

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE: ACTIQ SALES AND MARKETING PRACTICES LITIGATION	:	CIVIL ACTION NO. 07-4492
	:	
	:	

AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, DISTRICT COUNCIL 47 HEALTH AND WELFARE FUND, ET AL.,	:	
Plaintiffs,	:	CIVIL ACTION NO. 09-431
	:	
	:	
	:	
	:	
	:	

CEPHALON, INC.,	:	
Defendant.	:	

MEMORANDUM AND ORDER

Tucker, J.

August , 2009

Presently before this Court is Defendant’s Motion for Judgment on the Pleadings as to the Racketeer Influenced and Corrupt Organizations Act (“RICO”) Counts in the American Federation of State, County, and Municipal Employees’ (“AFSCME”) Complaint. For the reasons set forth below, the Court will deny Defendant’s Motion.

BACKGROUND

On January 29, 2009, Plaintiffs instituted this action to recover damages for payments to Defendant Cephalon, Inc. as a result of Defendant’s allegedly unlawful marketing of the drugs Provigil and Gabitril for unapproved, off-label uses. Compl. ¶ 1. Each named Plaintiff is a health and welfare trust fund which provides medical benefits, including prescription coverage, to its members and their dependents. Compl. ¶¶ 4-5. Plaintiffs allege that they have been injured through excessive prescription costs for the drugs Provigil and Gabitril, all resulting from an allegedly deceptive marketing scheme.

Defendant Cephalon is a pharmaceutical company that manufactures and sells several prescription drugs, including Provigil and Gabitril. Compl. ¶ 7. Provigil is a prescription drug approved by the United States Food and Drug Administration (“FDA”) to treat excessive daytime sleepiness associated with narcolepsy. Compl. ¶ 23. Gabitril is an FDA approved anti-epilepsy drug indicated as adjunctive therapy for

adults and children twelve (12) years of age or older in the treatment of partial seizures. Compl. ¶ 25.

Plaintiffs contend that because Defendant was aware that the market potential for Provigil and Gabitril was limited, Defendant engaged in an unlawful marketing scheme to promote off-label uses of these drugs. Plaintiffs argue that Defendant sought to accomplish this by providing financial incentives to physicians that constituted kickbacks for prescribing and speaking in favor of unapproved uses, as well as doubling its sales force between 2001 and 2002. Compl. ¶¶ 28-31. Plaintiffs further allege that Defendant pays its speakers one thousand, five hundred (\$1500) per lecture and hosts lectures at attractive locations, along with smaller programs at high-end restaurants. Compl. ¶¶ 47-50. According to Plaintiffs, while presentations note some side effects of these drugs, more serious side effects and severe results from various studies are falsely omitted. Compl. ¶¶ 54-55. Plaintiffs note that the FDA reprimanded Defendant for dissemination of false or misleading materials on the drug Provigil, and that the FDA required Defendant to add a bolded warning on the Gabitril label advising doctors of the association between Gabitril and seizures in non-epileptic patients. Compl. ¶¶ 42, 45. Consequently, Plaintiffs claim that Defendant has improperly promoted the medically unnecessary use of Provigil and Gabitril, which resulted in improper billing to Plaintiffs. Compl. ¶¶ 46.

In response, Defendant relies on this Court's May 22, 2009 decision where it concluded that the allegations in the complaint captioned *In Re Actiq Sales and Marketing Practices Litigation* were insufficient to establish a structure for the RICO enterprise that the Actiq plaintiffs alleged was created to promote the drug Actiq for medically unnecessary uses. After granting Defendant's Motion for Judgment on the Pleadings, the Court consolidated the Actiq complaint with the AFSCME complaint. Defendant now argues that the RICO counts in the AFSCME complaint should be dismissed for the same reasons, namely that the two complaints are virtually identical, and therefore the allegations in the AFSCME complaint must also be found insufficient to establish a structure for a RICO enterprise.

LEGAL STANDARD

A motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) is subject to the same standard of review applicable to a motion to dismiss under Rule 12(b)(6). *See Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). In considering a motion to dismiss under Rule 12(b)(6), the Court must accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, viewing them in the light most favorable to the plaintiff. *Taliaferro v. Darby Twp. Zoning Bd.*, 458 F.3d 181, 188 (3d Cir. 2005). A Rule 12(b)(6) motion should be granted only if it appears to a certainty that no relief could be granted under any set of facts that could be proved. Id.

Thus, the allegations in the complaint must transcend the speculative, and instead, state a claim to relief that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) Applying the plausibility standard, a court may accept as true only well-pleaded allegations, which does not include bald assertions or legal conclusions. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 2007). When evaluating allegations, a court must determine whether the allegations are well-pleaded allegations, such that the allegations are more than “merely consistent with a defendant’s liability.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). Essentially, the allegations in the complaint must “raise a right to relief above the speculative level,” and state a claim that is plausible on its face. *Twombly*, 550 U.S. at 555. “The issue is not whether a plaintiff will ultimately prevail but whether he or she is entitled to offer evidence to support the claims.” *Oatway v. Am. Int’l Group, Inc.*, 325 F.3d 184, 187 (3d Cir. 2003).

DISCUSSION

18 U.S.C. § 1962(c) makes it unlawful for any person employed by or associated with any enterprise to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity. In order to state a RICO claim under 18 U.S.C. § 1962, a plaintiff must first demonstrate statutory standing under RICO. A civil RICO plaintiff is required “to make two related but analytically distinct threshold showings: (1) that the plaintiff suffered an injury to business or property; and (2) that the

plaintiff's injury was proximately caused by the defendant's violation of 18 U.S.C. § 1962." *Maio v. Aetna, Inc.*, 221 F.3d 472, 483 (3d Cir. 2000). If statutory standing is met, plaintiff must then allege facts to establish the following: (i) the existence of an enterprise engaged in or affecting interstate commerce; (ii) that the defendant was employed by or associated with the enterprise; (iii) that the defendant participated, directly or indirectly, in the conduct or the affairs of the enterprise; and (iv) that the defendant participated through a pattern of racketeering activity that must include the allegation of at least two racketeering acts. *See Sedima, S.P. R. L. v. Imrex Co.*, 473 U.S. 479, 496 (1985).

Here, the Court is satisfied that the elements of statutory standing are met. Therefore, we move directly into the discussion of the existence of an enterprise.

A RICO enterprise is defined as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). To establish the existence of an enterprise, or an association-in-fact enterprise, a plaintiff must show evidence of an ongoing organization, formal or informal; evidence that the various associates of the enterprise function as a continuing unit; and evidence that the enterprise has an existence separate and apart from the pattern of activity in which it engages. *United States v. Ricobene*, 709 F.2d 214, 221 (3d Cir. 1983).

Courts have determined that an association-in-fact enterprise can satisfy the first element requiring the existence of an enterprise, however, there must be allegations allowing an inference that some sort of structure exists for decision-making, whether hierarchical or consensual, or some mechanism for controlling and directing group affairs on a continuous rather than ad hoc basis. *Ricobene*, 709 F.2d at 222. Yet, allegations which merely state that individual members performed particular roles and were aware of each other's activities, without more, is insufficient to plead the existence of an enterprise. *Seville*, 742 F.2d at 790 n. 5). Essentially, while Plaintiffs need not allege facts in their Complaints sufficient to prove the existence of an enterprise, at a minimum, Plaintiffs must identify the enterprise and provide details about its structure in more than vague terms. *Id.*

Under the rules of notice pleading, a plaintiff need not specifically allege all of the facts necessary to

establish these three enterprise elements in the complaint. *Seville Indus. Mach. Corp. v. Southwest Mach. Corp.*, 742 F.2d 786, 790 (3d Cir. 1984). However, the allegations of the complaint must not affirmatively negate any of these elements. *Id.* at 790. Further, there must be sufficient allegations to allow the existence of the three elements to be inferred. *See Lorenz v. CSX Corp.*, 1 F.3d 1406, 1412 (3d Cir. 1991).

Relying on *Boyle v. United States*, 129 S. Ct. 2237 (2009), Defendant argues that Plaintiffs have not provided sufficient allegations of an organizational structure for the alleged enterprise. In response, Plaintiffs emphasize the *Boyle* Court's holding that while an association-in-fact enterprise must have a structure, it is not required to have a structure beyond that inherent in the pattern of racketeering activity in which it engaged. *Boyle*, 129 S. Ct. at 2244-46.

According to the *Boyle* Court, "an association-in-fact enterprise must have at least three structural features: a purpose, relationships among those associated with the enterprise, and longevity sufficient to permit these associates to pursue the enterprise's purpose." *Boyle*, 129 S. Ct. at 2244. While the *Boyle* Court reiterated certain principles established in *United States v. Turkette*, 452 U.S. 576, 583 (1981), namely that "the existence of an enterprise is an element distinct from the pattern of racketeering activity and that proof of one does not necessarily establish the other," it noted the recognition in *Turkette* that "the evidence used to prove the pattern of racketeering activity and the evidence establishing an enterprise may in particular coalesce." Specifically, the *Boyle* Court found that the language in the RICO statute was not intended to mean that "the existence of an enterprise may never be inferred from the evidence showing that persons associated with the enterprise engaged in a pattern of racketeering activity."

Using the *Boyle* Court's reasoning, Plaintiffs argue that their complaint sets forth sufficient allegations to establish the three structural features necessary for an association-in-fact, and that a hub and spoke organizational, decision-making structure is visible, or can be inferred. This Court finds Plaintiffs' arguments persuasive.

Plaintiffs' complaint provides allegations which identify the structure in question in more than vague terms, as well as particular members of the enterprise and details regarding the actual operation of the

enterprise. Defendant argues that Plaintiffs' Complaint is "virtually identical" to the Actiq Complaint, however, this Court disagrees. While Plaintiffs' complaint unquestionably contains some allegations that are similar to the Actiq complaint, the gradations in Plaintiffs' complaint are sufficient to nudge the allegations over the line from that which is merely "speculative" and "conceivable," to that which states "a claim to relief that is plausible on its face." *Twombly*, 127 S. Ct. at 1974. Here, Plaintiffs have not only alleged a decision-making structure that goes beyond surface descriptions of the enterprise and associate roles, 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 are created to allegedly mislead physicians about the efficacy of Provigil and Gabitril for certain conditions, and how sales representatives were utilized in the course of Defendant's national marketing scheme. Furthermore, Plaintiffs have provided sufficient allegations to address the three structural elements that the *Boyle* Court required.

Defendant is adamant that *Boyle* does not relieve Plaintiffs of the burden to adequately plead the existence of a structure, and that to infer a structure from allegations that Defendant engaged in off-label promotion and had relationships with speakers is implausible. Yet, it is not merely the allegations of off-label promotion or outside relationships from which an association-in-fact enterprise can be inferred. Rather, an association-in-fact can be inferred from such allegations in conjunction with Plaintiffs' allegations regarding deceptive and misleading marketing tactics allegedly utilized by Defendant, such as omitting critical information about side-effects, training speakers and representatives to continue omitting such information in presentations, and allegedly re-directing marketing strategies away from FDA regulatory oversight. Taken together, this Court finds that Plaintiffs' allegations state a claim for relief that is plausible on its face, and therefore, will deny Defendant's Motion.

