UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *The Blackfeet Tribe of the Blackfeet Indian Reservation v. AmerisourceBergen Drug Corp., et al.* Case No. 18-op-45749	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

MEMORANDUM OF LAW IN SUPPORT OF GENERIC MANUFACTURERS' MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulations

I. INTRODUCTION[1]

Plaintiff The Blackfeet Tribe Of The Blackfeet Indian Reservation ("Plaintiff"), just like the Muscogee (Creek) Nation and other MDL plaintiffs, seeks to blame the opioid-abuse crisis on both generic and brand manufacturers (collectively, the "Manufacturers") of opioid medications approved by the federal Food and Drug Administration ("FDA"). As explained in the Manufacturer Defendants' Joint Motion to Dismiss The Tribes' First Amended Complaints ("Joint MTD"), the claims against all Manufacturers are flawed as a matter of law.[2] But Plaintiff also ignores that generic and brand manufacturers are different. Generic drug companies are subject to different preemptive federal laws and regulations than brand manufacturers, and they utilize a different business model (which does not involve the marketing of their generic medicines). As a result, the claims against them are particularly flawed, and generic manufacturers are not appropriate defendants in this case or any others that seek to impose liability on them for the opioid crisis, regardless of what state or federal law is being asserted. For the reasons expressed more fully in the *Muscogee* MTD, all claims against the Generic Manufacturers should be dismissed with prejudice under controlling Supreme Court and Sixth Circuit law.

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[1] Pursuant to ¶ 2(g) in CMO 1 (ECF No. 232), Watson Laboratories, Inc. ("Watson"), Actavis Pharma, Inc. ("Actavis Pharma"), Actavis LLC ("Actavis LLC"), Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. (collectively, the "Generic Manufacturers") raise only certain key common issues that warrant dismissal of the claims against them, in addition to those arguments raised in the Joint MTD. Generic Manufacturers do not raise defendant-specific challenges and defenses, but expressly reserve their right to raise those at a later time consistent with CMO 1. (ECF No. 232, at ¶ 2(j).) For purposes of this memorandum, emphasis in quotations is added, and internal citations, quotation marks, and alterations are omitted. Mallinckrodt LLC, SpecGx LLC, and Teva Pharmaceuticals USA, Inc. ("Teva USA") also join this motion to the extent Plaintiff's claims rest on allegations regarding their generic products. *See e.g.*, FAC ¶¶ 47-49, 76-78.

[2] The Generic Manufacturers adopt and incorporate herein the arguments made in the Joint MTD. Likewise, they adopt and incorporate herein the arguments made in the Motion to Dismiss, and accompanying Memorandum of Law, filed by the generic manufacturers in the *Muscogee* action ("*Muscogee* MTD").

First, Plaintiff primarily asserts a false marketing theory against the Manufacturers, but, despite more than 300 pages and 1000 Paragraphs, the Corrected First Amended Complaint ("FAC") does not contain a single particularized allegation of any marketing conduct or promotion by any of the Generic Manufacturers with respect to their generic products. The FAC certainly does not plead any of the necessary details to support their fraud claims, such as what false or misleading statements were said, to whom, where, and how they supposedly caused any medically inappropriate prescription for one of Plaintiff's citizens or that otherwise harmed Plaintiff. The failure to plead these fundamental details is not surprising, given the well-recognized 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 v. Actavis, PLC,* No. 14-cv-7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014), *affd sub nom. New York ex rel. Schneiderman v. Actavis PLC,* 787 F.3d 638 (2d Cir. 2015). Because there is no marketing of generic medicines, there is no false marketing to plead. All marketing-related claims against the Generic Manufacturers for the sale of generic medicines fail as a matter of law.

To conceal this fundamental problem, the FAC engages in rampant group pleading, lumping the Generic Manufacturers together with other independent companies under ***incorrect*** fictitious names (such as "Actavis"), and then grouping these fictional entities together with numerous other manufacturers and fourteen distributors and pharmacies. When the improper group allegations are properly stripped away, there is not a single factual allegation pleaded against any of the Generic Manufacturers with respect to the sale or marketing of generic opioids—much less any facts showing that any fraudulent marketing of generic opioids by these entities caused Plaintiff to incur some expense. Thus, all marketing claims against the Generic Manufacturers

should be dismissed for failure to plead the essential elements of those claims.

Second, for the reasons expressed in the *Muscogee* MTD, the state law claims against the Generic Manufacturers are preempted under federal law. Under *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), *Mutual Pharmaceutical Co., v. Bartlett*, 570 U.S. 472 (2013), and controlling Sixth Circuit law,[3] state law claims that would require generic manufacturers to provide warnings beyond those provided in their generic labels are preempted because they violate the "sameness" requirement of the Food Drug & Cosmetic Act ("FDCA"): that design and warnings of a generic drug must at all times be identical—indeed, the same—to those of its branded equivalent medicine. 21 U.S.C. § 355(j)(2)(A). Such broad preemption principles preclude state law claims that seek to force generic manufacturers to communicate information unilaterally beyond the content of the labels of their generic medicines because, in doing so, those communications would imply a difference between branded and generic medicines and would violate the "sameness" requirement imposed by federal law. *Mensing*, 564 U.S. at 617; *In re Darvocet*, 756 F.3d at 932-33; *Muscogee* MTD 12-22.

Here, because there are no specific allegations that the Generic Manufacturers promoted generic medicines (and, indeed, they did not), Plaintiff's claims against the Generic Manufacturers are necessarily predicated upon a failure to warn theory—that is, the Generic Manufacturers did not sufficiently disclose the risks of their generic opioid medicines, even though the labels of those FDA-approved medicines corresponded to their branded counterparts. Because these claims seek to force the Generic Manufacturers to provide warnings and communications beyond the labels of their generic medicines, they are preempted under controlling law.

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[3] *See, e.g., McDaniel v. Upshur-Smith Laboratories, Inc.*, 893 F.3d 941 (6th Cir. 2018); *In re Darvocet, Darvon, and Propoxyphene Prods. Liability Litig.*, 756 F.3d 917 (6th Cir. 2014); *Strayhorn v. Wyeth Pharma.*, 737 F.3d 378 (6th Cir. 2013).

Lastly, as in *Muscogee*, given Plaintiff's inability to plead false marketing claims against the Generic Manufacturers, Plaintiff resorts to allegations that the Generic Manufacturers did not report or halt suspicious orders and otherwise prevent diversion in violation of the federal Controlled Substances Act ("CSA") and Montana law. (*E.g.*, FAC ¶¶ 485-97, 1007, 1009, 1021.) Those claims fail, too, for the reasons discussed in the Joint MTD and the *Muscogee* MTD, including that there is no private cause of action to enforce these laws and the claims are preempted as a matter of law. (Joint MTD Part I-III, V; *Muscogee* MTD at 22-23.) Moreover, as in *Muscogee*, Plaintiff does not plead any facts demonstrating that any Generic Manufacturer failed to report a suspicious order to the Drug Enforcement Agency ("DEA") (or any other agency), much less that any such order caused the Plaintiff any harm. Indeed, there is not a single fact to show any Generic Manufacturer failed to comply with any statutory or regulatory anti-diversion obligations. These claims should be dismissed, too.

II. BACKGROUND

Plaintiff alleges Watson, Actavis Pharma, Actavis LLC, Teva USA, SpecGx LLC, Mallinckrodt LLC, Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. all sold generic medicines. (FAC ¶¶ 45-46 (alleging that Watson, Actavis Pharma, and Actavis LLC manufacturer and sell "generic versions" of opioid medicines), ¶¶ 47-49 (alleging that Teva USA is "in the business of selling generic" medicines and does so now), ¶¶ 64-65 (alleging that Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. manufacture and sell generic opioid medicines); ¶¶ 74, 77 (alleging that SpecGx LLC and Mallinckrodt LLC manufacture and sells "generic opioid product").)[4] Notwithstanding that Generic Manufacturers do not market and

[4] For some Generic Manufacturers, the FAC improperly lumps them with various families of branded manufacturers. For instance, Plaintiff incorrectly groups Watson, Actavis Pharma, and Actavis LLC ("Actavis Generic Entities") as part of what the FAC collectively (and inaccurately) refers to as "Actavis." (FAC ¶ 45.) Other than identifying the state of

promote generic medicines, the FAC alleges that all of the Manufacturers, including the Generic Manufacturers, engaged in a "massive marketing campaign premised on false and incomplete information" about opioids to influence "how and when opioids are prescribed by the medical community and used by patients." (*Id.* ¶ 10; *see also id.* ¶¶ 12-13.) The FAC also alleges that the Manufacturers, along with distributors and pharmacies, failed "to monitor report, and take steps to halt suspicious orders [of opioids] when they were identified, thereby perpetuating the oversupply of such drugs." (*Id.* ¶ 15.) Based upon these two legal theories (the same legal theories at issue in *Muscogee*), Plaintiff asserts an array of state and federal claims (Counts I-X), seeking to recover the downstream public costs it has expended in addressing the opioid epidemic. (FAC ¶¶ 852, 883.)

II. LEGAL ARGUMENT

To survive a motion to dismiss under Rule 12(b)(6), Plaintiff must provide "more than labels and conclusions . . . ." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Instead, the factual allegations must transcend the "speculative," "conceivable," and "possible," and must "state a claim to relief that is plausible on its face." *Id.* at 555–57, 566–67, 570. In making that determination, the Court must disregard "legal conclusions" and "conclusory statements," and must scrutinize the well-pleaded factual allegations to ensure that they are more than "'merely consistent with' a defendant's liability." *Ashcroft v. Iqbal*, 556 U.S. 662, 677–79 (2009). It is settled that "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are insufficient. *Id*. at 678.

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incorporation and principal place of business for Watson, Actavis Pharma, and Actavis LLC and incorrectly asserting that each "is owned by Allergan plc," Plaintiff asserts no individual allegations against any of the Actavis Generic Entities. (*Id.*)

Moreover, because Plaintiff's claims rest on an alleged fraudulent campaign to market opioid medicines and a failure to report suspicious orders (*E.g.*, FAC ¶¶ 4, 14, 326, 401), Plaintiff must satisfy Rule 9(b)'s particularity standard. *See Frank v. Dana*, 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).

Here, Plaintiff has asserted claims against the Manufacturers based upon two legal theories: (1) false marketing; and (2) failure to monitor and report diversion. (FAC ¶ 9.) Each of these legal theories fails as a matter of law for the reasons expressed in the Joint MTD. (Joint MTD Part I-V.) In addition, for the reasons explained in the *Muscogee* MTD, they are particularly flawed against the Generic Manufacturers given their unique business model and the federal laws and regulations that govern their conduct. (*Muscogee* MTD at 4-23.)

A. All Marketing Claims (Counts I And III-X) Fail As To Generic Manufacturers Because Plaintiff Does Not And Cannot Allege Any False Marketing Of Generic Medicines, Much Less Satisfy Rule 9(b).

Counts I and III-X are all based, in part, upon the allegedly false marketing of opioids.[5] As a result, each claim requires Plaintiff to plead facts that, at a minimum, satisfy several core requirements, including an actionable misrepresentation or other fraudulent conduct by each Defendant; a sufficient causal nexus between that supposed fraud or conduct and Plaintiff's alleged

[5] FAC ¶ 829 (RICO—Count I), ¶ 890 (federal common law public nuisance claim—Count III); ¶¶ 924, 929, 935, 940, 942 (state common-law public nuisance—Count IV), ¶¶ 964-65 (statutory public nuisance—Count V), ¶¶ 1052-54 (fraud claim—Count VII), ¶¶ 1071, 1081 (unjust enrichment—Count VIII), ¶¶ 1089-90, 1092 (civil conspiracy—Count IX), ¶¶ 111-12 (statutory consumer protection claim—Count X).)

harm; and a cognizable legal injury. Joint MTD Part I-III, V.A. The Joint MTD explains how Plaintiff does not and cannot satisfy these basic elements of its claims against any Manufacturer. *Id*.

But the false marketing claims in the FAC are also uniquely flawed as to Generic Manufacturers for another more fundamental reason: The FAC does not and cannot make a single particularized allegation of any marketing of generic opioids. Here, the FAC fails to allege a single statement attributable to any Generic Manufacturer about opioids—much less one that reached a Montana prescriber, one of Plaintiff's citizens, or the Plaintiff itself. Because of this failure, the FAC does not and is unable to plead the specific details of any such representation, such as who made it, when, to whom, and why it is purportedly false. Instead, Plaintiff's specific allegations about the individual Generic Manufacturers are confined to a few conclusory background paragraphs in the "Defendants" section of the FAC. (*E.g.*, FAC ¶¶ 45-46 ("Actavis Generic Entities"); ¶¶ 64-66 (Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.).) Other than these few paragraphs, the FAC does not mention any of the Generic Manufacturers by name. This fails to satisfy basic pleading requirements under *Iqbal*, much less Rule 9(b). *See Iqbal*, 556 U.S. at 678 (requiring facts to show that each defendant "has acted unlawfully."); *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 505-06 (6th Cir. 2008) (dismissing claims for failure to satisfy Rule 9(b)).

The reason why these fundamental facts are missing is clear: There are no such facts to plead because the Generic Manufacturers sold only generic products ***and did not promote them***. *Actavis, PLC*, 2014 WL 7015198, at *27. As explained in the *Muscogee* MTD, states encourage pharmacists to dispense generic drugs through drug substitution laws. *Muscogee* MTD at 4-6; *see also* Mont. Code Ann. § 37-7-505 (absent instructions from physician to contrary, pharmacist who

receives a brand prescription "may select a less expensive drug product with the same generic name, strength, quantity, dose, and dosage form as the prescribed drug"). Those laws now exist in all 50 states. *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 644 (2d Cir. 2015). They "either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician." *Id*. at 645. The substitution laws discourage generic manufacturers from promoting their particular generic products, since "expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors." *Id*. at 656. As such, because the Generic Manufactures did not promote their generic medicines, there is no false marketing to allege.

As in *Muscogee*, the FAC attempts to mask this deficiency by engaging in improper group pleading. For example, it inaccurately lumps together the three Actavis Generic Entities together with five other corporate entities (owned by a different company) under the fictitious "Actavis" name (FAC ¶ 46); the FAC then makes allegations against these fictitious entities. (FAC ¶¶ 193-196, 276, 313, 520-21, 554, 557.) Worse yet, the FAC lumps together all the Generic Manufacturers with other unrelated manufacturers of opioids as "Marketing Defendants," making hundreds of allegations using the name of this undifferentiated entity. (*E.g.* FAC ¶¶ 15-23, 110, 111, 115, 120, 133, 144-151, 201-202, 209-211, 221, 224-25, 226, 236, 237, 254-55, 263, 276, 316, 319-324, 332, 342, 344, 350.) And as a third layer of improper group pleading, the FAC lumps the Generic Manufacturers in with more than twelve separate distributors and pharmacies, asserting conclusory allegations against all "Defendants" collectively. (*E.g.* FAC ¶¶ 15-23.) As a matter of Sixth Circuit law, this is improper. *See, e.g., Hoover v. Langston Equip. Assocs., Inc.*,

958 F.2d 742, 745 (6th Cir. 1992); *Muscogee* MTD at 11-12; Joint MTD Part V.A.1.

Put simply, because Plaintiff does not and cannot make any allegations of marketing (much less false or misleading marketing) of generic opioid medicines, Plaintiff has failed to and cannot allege any of the essential elements of its false marketing claims, including a false or misleading statement, causation, or a cognizable injury. Because these defects cannot be cured, all such claims against the Generic Manufacturers should be dismissed with prejudice.

B. The State Law False Marketing Claims (Counts IV-X) Against The Generic Manufacturers Are Preempted.

Claims against Generic Manufacturers based upon the labeling of their generic medicines are subject to unique federal statutes and requirements that carry preemptive effect over state law claims. (*Muscogee* MTD at 12-22.) As the Supreme Court made clear in *Mensing* and *Bartlett*, the FDCA and its implementing regulations impose a "duty of sameness" on generic manufacturers that prohibit generic manufacturers from providing additional or different warnings for their generic medicines beyond the confines of the labeling for their branded counterparts. *Id.*; *Mensing*, 564 U.S. at 612-13, 618.[6]

The Supreme Court first held in *Mensing* that state-law claims seeking to require generic drug manufacturers to change FDA-approved labeling are preempted because it is impossible for generic drug manufacturers to simultaneously comply with state-law requirements and the federal law requirement of sameness. 564 U.S. at 617. There, the plaintiffs alleged state law failure-to-

[6] The "sameness" requirement goes further than just the physical label on the generic drug. This is because FDA defines "labeling" to include "[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints" and "similar pieces of printed, audio, or visual matter descriptive of a drug . . . for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer." 21 C.F.R. § 202.1(*l*)(2).

warn, fraud, and negligent misrepresentation claims against generic drug manufacturers of metoclopramide based on the manufacturers' alleged failure to provide adequate warning labels. *Id.* at 608–609. The Supreme Court recognized that if plaintiffs' allegations were true, then the manufacturers were required by state law to use different labeling. *Id.* at 612. Conversely though, the Supreme Court noted that under the FDCA, a generic manufacturer was "responsible for ensuring that its warning label is the same as the brand name's," and that this duty of "sameness" was "ongoing." *Id.* at 613. Because these conflicting duties rendered it impossible to comply with both state and federal law under plaintiffs' theory of the case, the Supreme Court concluded that the plaintiffs' state law claims were preempted. *Id.* at 618.

Notably, the *Mensing* Court expressly rejected the notion that manufacturers could provide additional warnings through "Dear Doctor" letters to physicians,[7] holding that those letters are subject to the sameness requirement and cannot include updated or even additional warnings that stray from an approved label. *Id.* at 615. Doing so violates the "duty of sameness" because "if generic manufacturers, but not the brand-name manufacturers, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Id.*

The Supreme Court subsequently reinforced *Mensing* in *Mutual Pharmaceutical Co., v. Bartlett*, 570 U.S. 472 (2013), where it held that any state law claim that brings into question the adequacy of, or would otherwise effect a change in, a generic drug manufacturer's labeling is preempted under *Mensing*. *Id.* at 486-87, 490. In *Bartlett*, the plaintiff asserted a design defect

[7] "Dear Doctor" letters are communications used by manufacturers to notify health care providers about new or updated warnings regarding a drug. *See* 21 C.F.R. § 200.5 ("Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care.").

claim under New Hampshire state law against a generic drug manufacturer based on severe side effects the plaintiff had allegedly suffered as a result of taking the generic form of the drug at issue. *Id.* at 478. As it did in *Mensing*, the Supreme Court analyzed whether the state law claim created a duty and found that, under New Hampshire law, design defect claims imposed a duty that could "be satisfied either by changing a drug's design or by changing its labeling." *Id.* at 482. The Supreme Court thus concluded that this claim was preempted because "state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id.* at 490.

Mensing and *Bartlett* squarely apply here and bar all of the Plaintiff's state law claims based upon the false marketing of generic medicines. Because the FAC fails to allege any specific affirmative marketing conduct with respect to generic medicines, Plaintiff's state law claims necessarily must be based upon a duty to warn incompatible with federal law—that is, to require the Generic Manufacturers to disclose something more than their FDA-approved warning labels with respect to generic opioids. (*E.g.* FAC ¶¶ 221, 255, 1055-56, 1112.) (alleging that "Defendants" failed to disclose various risks of opioids).) While Plaintiff's claims are not explicitly framed as failure-to-warn claims, this is of no consequence. The Montana public nuisance, negligence, negligent misrepresentation, fraud, unjust enrichment, civil conspiracy, and consumer protection claim against the Generic Manufacturers are at bottom failure-to-warn claims because they would require the Generic Manufacturers to alter their labels or make additional disclosures to avoid liability—something they cannot do given the "sameness" requirement of the FDCA and its accompanying regulations. *See, e.g., Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 391 (6th Cir. 2014) (explaining courts "have interpreted *Mensing* to broadly preempt claims

that are, at their core, claims that the generic manufacturer failed to provide additional warnings beyond that which was required by federal law of the brand-name manufacturers.") (collecting cases).

Nor can Plaintiff try to avoid preemption by arguing that its state law claims are based upon the theory that Generic Manufacturers should have sent letters to physicians that further communicated risk information about opioids. The Sixth Circuit and other courts have made clear that generic manufacturers are not permitted to communicate ***any warnings*** beyond a generic label if brand-name manufacturers have not already sent such a communication, because doing so "would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *In re Darvocet*, 756 F.3d at 932-33 (claims that generic drug manufacturers failed to send "Dear Doctor" Letters to healthcare professionals regarding generic medicine's risks were preempted because they would "violate the duty of sameness"); *see also McDaniel*, 893 F.3d at 944-948 (failure to warn claims based upon alleged failure to provide Medication Guide are impliedly preempted); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (per curiam) ("Under federal law, the inquiry is whether the brand-name manufacturers sent out a warning, not whether the proposed warning to be disseminated contains substantially similar information as the label. Because no brand-name manufacturer sent a warning based on the 2004 label change, the generic manufacturers were not at liberty to do so."); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013) (adopting the Fifth Circuit's reasoning in *Morris* and rejecting a "failure-to-communicate theory of liability" requiring generic manufacturers to communicate warnings that brand manufacturers had not yet communicated).

Put simply, regardless of how they are framed, Plaintiff's claims necessarily seek to hold the Generic Manufacturers responsible for failure to provide additional safety information

regarding generic opioids beyond what is in their labels. All such claims are preempted under established Supreme Court and Sixth Circuit law.

C. All Claims (Counts II-X) Based Upon Plaintiff's Failure To Prevent Diversion Theory Fail, Too.

As in *Muscogee*, Plaintiff also asserts RICO and state law claims against all Manufacturers, including the Generic Manufacturers, based upon a theory that they failed to monitor, report, and halt suspicious orders of opioid medications in violation of federal and state reporting laws. (*E.g.*, FAC ¶¶ 866, 877-78, 894-95, 929, 932-34, 937, 966-67, 979, 982, 988, 1007, 1013, 1019, 1022, 1055, 1080, 1099, 1113.) These claims rest on the same flawed allegations and legal theory asserted in *Summit County* and *Muscogee*, and, therefore, they fail as a matter of law for the reasons expressed in the Joint MTD and the motion to dismiss briefing in *Summit County*. Joint MTD Part I-II, II.C, V.A.2; *Muscogee* MTD at 24; *Summit* Manufacturer Joint Motion To Dismiss, ECF No. 499-1, at 28-38, 40-53.

In addition, like the claims in *Muscogee*, Plaintiff's failure to prevent diversion claims fail for another reason: there is not a single factual allegation pleaded against any Generic Manufacturer regarding its failure to comply with any diversion monitoring or reporting allegations. (FAC ¶¶ 474-636). As such, the FAC fails to identify a single suspicious order that any Generic Manufacturer failed to report; a single misleading statement or omission by any Generic Manufacturer regarding any federal or state diversion monitoring obligation (much less when they were made and to whom); or how any alleged failure to report by any Generic Manufacturer caused Plaintiff to incur some harm. For this reason alone, the claims should be dismissed.

III. CONCLUSION

For the foregoing reasons and those explained in the Joint MTD and *Muscogee* MTD, the Generic Manufacturers respectfully request that the Court enter an Order dismissing all claims against them.

Dated: August 31, 2018

Respectfully submitted,

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LOCAL RULE 7.1(F) CERTIFICATION

I certify that this case has been assigned to the "litigation track" pursuant to CMO One and that this Memorandum adheres to the page limitations set forth in CMO One § 6(f), CMO Four at 2-3, L.R. 7.1(f), and the Court's July 26, 2018 Order.

Dated: August 31, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on August 31, 2018, a copy of the foregoing **Memorandum Of Law Support Of Generic Manufacturers' Motion to Dismiss Plaintiff's First Amended Complaint** was filed electronically in MDL Master Docket No. 17-md-2804 and in No. 1:18-op-45749-DAP. Notice of this filing was sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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