UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL No. 2804**
	)	**Case No. 1:17-md-2804**
THIS DOCUMENT RELATES TO:	)	**Hon. Dan Aaron Polster**
The Muscogee (Creek) Nation v. Purdue Pharma L.P., et al., Case No. 1:18-op-45459-DAP	)	

THE GENERIC MANUFACTURER DEFENDANTS' OBJECTIONS TO THE APRIL 1, 2019 REPORT AND RECOMMENDATION ON THEIR MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

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I. INTRODUCTION

The Generic Manufacturers, which consist of Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. ("Actavis Pharma"), Watson Laboratories, Inc. ("Watson Laboratories"), Allergan Finance LLC ("Allergan),[1] Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC,[2] KVK-Tech, Inc. ("KVK"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Generic Manufacturers"), submit these joint objections to Magistrate Judge David A. Ruiz's April 1, 2019 Report and Recommendation ("R&R" or "Report") on their Motion to Dismiss ("Motion") Plaintiff's First Amended Complaint ("FAC").[3]

The R&R correctly found that Plaintiff's false marketing claims against the Generic Manufacturers based upon the failure to warn or communicate about the risks of opioids are preempted as a matter of controlling Supreme Court and Sixth Circuit law. (*See* R&R, 42); *see, e.g.*, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 930-36 (6th Cir. 2014). The R&R also correctly recognized the plausibility of Generic Manufacturers' "business model dictates that they engage in no advertising or marketing activities." (R&R, at 35, n.29.) Indeed, this is consistent with the well-settled

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[1] Although Plaintiff identifies Allergan Finance, LLC ("Allergan") as a Generic Marketing Manufacturer Defendant (FAC ¶157), Allergan is not actually responsible for marketing any generic opioid medicines. Nevertheless, Allergan joined the Generic Manufacturers' Motion to Dismiss Plaintiff's First Amended Complaint in light of Plaintiff's mistaken allegation, which must be taken as true. Allergan joins these Objections for the same reasons, and reserves all rights to argue that it is not properly included as a Generic Marketing Manufacturer Defendant.

[2] On April 12, 2019, this Court granted plaintiff's motion to substitute Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals of New York, LLC, for Amneal Pharmaceuticals, Inc. ("API"), which the Court has dismissed from the litigation. (Doc. #110, PageID #:1806.) Accordingly, Amneal Pharmaceuticals, LLC, and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal Defendants"), join this objection subject to the Court's preservation of all their jurisdictional and other defenses, as memorialized at CMO No. 1. (Doc. #232, PageID #: 1088.)

[3] To avoid duplication, the Generic Manufacturers adopt and incorporate herein the arguments made in the Objections brought by the Brand Manufacturers to the R&R ("Brand Manufacturers' Objections"). Additionally, while Generic Manufacturer Defendants will not repeat their previous arguments as to why the FAC should be dismissed as to them, including all preemption arguments made in their prior briefing, Generic Manufacturers do not waive the arguments set forth therein.

principle that generic manufacturers "compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete." *New York ex rel. Schneiderman v. Actavis, PLC*, No. 14-cv-7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014), *aff'd*, 787 F.3d 638 (2d Cir. 2015). For this very reason, the FAC does not identify any specific false or misleading statement by any Generic Manufacturer in Oklahoma—much less one connected to any tribal prescriber, resident, or harmful opioid prescription.

Nonetheless, despite the failure to plead such basic facts, the Report recommends denying the Generic Manufacturers' Motion with respect to the false marketing claims based entirely upon conclusory, group-pled allegations against "the class denominated 'Marketing Manufacturer Defendants.'" (R&R, at 42-43). This conclusion is wrong as a matter of law. Under *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and Rule 9(b), Plaintiff may not rely upon group pleading, but must plead specific acts of false or misleading promotion by each Generic Manufacturer—which, given that they do not promote the safety or efficacy of their opioid medicines, Plaintiff has not done and cannot do. As a result, the false marketing claims against the Generic Manufacturers should be dismissed.

Likewise, the Report recommends denying the failure to prevent diversion claims against the Amneal Defendants and KVK—the so-called "Diversion Manufacturer Defendants" ("DMDs")—based entirely upon group-pled allegations. This, too, is erroneous. Plaintiff does not plead any facts demonstrating that any Generic Manufacturer failed to report a suspicious order, much less that any such order caused the Plaintiff any harm. Plaintiff, in fact, offers no facts whatsoever about their suspicious-order-monitoring practices.

Put simply, the instant Motion presents the first opportunity in this MDL for the Court to address directly MDL plaintiffs' efforts to impose liability on manufacturers for the sale of generic opioids. There is simply no basis at law for Plaintiffs' extremely ambitious claims against manufacturers of generic opioids, given that that such medicines (1) are not promoted and (2) are subject to a federally imposed duty that prohibits generic manufacturers from providing risk disclosures that are different than those of their brand counterparts. The Court should not adopt the R&R to the extent that it recommends that the Generic Manufacturers' Motion be denied, because Plaintiff has failed to allege sufficient facts to state its claims in the FAC against the Generic Manufacturers.

II. STANDARD OF REVIEW

On a dispositive motion, including a motion to dismiss, the district court's review of a magistrate judge's report and recommendation is *de novo*. *See* Fed. R. Civ. P. 72(b)(3) ("The district judge must determine *de novo* any part of the magistrate judge's disposition [of a dispositive motion] that has been properly objected to."); *Allen v. Int'l Truck & Engine Corp.*, No. 3:07CV361, 2010 WL 749655, at *2 (S.D. Ohio Feb. 26, 2010) ("Whenever it rules on objections to the report and recommendations of a Magistrate Judge on a dispositive motion, such as a motion to dismiss, the District Court must apply a *de novo* standard of review.").

To survive a motion to dismiss under Rule 12(b)(6), Plaintiff must allege factual allegations that transcend the "speculative," "conceivable," and "possible," and must "state a claim to relief that is plausible on its face." provide "more than labels and conclusions . . . ." *Twombly*, 550 U.S. at 555. It is beyond dispute that "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are insufficient. *Ashcroft v. Iqbal*, 556 U.S. at 678. Moreover, because Plaintiff's claims rest on an alleged fraudulent campaign to market opioid medicines and a failure to report suspicious orders (FAC ¶¶ 4, 14, 326, 401),

Plaintiff must satisfy Rule 9(b)'s particularity standard. *See Frank v. Dana Corp.*, 547 F.3d 564, 570 (6th Cir. 2008). To do so, Plaintiff must plead the "who, what, when, where, and how" of any alleged fraud, *Republic Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 256 (6th Cir. 2012), including "the time, place, and content of the alleged misrepresentations," the "fraudulent scheme," "fraudulent intent," and "injury resulting from the fraud." *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006).

III. OBJECTIONS

A. THE R&R FAILS TO APPLY THE *TWOMBLY/IQBAL* STANDARD WITH RESPECT TO THE CLAIMS AGAINST THE GENERIC MANUFACTURERS AND, INSTEAD, RELIES UPON IMPROPER GROUP PLEADING.

The FAC falls far short of satisfying the federal pleading standards articulated under Rule 8 of the Federal Rules of Civil Procedure, as interpreted by *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). Particularly troubling here is Plaintiff's reliance on group pleading, which fails to provide the requisite "fair notice" of the claim being asserted against each Generic Manufacturer and the "grounds upon which it rests." *Twombly*, 550 U.S. at 555 (citations omitted); *see also Iqbal*, 556 U.S. at 678 (requiring facts showing each defendant has acted unlawfully). Indeed, it is well-settled that "conclusory allegations of collective, unspecified, and undifferentiated wrongdoing is not sufficient: 'vaguely lump[ing] all defendants together without providing any factual allegations that specify separate acts' fails to satisfy the *Iqbal/Twombly* standard." *Kurek v. Ohio Dept. of Develop. Disabilities*, No. 3:16CV623, 2017 WL 1555930, at *6 (N.D. Ohio Jan 20, 2017), *reconsideration denied sub nom. Kurek v. Ohio Dep't of Dev. Disabilities*, No. 3:16CV623, 2017 WL 2257744 (N.D. Ohio May 23, 2017) (internal quotations omitted)).

The Sixth Circuit has repeatedly applied this rule. In *Darvocet*, for instance, the Sixth Circuit dismissed claims against generic drug manufacturers because the plaintiffs did not identify

what specific generic manufacturers did what and provided "no factual basis" for their alleged claims and relied on "conclusory allegation[s]." *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 756 F.3d at 932; *see also Hoover v. Langston Equip. Assocs., Inc.*, 958 F.2d 742, 745 (6th Cir. 1992) (applying rule). Plaintiff's failure to identify which defendant is alleged to be responsible for which act or omission is fatal to its claims. *See Atuahene v. City of Hartford*, 10 Fed. App'x 33, 34 (2d Cir. 2001) ("By lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [plaintiff's] complaint failed to satisfy [Rule 8's] minimum standard.").

Here, the R&R failed to apply these principles. This failure is most evident in footnote 29, which recognizes that it is "plausible" that Generic Manufacturers do not market or promote their generic opioid medicines, but then goes on to criticize Generic Manufacturers for making no effort in their briefing to distinguish among themselves and to further suggest that Generic Manufacturers "will have the opportunity to individuate and clarify their status and what activities they have engaged as discovery progresses." (R&R, at 35, n.29.) That analysis turns the pleading standard on its head—and underscores the failures in the FAC. It is not Generic Defendants' duty to plead differentiating facts about themselves (and the FAC offers none), but Plaintiff's duty to plead facts to plausibly state false marketing or other claims against ***each Generic Defendant***.

As described below, Plaintiff has failed to satisfy its burden here as to its two sets of legal claims: (a) false marketing claims; and (b) failure to prevent diversion claims.[4] The FAC alleges no facts—let alone particularized facts—connecting each Generic Defendant to any purported unlawful conduct through its purported false marketing and diversion theories. Because Plaintiff failed to identify any such particularized facts in its pleadings, the R&R is flawed.

[4] The failure to prevent diversion claims are asserted only against the Amneal Defendants and KVK.

1. Plaintiff's False Marketing Claims (Counts I, III, IV, V, VI, And X) Fail to Satisfy *Twombly/Iqbal*

Plaintiff's claims are largely premised on allegedly fraudulent marketing activity. (FAC ¶¶ 358, 366-67 (Count I), 411-414 (Count III), 424 (Count IV), 436-438 (Count V), 450 (Count VI), 486 (Count X).) But the FAC does not contain a single false or misleading statement attributable to a Generic Manufacturer about one of its medicines—much less one that reached an Oklahoma doctor, a tribal citizen who received an opioid prescription, or Plaintiff itself.

The only specific, differentiating allegations against Generic Manufacturers are those involving their respective states of incorporation/organization and principal places of business. (*See* FAC, ¶¶ 33-36, 37, 38, 39, 41, 42.) Of course, Plaintiff's conclusory claim that each Generic Manufacturer "manufactured and distributed substantial amounts of name brand prescription opioids and their generic equivalents...." (FAC, ¶¶ 33-38 (as to Actavis LLC, Actavis Pharma, Watson Laboratories, Allergan, and Teva USA), ¶¶ 39, 41-42 (as to API and KVK-Tech)), is insufficient to plead any false marketing and to satisfy the pleading standards established by *Twombly* and *Iqbal*. The facial plausibility standard requires Plaintiff to plead ***specific*** facts of wrongdoing implicating ***each named Generic Defendant***. *See Iqbal*, 556 U.S. at 678 ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."); *In re Darvocet, Darvon, & Propoxphene, Prods. Liab. Litig.*, 756 F.3d at 932 (rejecting conclusory allegation that "Generic Manufacturers failed to update their warnings" because it is "akin to Iqbal's conclusory allegation that Ashcroft acted out of discriminatory motive" and "to Twombly's conclusory allegation that Bell Atlantic conspired with its competitors.").

The Magistrate Judge correctly held that Plaintiff's failure to warn and communicate claims against the Manufacturer Defendants are preempted (R&R at 42), yet found that Plaintiff

had pled "other [affirmative] marketing-related allegations that support the state law claims against the Generic Manufacturers ***as members of the class denominated 'Marketing Manufacturer Defendants***.'" (*Id.* (emphasis added); *see also id.* at 27 (recommending that group pleading is sufficient and citing allegations against "Marketing Manufacturer Defendants.").) This reliance upon group pleading is improper. Critically, the R&R does not identify a well-pled allegation showing that any Generic Manufacturer made a false or misleading statement about their medicines in Oklahoma. And for good reason—they do not promote them. *Actavis, PLC*, 2014 WL 7015198, at *27.

Given that plausibility is "a context-specific task," *Ashcroft*, 556 U.S. at 679, the R&R erred by failing to recognize the utter absence of key details regarding any false or misleading statements attributable to the Generic Manufacturers in Oklahoma. Both the R&R and the FAC fail to identify:

- A single false and/or misleading statement made by each Generic Manufacturer to a consumer or physician concerning the promotion of their products;
- A single Oklahoma doctor that was misled into writing an opioid prescription as a result of a false or misleading statement by a Generic Manufacturer;
- A single opioid prescription in Oklahoma that was written because of a false or misleading statement by each Generic Manufacturer;
- A single tribal resident who received a harmful opioid prescription because of some false or misleading statement by each Generic Manufacturer; or
- A single third-party statement about opioids attributable to any Generic Manufacturer.

Plaintiff cannot bring false marketing claims against the Generic Manufacturers without these basic facts. And by failing to require Plaintiff to plead this type of basic information, as required by *Twombly* and *Iqbal* and their progeny, the R&R deviated from controlling law.

2. Plaintiff's Diversion Theory Against the Amneal Defendants And KVK-Tech Fails to Satisfy *Twombly/Iqbal*.

The FAC lacks factual allegations to satisfy key elements of Plaintiff's state law diversion claims. Specifically, the FAC does not identify any misconduct, causation, or a cognizable injury, to put the Amneal Defendants and KVK-Tech on notice that each engaged in purported impermissible "diversion." Indeed, the only allegations asserted against those Defendants, by name, are general allegations where Plaintiff (1) labels them in various categories, and (2) identifies their purported principal places of business, where they are authorized to conduct business, and where they allegedly have sold and/or distributed their products. (*See, e.g.*, FAC, ¶¶ 38, 39, 41, 42, 157.) This is insufficient to show any improper conduct regarding diversion efforts.

To try to conceal the absence of any wrongful conduct, the DMDs are grouped together with a handful of other Manufacturing and/or other "Diversion" Defendants. As explained above, though, this type of group pleading is improper, as it does not inform each defendant of its purported actionable conduct and certainly does not state a plausible claim. *See, e.g. Seni ex rel. Ciber, Inc. v. Peterschmidt*, No. 12-CV-00320-REB-CBS, 2013 WL 1191265, at *3 (D. Colo. Mar. 22, 2013).[5] For example, while Plaintiff calls out alleged acts and/or omissions by other specific "Diversion" Defendants, it merely alleges vague, conclusory, and non-specific allegations about

[5] The court in *Seni* explained as follows:

> Even when the enhanced pleading requirements of Rule 9(b) are not at issue, such group pleading does not provide the specificity required by *Twombly*, *Iqbal*, and related cases. Such general group pleading is not sufficient to present a plausible claim that a particular individual has particular knowledge, a particular motivation, or took a particular action. The fact that one individual had certain knowledge or motivation or took a certain action does not create an assumption or presumption that others in a group with that individual share that knowledge or motivation or took the same action. Group pleading seeks to state a claim against individuals based on such assumptions or presumptions. In the context of the claims asserted in the plaintiff's complaint, more detail is required to state a claim against an individual.

Id. (citing *Robbins v. Oklahoma*, 519 F.3d 1242, 1249-50 (10th Cir. 2008)).

the DMDs, without actually putting them on notice of any instance of alleged wrongful diversion conduct each DMD purportedly committed.

In recommending that plaintiff met its pleading obligations, the R&R utilized the same improper group analysis that defines the FAC. (*See* R&R, 25-27.) Contrary to the conclusion reached in the R&R, the FAC fails to allege any actionable, well-pleaded diversion conduct, including:

- Specific duties the DMDs had to the Nation and its citizens pursuant to federal and Oklahoma law, including the federal and state controlled substances acts, regarding purported failures to maintain effective controls against diversion;
- The suspicious orders each DMD allegedly failed to report or otherwise monitor and how such a purported failure actually damaged Plaintiff;
- A specific instance of diversion by any particular DMD that warrants liability for the entire spectrum of costs the Nation claims to have incurred as a result of misuse and abuse of opioids in the Nation;
- Factual allegations showing that, had the DMDs reported specific, alleged suspicious orders to the DEA then the corresponding report(s) would have led to an enforcement action and that enforcement action would have, in fact, led to a lowering of the national production quotas and/or averted prescription opioid diversion and averted corresponding societal harms to the Nation;
- A single suspicious order based on unusual size, deviation from a normal pattern, or in unusual frequency that any DMD knew about and was a part of, or even such an order that entered and affected the Nation that would have violated 21 C.F.R. 1301.74(b); or
- Allegations of which types of orders were suspicious or which of the three "suspicious order" categories (identified in 21 C.F.R. 1301.74(b)) such orders allegedly fell into.

Put simply, the FAC is insufficient under federal pleading standards and does not support any claim against the purported "DMDs." *Nevolas v. Boston Sci. Corp.*, No. CIV-15-894-M, 2016 WL 1532259, at *4 (W.D. Okla. Apr. 15, 2016), *appeal dismissed* (Aug. 26, 2016); *Ross v. University of Tulsa*, No. 14-CV-484-TCK-PJC, 2015 WL 4064754, *2 (N.D. Okla. July 2, 2015).

B. PLAINTIFF DOES NOT COME CLOSE TO SATISFYING RULE 9(B)'S PLEADING STANDARD FOR FRAUD-BASED CLAIMS.

Even if Plaintiff had pled sufficient facts to satisfy *Iqbal* and *Twombly* (and it has not), Plaintiff has not come close to pleading the details of any specific fraudulent misrepresentations, conduct, and/or other actions against each Generic Manufacturer. To comply with Rule 9(b), it is not enough to make conclusory, unsupported statements about alleged fraudulent conduct on the part of these defendants; instead, Plaintiff must alleged specific details, including what specific false or misleading statements were made, when, by whom, and where. *Republic Bank & Tr. Co.*, 683 F.3d at 256; *Hoover*, 958 F.2d at 745; *McCutchen v. CSAA Fire & Cas. Ins. Co.*, No. 17-CV-256-JHP-JFJ, 2018 WL 312719, at *1 (N.D. Okla. Jan. 5, 2018).

The R&R acknowledged that Rule 9(b) applies (R&R at 24-25), yet never applied it to the Generic Manufacturers. For instance, because Plaintiff's false marketing claims sound in fraud,[6] they must satisfy Rule 9(b). But the FAC does not contain even a single statement attributable to a Generic Manufacturer about one of its medicines—much less one that reached an Oklahoma doctor, a tribal citizen, or Plaintiff itself. Because of these core failures, the FAC clearly does not plead the requisite details of any fraudulent conduct, such as who made an allegedly false statement, when, to whom, and why it is purportedly false. *See, e.g.*, *Hoover*, 958 F.2d at 745 (dismissing complaint because plaintiffs "had not alleged with specificity who had made particular misrepresentations and when they were made but rather plaintiffs had articulated general averments of fraud attributed to 'the defendants'").

In fact, Plaintiff does not even attempt to satisfy Rule 9(b) with respect to any of its fraud-based allegations against any of the Generic Manufacturers. The FAC fails to detail:

[6] FAC ¶¶ 358, 366-67 (Count I), 411-414 (Count III), 424 (Count IV), 436-438 (Count V), 450 (Count VI), 486 (Count X).

- How, if at all, each Generic Manufacturer actually marketed or sold its products to the Nation's residents;
- What, if any, allegedly false or misleading statement(s) each Generic Manufacturer made to the Nation and its citizens;
- Why each alleged statement was supposedly false or misleading;
- Where and when each Generic Manufacturer made any such statement and/or alleged misrepresentation;
- Which, if any, Nation's residents or prescribers actually received or saw such marketing or advertisements directed by Generic Manufacturers;
- Which prescribers, if any, relied upon any false or misleading statement in writing an opioid prescription; and
- What information or material was supposedly false or fraudulent in any report submitted by each DMD.

These failures are wholly insufficient to state a claim against the Generic Manufacturers under the *Twombly/Iqbal* pleading standard, much less under Rule 9(b). Accordingly, contrary to the conclusion set forth in the R&R, all false marketing claims against the Generic Manufacturers should be dismissed as a matter of law.

C. FEDERAL AND OKLAHOMA STATE DIVERSION STATUTES DO NOT PERMIT A PRIVATE CAUSE OF ACTION.

If adopted, the R&R effectively would allow Plaintiff to create private rights of action for and to enforce alleged violations of the Controlled Substances Act ("CSA") and the Oklahoma Uniform Controlled Substances Act ("OCSA"), despite the absence of any legislative intent to permit such a private cause of action.[7] Such a conclusion is contrary to the relevant precedent, because permitting plaintiffs to bring such claims "would, in effect, be permitting a private cause

[7] Oklahoma federal courts and the Tenth Circuit have recognized that the CSA does not create a private right of action. *Safe Streets All. V. Hickenlooper*, 859 F.3d 865 (10th Cir. 2017) ("Where a federal statute simply does not create substantive rights…it is unnecessary to address any remaining issues about a private citizen's ability to enforce that statute or obtain relief.") (internal citations omitted.); *see also McKesson*, 2018 WL 340042 ("The CSA does not provide a private right of action. Instead, it delegates the power of enforcement of federal drug policy to the federal government…However, courts have rejected private attempts to enforce the CSA through other vehicles.").

of action under" a statute or regulation that does not allow for one—in disregard of legislative intent. *Myers v. United States*, 17 F.3d 890, 901 (6th Cir. 1994) ("[W]ere we to permit them [plaintiffs] to proceed on the basis of negligence per se, **we would, in effect, be permitting a private cause of action under the Act. This we refuse to do**.") (emphasis added).

The R&R ignores the plethora of case law Defendants presented in their motions to dismiss supporting the prohibition against private rights of action under the CSA and OCSA. Those cases uniformly prohibit plaintiffs from using other vehicles, such as state law claims, to effectively enforce the CSA – precisely as plaintiff attempts to do here.[8]

When confronted with that authority, Plaintiff argued that it does not seek to enforce the CSA and OCSA, but, instead, asserts state law claims based upon alleged violations of those statutes. (*See* R&R, R. 109, Page ID #1777.) Courts across the country have specifically rejected similar arguments. *See, e.g.*, *McKesson*, 2018 WL 340042, at *5 (rejecting argument that plaintiffs were not seeking to enforce CSA, but seeking redress under tribal law and recognizing that "courts have rejected private attempts to enforce the CSA through other vehicles.").[9] Oklahoma law

[8] *See, e.g., Safe Streets*, 859 F.3d at 865; *McKesson*, 2018 WL 340042; *Myers*, 17 F.3d at 901; *Jones v. Hobbs*, 745 F. Supp. 2d 886, 890-94 (E.D. Ark. 2010); *Hatfield v. Arbor Springs Health and Rehab Center*, No. 3-12CV528-MHT, 2012 WL 4476612 at *3; *Bowling v. Haas*, No. 3:07-032-KKC, 2010 WL 3825467 (E.D. KY Sept. 23, 2010); *United States v. Real Prop. & Improvements Located at 1840 Embarcadero, Oakland, California*, 932 F.Supp. 2d, 1064, 1072 (N.D. Cal. Jan. 7, 2013); *Ringo v. Lombardi*, No. 09-4095-CV-C-NKL, 2010 WL 33100240, at *2 (W.D. Mo. Aug. 19, 2010).

[9] *See also Jones*, 745 F. Supp. 2d at 890-94 (rejecting plaintiffs' attempt to bypass CSA by seeking declaratory judgment under state law); *Hatfield v. Arbor Springs Health and Rehab Center*, 2012 WL 4476612 at *3 (M.D. Ala. 2012) ("Controlled Substances Act does not create the wrongful termination claim that plaintiff asserts in this action. The provisions of the Act on which plaintiff relies do not provide expressly for a private civil cause of action, nor does the Act imply a private right of action."); *Bowling v. Haas*, 2010 WL 3825467 (E.D. KY 2010) ("any action which seeks a determination that certain conduct would be contrary to the terms of the CSA…constitutes an effort to enforce those statutes, regardless of whether that determination is a predicate to only a declaration to that effect, or to further relief by way of civil penalty, disgorgement, destruction of offending articles, further injunctive relief, or criminal prosecution."); *United States v. Real Prop. & Improvements Located at 1840 Embarcadero, Oakland, California*, 932 F. Supp. 2d 1064, 1072 (N.D. Cal. 2013) (concluding that seeking injunction is tantamount to acting as "the Government in a civil enforcement or criminal prosecution under the CSA," and "because Claimants have no right of action under the CSA to force a [drug dispensary] to cease its operations, they cannot take such action using Rule g(7)(a)."); *Ringo v. Lombardi*, 2010 WL 33100240, *2 (W.D. Mo. 2010) ("CSA does not specify a private remedy for those aggrieved by violations of the CSA.").

recognizes and applies this principle, too. *See Public Service Co. of Oklahoma v. A Plus, Inc.*, 2011 WL 3329181 at *8 (W.D. Okla. 2011) (applying principle to dismiss state law claims); *Paulson v. Sternlof*, 15 P.3d 981, 984 (Okla. Civ. App. 2000) (same).

The law is clear on this point – no private right of action exists to enforce or implement the regulations contained in the CSA and OCSA. This applies even where a plaintiff attempts to use other vehicles, such as state law claims based on alleged violations of those regulations, as Plaintiff does here. Because the R&R is contrary to authority from this Circuit and in Oklahoma, it should not be adopted. As the Court in *Jones* explained: "When we conclude that Congress has decided not to provide a particular federal remedy, we are not free to 'supplement' that decision in a way that makes it 'meaningless.'" *Jones*, 745 F. Supp. at 892.

D. The R&R Errs As A Matter Of Law In Several Other Ways.

The R&R erred as a matter of law for the additional reasons set forth in the Brand Manufacturers' Objections. First, Plaintiff cannot proceed on a products-based public nuisance claim under Montana or Oklahoma law. (Brand Mfgr's Objections, at 1-5.) Second, Plaintiff cannot recover compact funds used to provide health care under federal law. (*Id.* at 6-11.) Third, Plaintiff cannot recover public service costs under Oklahoma or Montana law under the common-law free public services doctrine. (*Id.* at 11-13.) Fourth, Plaintiff cannot satisfy the remaining other elements of their claims. (*Id*. at 13-15.)

IV. CONCLUSION

There is simply no basis for the claims against the Generic Manufacturers, including false marketing claims based upon opioid medicines that the Generic Manufacturers do not promote and that are subject to strict federal duties (different from those imposed on manufacturers of brand medicines). Indeed, neither the R&R nor the FAC identifies a single false or misleading statement—or any other act of misconduct—made by any Generic Manufacturer in Oklahoma or

elsewhere. Accordingly, the Court should not adopt the R&R to the extent that it recommends that the Generic Manufacturers' Motion be denied.

Respectfully submitted,

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CERTIFICATION OF COMPLIANCE

In compliance with the Northern District of Ohio LR 7.1(f) and the page limitations set forth in the Report and Recommendation, Doc. 1499, the undersigned hereby certifies that these Objections comply with the agreed upon and ordered page limitations of 15 pages for the Generic Manufacturing Defendants' joint objections to the Magistrate Judge's Report and Recommendation.

/s/ Thomas E. Rice

CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2019, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Thomas E. Rice