has nothing to do with fault or diligence); *Arivella v. Lucent Technologies, Inc.*, 623 F.Supp.2d at 179.

[50] *See United States Complaint in Intervention, United States of America ex rel. Christopher R. Gobble v. Forest Labs., Inc.,* No. 05-cv-10201 (NMG)(D. Mass. Feb 13, 2009; *unsealed* Feb. 25, 2009). Plaintiffs contend that February 13th is the appropriate "trigger" date for statute of limitations purposes. Only in February 2009, when the U.S. government *qui tam* complaint was unsealed alleging Defendants' unlawful practices, did Plaintiffs' claim become discoverable. The truth about Defendants' scheme was not revealed until that date.

[51] It is clear from the calculations that Plaintiffs' RICO and state law claims fall well within the applicable statute of limitations period. *See, Arivella v. Lucent Technologies, Inc.*, 623 F.Supp.2d at 179 ("there is nothing subjective about *American Pipe*; all that is left for this court is simple math.")

A. Plaintiffs Have Standing to Pursue RICO Violations

Defendants' motion ignores the law of this Circuit and cites to a plethora of out-of-circuit cases for the proposition that Plaintiffs lack standing. This argument is without merit.

To state a RICO claim, Plaintiffs must first establish statutory standing by alleging: (1) an injury to business or property; and (2) that the injury was caused by [defendants'] violations of RICO.[53] To have standing, the injury alleged cannot be derivative of another individual's harm or unconnected to the RICO scheme.[54] "When a defendant's wrong makes it difficult for the plaintiff to prove damages, all reasonable doubts about the amount of damages are resolved in the plaintiff's favor."[55] "Once the plaintiff proves injury, broad latitude is allowed in quantifying damages, especially when the defendant's own conduct impedes quantification."[56]

Here, Plaintiffs have sufficiently alleged direct and concrete injuries in the form of payments for Celexa/Lexapro prescriptions written as a result of Defendants' illegal marketing and promotion.[57] Defendants' contention that Plaintiffs have failed to plead a "cognizable injury" ignores that courts have repeatedly held defendants liable for misleading and false statements, when those statements detrimentally affect a purchaser.[58] For example, in *Neurontin*, the court found that due to misrepresentations made to the market, the plaintiffs [TPPs] have adequately

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[52] *See, e.g.*, Compl. ¶¶ 162 – 185.
[53] 18 U.S.C § 1962; *First Nationwide Bank v. Gelt Funding Corp*., 27 F.3d 763, 767 (2nd Cir. 1994).
[54] *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268 (1992).
[55] *Phoenix Bond & Indem. Co. v. Bridge*, 911 F. Supp. 2d 661, 675 (N.D. Ill. 2012).
[56] *Id*. at 675.
[57] *See, e.g.*, Compl. ¶¶ 7, 140, 148, 149, 174.
[58] *In re Neurontin Mktg., Sales Practices & Prod. Liab. Litig.*, 433 F. Supp.2d 172 (D. Mass. 2006); *See also, In re Avandia Mktg., Sales Practices & Products Liab. Litig.*, 2013 WL 5761202, * 5 (E.D. Pa. Oct. 23, 2013)(holding that plaintiffs' claims related to defendant's misleading marketing efforts "sufficiently allege[d] an economic injury at this pleading state of litigation."); *Desiano v. Warner Lambert.*, 326 F.3d 339, 342 (2nd Cir. 2003)(finding plaintiffs adequately alleged an injury where the defendant promoted a drug as effective "knowing that its own clinical trial data showed ... users were three to six more likely to suffer liver injury than patients taking the placebo"); *In re Warfarin Sodium Antitrust Litig.*, 391 F. 3d 516, 531 (3d Cir. 2004)(holding that "TPPs, like individual consumers, suffered direct economic harm when, as a result of [defendants] alleged misrepresentations, they paid supracompetitive prices ...")

made out a claim that they paid for too much the drug as a result of the alleged fraud.[59]

The standing requirements for RICO also require a plaintiff to allege "but for" causation and "some direct relation between the injury asserted and injurious conduct alleged."[60] RICO injury must be direct in that it can be neither derivative of harm to another nor unconnected to the RICO scheme,[61] but a plaintiff satisfies this element if the alleged harm was the reasonably foreseeable or anticipated natural consequence of the defendant's actions.[62] Thus, "a person can be injured 'by reason of" a pattern of mail fraud even if he has not relied on any misrepresentations."[63]

Here, the intended, foreseeable, and direct result of Defendants' decision to market "off-label", misrepresenting material facts and purposefully omitting and suppressing negative information through its marketing strategies was intended to cause physicians to write more Celexa/Lexapro prescriptions which were paid for by TPPs.[64] As the First Circuit recently recognized in a case concerning off-label promotion to physicians,

> "individualized decisions made by thousands of physicians" … do not introduce such attenuation into [plaintiff's] causal theory as to prevent a reasonable jury from finding proximate causation …A reasonable jury could have concluded, based on the evidence, that defendants' scheme relied upon the expectation that fraudulent off-label marketing to doctors would induce them to act in a foreseeable fashion – *i.e.*, to write off-label prescriptions for Neurontin that would be paid for by [plaintiff].[65]

Just as with *Neurontin*, Defendants' scheme relied upon the expectation that its illegal

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[59] *In re Neurontin Mktg., Sales Practices & Prod. Liab. Litig.*, 433 F. Supp.2d at 185-86.
[60] H*emi Group LLC v. City of New York*, 559 U.S. 1, 9 (2010).
[61] *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 71-72 (1992).
[62] *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 658 (2008).
[63] *Id.* at 642.
[64] *Compare Hemi Grp., LLC v. City of New York*, 130 S. Ct. 983, 992 (2010)(*citing Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 658 (2008)) (proximate causation established where misrepresentations are made to an intermediate third party, but that party suffers no injury; rather, the harm flows through to the plaintiffs, as the only parties injured by the misrepresentations), *with Holmes*, 503 U.S. at 268, 271 (where RICO misconduct caused stock prices to collapse, the plaintiffs' obligations to cover the losses of broker-dealers amounted to an injury that was "purely contingent" on, or derivative of, the harm suffered by broker-dealers) and *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 454, 458 (2006) (where a plaintiff alleged a competitor cheated the State of New York out of sales taxes, thereby enabling it to undercut the plaintiff's prices, the more direct victim was the State of New York).
[65] *In re Neurontin Mktg. & Sales Practices Litig*., 712 F.3d 51, 59 (1st Cir. Apr. 3, 2013).

off-label marketing enterprise and fraudulent promotional campaign (including the suppression of material information) would induce physicians to write prescriptions for Celexa/Lexapro for pediatric use that TPPs would then pay for.

Defendants attempt to defend their marketing efforts by pointing out alleged factual deficiencies in Plaintiffs' complaint, *i.e.* failing to identify "a payment for a prescription that was ineffective" or "cheaper medications that would have cost less money." (Def. Br. at 12). These arguments should be rejected, just as similar arguments were rejected in *Neurontin*.[66]

Here, the injury to Plaintiffs is not speculative or conjectural. It is concrete in that Plaintiffs and other TPPs paid for prescriptions that resulted from Defendants' illegal marketing scheme.[67] Therefore, Plaintiffs have stated a viable claim for injury.[68] Under First Circuit precedent, Plaintiffs have sufficiently pled injury and causation to have standing under RICO.

B. Plaintiffs Sufficiently Allege a RICO Enterprise

"Liability under RICO depends on a showing that the defendant conducted or participated in the conduct of the 'enterprise's affairs' not just [its] own affairs.'"[69] This requirement "is simply another reference to the fact that a RICO defendant must be distinct from the alleged enterprise."[70] A RICO "enterprise" can include legal entities like corporations, but also "groups of individuals associated in fact although not a legal entity."[71]

In *Boyle v. United States*, the Supreme Court considered the structural requirements of

[66] *In re Neurontin Marketing and Sales Practices Litigation*, 712 F.3d 21, 33 (1st Cir. Arp. 3, 2013)("*Kaiser Opinion*")(court rejected the argument that Neurontin was effective for off-label purposes and therefore no injury occurred).
[67] Compl. ¶¶ 7, 97, 98, 146-149.
[68] *See In re In re Avandia Mktg., Sales Practices & Products Liab. Litig.*, 2013 WL 5761202, at *2-6 (court found that deceptive information concerning Avandia's safety known by [defendant] supported a RICO cause of action by third party payor.)
[69] *Chen v. Mayflower Transit, Inc.*, 315 F. Supp. 2d 886, 905 (N.D. Ill. 2004) (*quoting Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993)).
[70] *Id.* at 906.
[71] 18 U.S.C. § 1962(4).

an association-in-fact enterprise.[72] The Court held that no more is required than a common purpose, relationships between the members, and sufficient longevity to carry out the purpose of the enterprise.[73] This definition is broad and encompasses the combination of Defendants, Defendants' employees, consultants, independent physicians not otherwise affiliated with Defendants, outside marketers and organizers, and other individuals who make up the Celexa and Lexapro Off-label Marketing Enterprise (the "Enterprise").

Relying on *Boyle*, Defendants argue that Plaintiffs have not provided sufficient allegations of an organizational structure for the alleged Enterprise. (Def. Br. at 13) To the contrary, Plaintiffs adequately pled an associate-in-fact enterprise sufficient to meet the structural elements required in *Boyle*. For example, the complaint alleges that the Enterprise was established and supported by Defendants for the common purpose to deceive the medical community and public about the safety and efficacy of Celexa/Lexapro for pediatric uses, suppress evidence, induce physicians and promote the drugs for off-label purposes to achieve increased utilization of Celexa/Lexapro in the pediatric population.[74] In order to achieve this, Defendants joined together with external researchers, physicians and a communications firm to host events designed to promote Celexa/Lexapro and publish articles touting the drugs' effectiveness for a series of off-label pediatric uses.[75] Defendants' contention that "non-Forest

[72] *Boyle v. United States*, 556 U.S. 938 (2009).
[73] *Id.* at 939.
[74] Compl. ¶ 165.
[75] *Id.* ¶¶ 100, 101, 106, 116, 117, 119-121, 164, 165. *See also, District 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F.Supp.2d 508, 526 (D.N.J. 2011)(holding plaintiffs sufficiently pled the existence of an enterprise under RICO which included defendants, the network of marketing firms employing physicians and research organizations, contracting with third-party advertisers, proliferation firms and outside consultants, used to promote the off-label use of Risperdal.) *See also, In re Neurontin Mktg., Sales Practices & Products Litig.*, 433 F.Supp. 2d 172, 181 (D. Mass. 2006)(holding that alleged common purpose of promoting off-label uses of Neurontin violated the law, which is adequate under the RICO statute, as construed expansively.")

members were unaware of the concealed study results," is of no concern.[76]

Furthermore, Defendants' reference to *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Walgreen Co.* ("*Walgreen*") is without merit. There, the court found that the plaintiff did not sufficiently allege that the defendant companies conducted the affairs of an enterprise, "as opposed to their own affairs," for reasons not applicable here.[77] The court found, for example, that the complaint did not allege "that officials from either company involved themselves in the affairs of the other."[78] Here, unlike in *Walgreen*, independent physicians, consultants and marketing firms were members of the Enterprise.[79] Further, when an enterprise enables a defendant to engage in conduct "in a way that would be [otherwise] impossible" if the defendant were acting alone, a plaintiff has adequately alleged facts that an enterprise's affairs are distinct from that of a defendant.[80]

C. Plaintiffs Have Pled a Pattern of Racketeering Activity and the Predicate Acts with Particularity.

To demonstrate a pattern of racketeering activity under RICO, a plaintiff must prove "two or more predicate acts."[81] Courts have defined "a scheme to defraud" very liberally to mean "any deliberate plan of action or course of conduct by which someone intends to deceive or cheat

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[76] *In re Pharm. Indust. Avg. Wholesale Price Litig.*, 307 F.Supp.2d 196, 205 (D. Mass. 2004)("members of an enterprise do not have to share all objectives so long as they have one in common."); *In re Actiq Sales & Mktg. Practices Litig*., 2009 WL 2581717, * 4 (E.D. Pa. 2009)(finding existence of RICO enterprise because plaintiffs alleged a decision-making structure beyond surface descriptions of the enterprise, but also details about the ongoing functions of the alleged enterprise, descriptions of monetary and other incentives used to attract speakers and other participants to the enterprise, specifics regarding the manner in which presentations were created to allegedly mislead physicians about the efficacy of [drugs] for certain conditions, and how sales representatives were utilized in the course of Defendant's national marketing scheme.); *Compare with* Compl ¶¶ 101 (Defendants sponsored 20 seven-city CME presentation with Dr. Wagner); ¶ 106 (plublished misleading article in June 2004 issue of medical journal); ¶ 117 (paid Dr. Bostic over $750,000 in honoria for off-label presentations on Celexa and Lexapro); ¶ 119 (hosted advisory boards with $500 honoria paid to attendees).

[77] *United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Walgreen Co.*, 719 F.3d 849, 854 (7th Cir. 2013).

[78] *Id.*

[79] See Compl. ¶¶ 100, 101,105, 106, 117, 121, 131.

[80] *Chen*, 315 F. Supp. 2d at 905.

[81] *Id.* at 908. (*citing Corley v. Rosewood Care Center, Inc. of Peroia*, 142 F.3d 1041, 1048 (7th Cir. 1998).

another or by which someone intends to deprive another of something of value."[82] At the motion to dismiss stage, Rule 9(b) requires only that the plaintiff identify the alleged misrepresentations, not actually prove that the statements were false.[83] The pleadings must be specific enough to put defendants on notice of the conduct alleged. A violation of the mail and wire fraud statutes can occur by way of "[d]eceitful statements, half truths, or the knowing concealment of material facts."[84]

In RICO claims relating to mail and wire fraud, courts often relax the Rule 9(b) pleading requirements when the information necessary to plead with the requisite particularity is within the exclusive control of the defendants pending further discovery.[85] Plaintiffs are not required to allege each specific conversation or representation, where the very nature of the defendants' scheme renders this impossible at the pleading stage.[86] Courts frequently recognize the need to relax Rule 9(b)'s pleading requirements in the RICO context when a plaintiff has restricted access to information.[87] Indeed, Plaintiffs have not had the benefit of any discovery in the MDL.

Here, Plaintiffs have alleged violations of the federal mail and wire fraud statutes (18 U.S.C. §§ 1341, 1343) and the Travel Act (18 U.S.C § 1952). The elements necessary to establish a claim for mail or wire fraud are: (1) a scheme to defraud; (2) the use of mails or wires for the purposes of executing the scheme; and (3) fraudulent intent.[88] The Travel Act prohibits traveling in interstate commerce or using mail in interstate commerce with the intent to

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[82] *Levine v. First Am. Title Inc. Co.*, 682 F.Supp.2d 442, 462 (E.D. Pa. 2010).
[83] *See Bankers Trust Co. v. Old Republic Ins., Co.*, 959 F.2d 677, 683 (7th Cir. 1992)
[84] *Levine*, 682 F.Supp.2d at 462.
[85] *See New England Data Services, Inc. v. Becher*, 829 F.2d 286, 290-91 (1st Cir. 1987); s*ee also North Bridge Assoc., Inc. v. Boldt*, 274 F.3d 38, 44 (1st Cir. 2001)(noting that where "the specific information [concerning the defendants' use of interstate mail or telecommunications facilities] is likely in the exclusive control of the defendant, the court should make a second determination as to whether the claim as presented warrants the allowance of discovery and if so, thereafter provide an opportunity to amend the defective complaint")(quoting *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 43 (1st Cir. 1991)).
[86] *See Zito v. Leascomm Corp*., 2004 WL 2211650, *12 (S.D.N.Y. 2004).
[87] *Corley v. Rosewood Care Center Inc.*, 142 F.3d 1041, 1051 (7th Cir. 1998)
[88] *Bridge*, 553 U.S. at 647; *United States v. Pharis*, 298 F.3d 228, 234 (3rd Cir. 2002).

"promote, manage, establish, carry on, or facilitate ... any unlawful activity," and thereafter engaging in the promotion of that unlawful activity.[89]

Contrary to Defendants' baseless assertions that Plaintiffs' allegations fail to meet the requisite pleading standard for fraud under 9(b), the complaint includes specific allegations about the use of mail or wire and/or travel to perpetuate their illegal scheme. Plaintiffs' have alleged numerous instances where mail was used to carry out the Enterprise or where travel to meetings occurred, satisfying the pleading requirement.[90] These allegations are sufficient to establish predicate acts and a pattern of racketeering activity.

D. Plaintiffs Have Sufficiently Pled a RICO Conspiracy Claim

Defendants have not raised any independent basis to dismiss the RICO conspiracy claim (beyond its arguments against the underlying RICO claim). As the complaint alleges all of the elements of its RICO enterprise claim under 18 U.S.C. § 1962(c), the RICO conspiracy claim should also stand.

III. *Plaintiffs Adequately Pled Claims under Illinois and New Mexico Law*

To allege a violation of the Illinois Consumer Fraud Act, ("ICFA")[91], Plaintiffs must plead that: (1) the defendants engaged in an unfair and/or deceptive act or practice; (2) the defendants intended for the plaintiffs to rely on the unfair and/or deceptive act or practice; (3) the unfair and/or deceptive act or practice occurred in the course of conduct involving trade or commerce; and (4) the plaintiffs suffered actual damage proximately caused by the unfair and/or deceptive act or practice.[92] An act or practice is unfair if it: (1) offends public policy; (2) is

[89] 18 U.S.C. § 1952(a).
[90] *See* Compl. ¶¶ 101, 106, 115, 169.
[91] 815 ILCS 505/1, *et. seq.*
[92] *Zekman v. Direct Am. Marketers, Inc.*, 182 Ill.2d 359, 373 (1998)(Deceptive acts or practices include, *inter alia*, the use or employment of any deception, misrepresentation, fraud, or concealment, suppression, or omission of any material fact.)

immoral, unethical, oppressive, or unscrupulous; or (3) causes substantial injury to consumers.[93]

To state a claim under the New Mexico Unfair Practices Act ("NMUPA")[94], a complaint must allege: (1) the defendant made an oral or written statement, a visual description or a representation of any kind that was either false or misleading; (2) the false or misleading representation was knowingly made in connection with the sale, lease, rental, or loan of goods or services in the regular course of the defendant's business; and (3) the representation was of the type that may, tends to, or does deceive or mislead any person.[95]

[T]he NMUPA does not require that the defendant's conduct actually deceive a consumer; it permits recovery even if the conduct only 'tends to deceive.'[96] Accordingly, a claimant need not prove reliance upon a defendant's deceptive conduct in this context.[97] "The 'knowingly made' requirement is met if a party was actually aware that the statement was false or misleading when made, or in the exercise of reasonable diligence should have been aware that the statement was false or misleading."[98] Actual damages are not required.[99]

Here, Plaintiffs' complaint sufficiently alleges each element of the respective claims. Just as the complaint adequately pleads a pattern of racketeering under RICO, it pleads deceptive conduct under Illinois and New Mexico statutes.[100] Plaintiffs have suffered an actual loss by purchasing a drug for a use that was neither approved nor shown to be efficacious in pediatric

[93] *Robinson v. Toyota Motor Credit Corp.*, 201 Ill.2d 403, 417-18 (2002)("All three criteria do not need to be satisfied to support a finding of unfairness.")
[94] N.M. Stat. § 57-12-1, *et seq.*
[95] *Lohman v. Daimler-Chrysler Corp.,* 142 N.M. 437, 439 (N.M. Ct. App. 2007).
[96] *Id.* at 444.
[97] *Id.*
[98] *Guidance Endodontics, LLC v. Dentsply Intern., Inc*., 728 F.Supp.2d 1170, 1186 (D. New Mexico 2010).
[99] *Pedroza v. Lomas Auto Mall, Inc.,* 663 F.Supp.2d 1123 (D. New Mexico 2009)(following the New Mexico Supreme Court's interpretation, purchasers were not required to prove actual loss or causation to recover statutory damages under UPA).
[100] See Compl ¶¶ 3,4, 7, 54, 85, 87, 146, 147, 190 – 193, 202 – 206.

patients.[101]

Plaintiffs establish the proximate cause element by proving that Defendants misrepresented and/or omitted material information – the type of information upon which a physician, patient or buyer would be expected to rely in making a decision to prescribe, use or purchase Celexa or Lexapro.[102] The very case Defendants rely upon[103] actually supports Plaintiffs' claim - *i.e.*, "it is enough that the statements by the defendant be made with the intention that it reach the plaintiff and influence his action."[104] Here, Defendants' unlawful promotion and marketing of Celexa/Lexapro for pediatric uses resulted in the denial of Plaintiffs' and other class members' opportunity to make fully informed decisions about whether and how to include Celexa/Lexapro on their formularies and caused them to pay for more prescriptions than Plaintiffs would have absent Defendants' unlawful conduct.[105]

To prevail on a claim of unjust enrichment under Illinois law, "a plaintiff must present evidence that the defendant unjustly retained a benefit to the plaintiff's detriment and that the defendant's retention of that benefit violated fundamental principles of justice, equity, and good conscience."[106] In New Mexico, however, to prevail on an unjust enrichment claim, a plaintiff only must show that (1) another has been knowingly benefitted at one's expense (2) in a manner such that allowance of the other to retain the benefit would be unjust.[107]

Plaintiffs' complaint alleges that Defendants have been unjustly enriched by [their] fraudulent acts and omissions; that "in exchange for payments made for Celexa/Lexapro,

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[101] Compl. ¶¶ 6, 7, 98, 141, 148, 149, 196.
[102] Compl. ¶¶ 7, 85, 86, 95, 147. See also, *See In re In re Avandia Mktg., Sales Practices & Products Liab. Litig.*, 2013 WL 5761202, at * 10 (holding allegations of proximate causation sufficient as to the Illinois Consumer Fraud Act for same reasons RICO allegations were sufficient.)
[103] *De Bouse v. Bayer AG*, 235 Ill.2d 544, 560 (2009).
[104] *Id.* at 555.
[105] Compl. ¶¶ 6, 7, 141, 146 – 149.
[106] *See BancInsure v. BMB Elec. Co.*, 2004 WL 765124, at *3 (N.D. Ill. Apr. 8, 2004) (quoting *HPI Health Care Servs., Inc. v. Mt. Vernon Hosp., Inc*., 545 N.E.2d 672, 679 (Ill. 1989)).
[107] *Ontiveros Insulation Co., Inc. v. Sanchez,* 3 P.3d 695, 698 (N.M.Ct.App. 2000).

Plaintiffs and Class members expected the drugs to be safe and medically effective for the conditions it was prescribed; Plaintiffs paid a higher price than would have been paid;" and that "Defendants received billions of dollars in profits, representing ill-gotten gains" through voluntarily accepting and retaining these payments with full knowledge and awareness of their fraudulent conduct.[108] Otherwise stated, Plaintiffs have sufficiently pled that they conferred a monetary benefit on Defendants, that Defendants appreciated the benefit, and that Defendants retained the benefit under inequitable circumstances.

Remarkably, Defendants also assert that Plaintiffs' complaint "does not adequately plead that Defendants' benefitted *at Plaintiffs' expense,*" yet they fail to acknowledge that TPPs are the "intended victim" and suffer at *their expense* from the illegal scheme.[109] (emphasis added) At this stage, Plaintiffs have sufficiently pled a claim under both Illinois and New Mexico law for violations of the respective consumer fraud statutes and for unjust enrichment.

In addition, Defendants' assertion that the claims under the consumer fraud statutes for states other than Illinois and New Mexico should be dismissed is premature at this stage of the litigation. The issues applicable to choice of law and standing to bring claims on behalf of absent class members are not appropriately addressed prior to class certification and certainly not within the gambit of a Rule 12(b)(6) motion. Defendants cite no authority where potential issues concerning choice of law are properly addressed in the context of a Rule 12(b)(6) motion.[110] Accordingly, at this early stage of the proceedings, it would be premature to narrow the scope of

[108] See Compl. ¶¶ 141, 223-226.

[109] *In re Neurontin Mktg. and Sales Practices Litig.* 712 F.3d 21, 38-39 (1st Cir. 2013)(here [defendant] has always known that, because of the structure of the American health care system, physicians would not be the ones paying for the drugs they prescribed …those payments came from [plaintiff] and other TPPs.")

[110] *See In re Bayer Corp. Combination Aspirin Prod. Mktg. & Sales Practices Litig.*, 701 F.Supp.2d 356, 378 (E.D.N.Y. 2010), *citing, Pirelli Armstrong Tire Corp. v. Walgreen Co.*, 2009 WL 27777995, * 3 (N.D. Ill Aug. 31, 2009); *Whitson v. Bumbo*, 2008 WL 2080855, * at 1 (N.D. Cal. 2008)(holding that defendant's argument that plaintiff failed to state a claim because of variations betweeen state laws was "raised prematurely" and would "be more timely and appropriately addressed …if and when plaintiff moves for class certification").

state laws pursuant to which Plaintiffs can pursue their claims.

IV. *If the Court does not deny Defendants' Motion to Dismiss in its entirety, the Court should permit amendment of the Complaint.*

Defendants' argument that the Court should dismiss all claims with prejudice and not permit any amendment is incorrect. As set forth above, the Court should deny Defendants' Motion to Dismiss in its entirety. If the Court does not deny the motion, however, it should "freely give leave" under Fed.R.Civ.P. 15(a)(2) for Plaintiffs to amend.[111]

CONCLUSION

For the reasons set forth above, Defendants' Motion to Dismiss should be denied.

Dated: June 13, 2014

Respectfully submitted,

/s/ Thomas G. Shapiro

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[111] In general, Courts will allow a plaintiff to file an amended complaint if it is possible to rehabilitate any pleading deficiencies identified.

CERTIFICATE OF SERVICE

I, Thomas Shapiro, hereby certify that, on June 13, 2014, I electronically filed the foregoing document using the CM/ECF system, which shall send electronic notification to counsel of record.

/s/ Thomas G. Shapiro
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