UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**CASE NO. 1:17 MD 2804**
	)	
	)	**JUDGE DAN AARON POLSTER**
THIS DOCUMENT RELATES TO:	)	
	)	**OPINION AND ORDER**
***Track One* Cases**	)	**RE: PREEMPTION**
	)	

Four sets of defendants, some overlapping, have filed separate motions for summary judgment on the issue of federal preemption of state law claims and federal preclusion of federal claims. The moving defendants are identified as follows: Non-RICO Small Distributors[1] (**Doc #: 1873**), several Pharmacies and Distributors[2] (**Doc #: 1883**), Manufacturers[3] (**Doc #: 1926**), and

[1] The motion identifies the "Small Distributors" as H.D. Smith, LLC, Anda, Inc.; Henry Schein, Inc.; and Prescription Supply, Inc. (Doc #: 1873 at 1.) The Court subsequently severed all but Defendant Henry Schein, Inc. (Doc #: 2399.)

[2] "Pharmacy Defendants" are CVS Rx Services, Inc. and CVS Indiana, L.L.C. ("CVS Distributors"); Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center ("Rite Aid"); Walgreen Co. and Walgreen Eastern Co. ("Walgreens"); HBC Service Company, an unincorporated operating division of Giant Eagle, Inc. ("Giant Eagle"); Discount Drug Mart ("DDM"); and Walmart Inc. ("Walmart"). "Distributor Defendants" who join in this motion are AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. (Doc #: 1883-3 at 1 n.1.)

[3] Specifically, the motion identifies "Manufacturers" as "Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. …, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc., Johnson & Johnson, Noramco, Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc, Cephalon, Inc., Allergan plc f/k/a Actavis plc, Allergan Finance, LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc., Allergan Sales, LLC, Allergan USA, Inc., Watson Laboratories, Inc., Actavis

Generic Manufacturers[4] (**Doc #: 1860**). Plaintiffs filed a single opposition brief addressing Generic Manufacturers' motion (Doc #: 2251), and a consolidated memorandum of opposition addressing the other three motions (Doc #: 2171). The moving Defendants then filed reply briefs. (Doc ##: 2447 (Generic Manufacturers), 2455 (Manufacturers), 2465 (Non-RICO Small Distributors), 2467 (Pharmacies and Distributors)). This Opinion and Order addresses all four motions.

I.

The allegations underlying the *Track One* complaints,[5] as well as in much of this multidistrict litigation ("MDL"), have been accurately set forth by Magistrate Judge David A. Ruiz in the Summit County R & R (Doc #: 1025 at 3-11), the Muscogee Nation R & R (Doc #: 1499 at 8-14), and the Blackfeet Tribes R & R (Doc #: 1500 at 4-6). Most preemption issues raised in the four pending motions have already been raised, addressed, and ruled on as a matter of law in the three R & Rs,

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LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc, Mallinckrodt, plc, Mallinckrodt LLC, SpecGx LLC, Allergan Sales, LLC, Allergan USA, Inc., Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida." (Doc #: 1926 at 1.)

[4] The motion identifies the "Generic Manufacturers" as "Actavis Pharma, Actavis LLC, Watson, Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida (collectively, the 'Actavis Generic Defendants'); Endo Pharmaceuticals Inc. and Endo Health Solutions Inc. (collectively, "Endo Defendants"); Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (… collectively, "Par Defendants"); Teva Pharmaceuticals USA, Inc. ('Teva USA'), Inc.; and the generics business of Mallinckrodt LLC and SpecGx LLC (together, "Mallinckrodt"). (Doc #: 1860.) There is significant overlap between "Manufacturers" and "Generic Manufacturers," as the latter are included in the former but not *vice versa*.

[5] The reference to *Track One* cases are to *County of Summit, Ohio, et al. v. Purdue Pharma LP, et al.*, Case No. 1:18-op-45090 and *County of Cuyahoga, Ohio v. Purdue Pharma LP, et al*, Case No. 1:17-op-4500, both of which will be tried together in October 2019.

as set forth in greater detail below. Since no party filed objections challenging Magistrate Judge Ruiz's recommended rulings on the subject of preemption (Doc #: 1203 at 2; Doc #: 1680 at 28), they became rulings of the Court and the law of the MDL.

A. Summit County R & R (Doc #: 1025).

In *Summit County*, Manufacturer Defendants moved to dismiss all of Plaintiffs' state law claims, arguing they were preempted because they conflicted with decisions of the Food and Drug Administration ("FDA") regarding approval and labeling of prescription opiates. Without repeating in great detail Manufacturers' arguments, they generally contended that: (1) state law claims involving the marketing of opioids were preempted when a claim would require a drug manufacturer to make statements about safety or efficacy in marketing materials that *differed* from what the FDA required; (2) state law claims involving off-label use were preempted because the FDA was invested with exclusive authority and a variety enforcement options existed to address off-label promotion; and (3) the diversion-monitoring theory advanced by Plaintiffs was preempted because state law would stand as an obstacle to the accomplishment and execution of the FDA's objectives.[6] In other words, Manufacturers argued that each of Plaintiffs' claims would undermine the FDA's decision to make prescription opioids available to the public and would also force Manufacturers to stop selling those drugs over concerns about liability.

The Court declined to read Plaintiffs' allegations so narrowly. The Court found that the state law claims were "not premised upon inappropriate labeling or a fraud on the FDA, but rather

[6] As Defendants did not raise express preemption or field preemption, their defenses were based solely on conflict preemption, which occurs when either: (1) compliance with both federal and state laws is a physical impossibility, or (2) state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Yates v. Ortho-MdNail-Jannsen Pharmaceuticals, Inc*., 808 F.3d 281, 293-94 (6th Cir. 2015).

fraudulent marketing in the promotion and sale of their opioids" (Summit R & R at 50); Plaintiffs were not seeking to enforce the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), but their allegations were "of the type that would traditionally be brought as state law claims [prior to the enactment of the FDCA]" (*id*. at 52);[7] and the argument that state law imposed a duty to monitor the sale of opioids with due care was not inherently "inconsistent with the purposes of the FDCA, and thus not preempted" (*id*. at 54).[8]

B. Muscogee Nation R & R (Doc #: 1499).

1. Manufacturers.

In *Muscogee Nation*, Manufacturers asserted a new basis for preemption not briefed in the Summit County motion to dismiss.[9] Manufacturers argued that Plaintiffs' state law claims were preempted because it would be impossible for them to comply with federal law requirements and state law judgments arising from those claims. In support, Manufacturers narrowly construed Plaintiffs' claims as seeking label changes and cited the FDA's July 2012 response to a citizen petition from Physicians for Responsible Opioid Prescribing (the "PROP" Petition), which rejected PROP's proposed label changes, as "clear evidence" the FDA would not have approved *Plaintiffs'* purported label changes.[10]

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[7] In support, the Court cited *Loreto v. Procter & Gamble Co.*, 515 Fed. App'x 576, 579 (6th Cir. 2013).

[8] Here, the Court cited *Wyeth v. Levine*, 555 U.S. 555 (2009) (rejecting a similar argument, noting that "with limited resources to monitor the 11,000 drugs on the market, the FDA appears to view state tort law as a 'complementary' form of drug regulation"). *Id*. at 574-75.

[9] The Court need not discuss preemption arguments previously raised and decided.

[10] "A failure to warn claim is preempted where the manufacturer of the drug proves that it was impossible to comply with state and federal law by submitting 'clear evidence that the FDA would not have approved a change' to the drug's label." *Rheinfrank v. Abbott Lab., Inc.*, 119

The Court agreed with Manufacturers that representations made in their marketing materials must be consistent with specific pre-approved labels submitted to the FDA; state law claims seeking to impose liability on Manufacturers for failing to include statements on their marketing materials regarding the correct dosage and duration of treatments were preempted; and any manufacturer that markets its product with FDA-approved warnings cannot be liable under state law for failing to issue different warnings if the manufacturer can show clear evidence the FDA would have rejected those different warnings.

The Court also found it was unable to conclude the PROP letter satisfied *Wyeth*'s clear-evidence standard for several reasons. Plaintiff was not seeking label changes; the Court could not rule on the preemptive effect of the FDA letter in the absence of a full record; and, more importantly, even if the Court were to agree with the argument the FDA letter had some preemptive effect, this would not preempt every theory of liability articulated by Plaintiffs, *e.g.*, fraudulent marketing and the failure to monitor and prevent opioid diversion.

2. Generic Manufacturers

In *Muscogee Nation*, Plaintiffs contended that Generic Manufacturers had an obligation to send "Dear Doctor" letters to healthcare providers, warning them about the risks associated with opioid use, that the brand-name manufacturers failed to send. Generic Manufacturers countered that liability could not be imposed upon them under state law for failing to send such warning letters because that would violate the "sameness principle" – an FDCA requirement that generic medications must be the same as their branded equivalents in every clinically significant way, including labeling. The Court agreed with Generic Manufacturers, citing *PLIVA v. Mensing*,

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F.Supp.3d 749, 762 (S.D. Ohio 2015) (quoting *Wyeth v. Levine*, 555 U.S. at 571).

wherein the Supreme Court held that Dear Doctor letters qualify as "labeling" for purposes of the FDCA. 564 U.S. 604, 612 (2011). (Doc #: 1499 at 35-36.) Nevertheless, the Court found that preemption did not bar the state law claims "to the extent they were founded upon allegations the Generic Manufacturers engaged in aggressive and misleading marketing and inadequate anti-diversion activities." (*Id*. at 42.)

C. Blackfeet Tribes R & R (Doc #: 1500).

1. Manufacturers.

The arguments Manufacturers made in their *Blackfeet Tribes* motion to dismiss echoed arguments they made in *Muscogee Nation*, and the Court reaffirmed its rulings.

2. Generic Manufacturers

Generic Manufacturers asserted a new basis for preemption, not previously briefed. They contended that, by the very nature of a generic manufacturer's business model, they could neither market nor promote their opioids; thus, they could not be liable under state law for falsely marketing or promoting them. (Doc #: 1500 at 15.) Generic Manufacturers also argued the complaint contained no allegations they engaged in marketing, and accused Plaintiffs of improper group pleading without distinguishing between the various Generic Manufacturers, lumping together as "Marketing Defendants" both generic and brand-name manufacturers. (*Id*.)

The Court recognized that, unlike the complaint in *Muscogee Nation*, the *Blackfeet Tribes* complaint did not contain specific allegations against Generic Manufacturers. (*Id*.) The Court concluded, however, that the complaint contained plausible allegations of fraudulent marketing and failure to monitor against all manufacturers, including Generic Manufacturers, and by "merely denying those allegations, the Generic Manufacturers created material issues of fact not suitable for

resolution on a motion to dismiss." (*Id.*)

II.

The Court incorporates by reference the summary judgment standard of review articulated in Doc #: 2483 at 2-4.

III.

A. Manufacturers MSJ (Doc #: 1926).

On summary judgment, Manufacturers contend discovery has now made it "abundantly clear that Plaintiffs *are* pursuing preempted claims that challenge FDA-approved labeling for the Manufacturers' opioid medications."[11] (Doc #: 1926-1 at 10.) Manufacturers contend that the FDA's 2013 reevaluation and rejection of PROP's proposed label changes, and a May 2019 FDA Memo declining to recommend limits on doses, now constitute "clear evidence" the FDA would reject Plaintiffs' purported label changes because it would be impossible for Manufacturers to comply with federal law and also defend state law claims. Furthermore, "[a]s this Court has recognized, the term 'labeling' as used in the FDCA broadly encompasses representations made in marketing materials.'" (*Id.* at 11 (citing Muscogee R & R at 30)).

[11] In support of this contention, Manufacturers cite testimony of Plaintiffs' experts who have asserted, for example, that: (1) it is dangerous to prescribe narcotic drugs to patients suffering from chronic pain; (2) drug manufacturers overstated the benefits of long-term use for chronic pain; and (3) manufacturers falsely stated that opioid medications lead to improved functionality and can be used for indications such as back pain and osteoarthritis. (Doc #: 1926-1 at 6-7.) But this testimony does not change the nature of Plaintiffs' claims; rather, it is evidence that is relevant to the question of whether Manufacturers *knowingly* engaged in false and misleading promotion of their opioid medications. Moreover, if Manufacturers take issue with Plaintiffs' experts' opinions, they can seek to limit or exclude those opinions in a *Daubert* motion and challenge them at trial.

The Court has previously rejected Manufacturers' narrow construction of Plaintiffs' allegations as effectively demanding nothing more than label changes, and does so again. Plaintiffs allege that Manufacturers, despite knowing the highly addictive properties of opioids, initiated a massive marketing campaign based on false and misleading information, causing a dramatic increase in opioid prescriptions, creation of a black market for opioids, enormous profits for Manufacturers, and the public health crisis we find ourselves in today. Plaintiffs allege Manufacturers engaged in a series of marketing strategies – funding pain advocacy groups, key opinion leaders, and continuing medical education courses – all to spread messages that the risk of addiction is manageable even for patients with a history of drug abuse, signs of opioid addiction are actually attributable to untreated pain (requiring more opioids), withdrawal can be easily managed, and the risk of addiction from chronic opioid therapy is rare. Despite Manufacturers' contention to the contrary, the Court has *never* held that the term "labeling" is so broad it encompasses the massive marketing campaign alleged here.

Manufacturers recommend this Court follow *State of North Dakota v. Purdue Pharma, LP, et al.*, No. 08-2018-CV-01300 (N.D. Dist. Ct. May 10, 2019). There, the court construed North Dakota's allegations (similar to those Plaintiffs assert here) as nothing more than challenges to Purdue's FDA-approved labels, and concluded it would be impossible for Purdue to comply with both state and federal law because the FDA's rejection of PROP's label changes constituted clear evidence the FDA would reject *Plaintiffs'* purported label changes. The district court also determined that Purdue's marketing scheme was consistent with its labels.

There are several problems with this argument. First, Plaintiffs simply have not proposed any label changes. Second, there is no evidence the FDA approved or endorsed Manufacturers'

campaign message that the risk of addiction is manageable for patients with a history of addiction problems, or that signs of opioid addiction are actually pseudoaddiction ameliorated with *more* opioids. Third, and more importantly, *North Dakota* is, by leaps and bounds, an outlier on the question of preemption.[12]

Manufacturers also contend Plaintiffs' state law claims premised upon a fraud on the DEA are preempted. The Court has already ruled Plaintiffs' marketing-based claims are not premised on a fraud upon the DEA, and thus do not run afoul of *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001)." (Doc #: 1499 at 43 (citing Doc #: 1025 at 50-51).)

Manufacturers assert that Plaintiffs' RICO claims "are based on the same allegations of inappropriate marketing and labeling that underlie their state law claims" and "Plaintiffs seek to impose liability under RICO for the Manufacturers' failure to make certain warnings that the FDA expressly rejected under the FDCA." (Doc #: 1926-1 at 14.) This argument misrepresents Plaintiffs' allegations as previously noted and is rejected for the same reasons.

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[12] *See, e.g., State of Ohio, ex rel. Dewine v. Purdue Pharma, LP, et al.*, No. 17 CI 261, 2018 WL 4080052 at *3 (Common Pleas Ct., Ross County, Ohio Aug. 22, 2018) (finding no preemption because "it is evident in the Plaintiff's complaint that its claims are based upon misrepresentations made by the Defendants concerning the use and safety of opioids which go far beyond labeling."); *Grewal v. Purdue Pharma, LP, et al.*, No. ESX-C-245-17, 2018 WL 4829660 at * (N.J. Ch. Oct. 2, 2018) ("Here, the Court finds that the State's allegations do not conflict with federal law. The State does not claim that the FDA-approved labeling was inadequate. Nor does the State seek to change the labeling. The State alleges that Purdue's marketing was inconsistent with or not covered by FDA approvals."); *City of Chicago v. Purdue Pharma, LP*, 211 F. Supp. 3d 1058 (N.D. Ill. 2016) (concluding that the City's allegations primarily sound in fraud and do not challenge the propriety of the labeling of opioids); *State of New Hampshire v. Purdue Pharma, LP, et al.*, Case No. 217-2017-CV-00402, 2018 WL 4566129, at *2-4 (N.H. Super. Sep. 18, 2018) (denying defendants' motion to dismiss based on preemption because their conflict preemption theory presupposed their marketing efforts were consistent with their drug labeling); *State of Washington v. Purdue Pharma, LP, et al.*, No. 17-2-25505-0 SEA ¶ 5 (Wash. Super. Ct. May 14, 2018) (finding the manufacturer engaged in conduct that exceeded the parameters of its labeling).

B. Generic Manufacturers' MSJ (Doc #: 1860).

1. Preemption.

The preemption argument raised by Generic Manufacturers fails for the same reasons Manufacturers' preemption argument fails – namely, Plaintiffs' state law claims are *not* predicated upon violations of the FDA or CSA, nor are they accurately characterized as "fraud on the FDA" or "fraud on the DEA" claims. Also, to the extent Generic Manufacturers rely on the *Muscogee* R & R, they ignore the express language therein. With respect to Generic Manufacturers' preemption arguments, the *Muscogee* R & R agreed only with the *narrow* argument that liability could not be "impose[d] upon the Generic Manufacturers … for not sending warnings that the Brand-Name Manufacturers had not sent," explaining that Generic Manufacturers "would have violated the sameness principle by sending 'Dear Doctor' letters and other communications that surpassed the transmission of information the Brand-Name Manufacturers had communicated." (Doc #: 1499 at 42.) However, the *Muscogee* R & R expressly cautioned that, "to the extent that the state-law claims depend upon [such] allegations—and *only to that extent*—the undersigned recommends finding they are preempted because it would be impossible for Generic Manufacturers to comply with both federal law and the supposed state law duty." *Id*. (emphasis added).

Furthermore, the *Muscogee* R & R observed that, because Plaintiff had pleaded other marketing-related allegations that support the state law claims against Generic Manufacturers, preemption did not bar any of those claims "to the extent they are founded upon allegations that Generic Manufacturers engaged in aggressive and misleading marketing and inadequate anti-diversion activities." (*Id*.) Despite not objecting to the preemption portions of the *Muscogee* R&R,

Generic Manufacturers again raise a preemption argument.[13] (Doc #: 1680 at 28.) Because neither the Summit nor the Cuyahoga Plaintiffs have grounded their causes of action upon the theory that Generic Manufacturers should have sent "Dear Doctor" letters, the Court finds none of Plaintiffs' state law claims are preempted.

2. Evidence of Marketing by Manufacturers of Generics.

In addition to the preemption argument, Generic Manufacturers assert that Plaintiffs' false marketing claims fail because Generic Manufacturers never promoted the safety or efficacy of their opioids. (Doc #: 1860 at 1-7.) Generic Manufacturers' arguments are without merit and seek to recharacterize Plaintiffs' claims by suggesting Plaintiffs must show false marketing with respect to the Generic Manufacturers' specific generic opioids. As explained in the Summit R & R, Plaintiffs assert manufacturers of opioids, *including* the moving Generics Manufacturer groups herein, initiated a massive marketing campaign based on false and misleading information to cause a dramatic increase in opioid prescriptions. This was accomplished through the so-called "nine categories" of falsehoods and misrepresentations that manufacturers allegedly disseminated through "front groups," through the sponsorship of continuing medical education courses, and through the retention of "key opinion leaders." (See generally Summit R & R, Doc #: 1025 at 3-8; Summit 3AC, Doc #: 1466 ¶¶ 172-436; Cuyahoga 3AC, Doc #: 1631 ¶¶ 157-434.)

The moving Defendants' emphasis on the lack of marketing of generics specifically—and the high percentage of their sales that derive from generics opioids versus brand names—misstates

[13] In their objections to the *Muscogee* R & R, the Generic Manufacturers indicated in a footnote that they would 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," but denied waiving those arguments, despite not making any specific objection to the Magistrate Judge's recommendation. (Doc. #: 1592 at footnote 3.)

the question at hand. The causes of action are not asserted against the moving defendants in their capacity as manufacturers of *generic* opioids, or *in their capacity* as manufacturers of *brand name* opioids, but simply as manufacturers of opioid drugs. Therefore, if Plaintiffs can point to evidence supporting their theory that *all* manufacturers engaged in the false marketing of opioids generally, frequently through unbranded promotion, any distinction between those defendants who manufactured brand name opioids, those who manufactured generic opioids, or, as appears to be most common, those who manufactured both, would be rendered largely immaterial.

As stated in the deposition testimony of Plaintiffs' expert David Kessler, M.D.,

> To the extent the opioid manufacturers contributed to a change in the prescribing of opioid — the class of opioids, that would refer to affect both branded — especially unbranded promotion is going to raise the prescription level of both branded and generics… that's sort of where I — enter an opinion on, that when you do unbranded promotion for a class, and that class is opioids as opposed [to brand names] … then it affects all, including the generics, and that is covered in the report.

(Doc #: 1963-16 at 661-662.)

Plaintiffs' brief has pointed to numerous pieces of evidence that, viewed in the light most favorable to the non-moving party, are capable of supporting their allegations against all four groups of moving Generic Manufacturers. The evidence, cited by the Court below, creates a genuine issue of material fact as to whether the four groups of moving Generic Manufacturers engaged in the fraudulent promotion of opioids as a class of drugs–without distinguishing between branded and generic opioid products. Generic Manufacturers' reply is largely unresponsive to the Plaintiffs' argument that the moving Defendants engaged in unbranded promotion of all opioids, and reiterates the faulty premise that the allegedly false statements identified by Plaintiffs must be tied to a specific generic drug. (Doc #: 2447.)

a. Endo/Par Entities[14]

Plaintiffs contend that Endo provided at least $31 million in funding to a front group, the National Initiative on Pain Control ("NIPC'), between 2001 and 2012. (Doc #: 2251 at 13.) Linda Kitlinski, former Endo Director of Clinical Development and Education and NIPC's direct contact person at Endo, testified during her deposition that the strategy for Opana ER, an extended release oxymorphone pill, was to "refocus the attention to the appropriate clinical use of opioid analgesics." (Doc #: 1963-20 at 113; Doc. #: 2251, Ex. 36 at 2.) In an email, she indicated that "educational programs that are not done through an 'independent third-party' will be perceived as inappropriately promotional" and agreed with her colleagues that "opioids should be the focus of the new NIPC module." (Doc. #: 2251, Ex. 37 at 2.)

Plaintiffs further draw this Court's attention to the following allegedly false or fraudulent statements that NIPC made regarding opioids generally, without focusing on brand names or generics: (1) "Addiction to opioids in the context of acute pain treatment is rare in those with no history of addictive disorder" (*id*., Ex. 39 at 10); (2) describing as "pseudoaddiction" a patient's pattern of drug-seeking behavior and suggesting such behavior is merely a sign of "inadequate pain management" (*id*., Ex. 40 at 83); and (3) a patient's "level of function should improve," allowing

[14] The MSJ labels Endo Pharmaceuticals Inc. and Endo Health Solutions Inc. collectively as "Endo Defendants," and separately labels Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. collectively, as "Par Defendants." (Doc #: 1860.) However, all four of these defendant companies are "wholly owned subsidiaries of Endo International plc," according to the submitted Corporate Disclosure Statement filed jointly by all four defendants and are all represented by the same counsel. (Doc #: 557.) In its reply, without mentioning its connection to Endo, the Par Defendants state that Plaintiffs pointed to no evidence of false marketing specifically by them. (Doc #: 2447 at 10.) Because neither the motion itself (Doc #: 1860) nor the reply (Doc #: 2447) offer any evidence as to the inter-workings or operations of these sibling companies, summary judgment for the Par Defendants is not warranted. For the purposes of this motion, the Court treats the Endo and Par entities as one corporate grouping.

him or her to "participate in activities of daily living, such as work and hobbies," after long-term opioid use (*id*., Ex. 41 at 3.)[15]

Endo also allegedly utilized the American Pain Foundation ("APF") to spread its message by supporting APF's publication of a *Pain Action Guide*. (Doc #: 2251 at 14.) The *Pain Action Guide* made the following alleged misrepresentations: "Pain medications rarely cause addiction…. Unless you have a history of substance abuse, there is little risk of addiction when these medications are properly prescribed by a doctor and taken as directed." (Doc #: 2251, Ex. 47 at 10.)

Another former Endo employee, George Stevenson, stated that while generics were not promoted directly to physicians (Doc #: 1971-3 at 213), promotion of the brand-names created a sales "pie," part of which "converts immediately to the generic flavor" (*id*. at 214). The share of the pie that goes to generic opioids almost always increases over time. (*Id*.) Furthermore, Stevenson agreed that, although generics were not marketed directly to physicians, there was some sales effort directed by the national account executives to retailers and wholesalers. (Doc #: 1971-3 at 277.) Thus, Endo plainly was aware that brand-name marketing would inure to the benefit of its generic drugs.

Given the above evidence, a reasonable finder of fact could find that Endo intentionally promoted *all* opioid sales through front groups that made false representations. Moreover, a finder of fact could also reasonably conclude that Endo's brand-name marketing was also intended to

[15] The Court's identification of these examples, as well as other examples of alleged false or misleading statements cited below, should not be misconstrued as affirmative findings by the Court that the identified assertions are indeed false, misleading, or fraudulent, which remain an issue for the trier of fact. Plaintiffs' expert, David Kessler, M.D., has opined that Endo (Doc #: 2000-8 at 316-317), Actavis (*Id*. at 318), Teva (*Id*.), and Mallinckrodt (*Id*. at 318-319) all falsely or misleadingly minimized the risks of opioid abuse/addiction and/or falsely represented the safety and efficacy of their opioid products. Thus, a geuine issue of material fact remains.

directly benefit their generic variants of the same drug. Therefore, genuine issues of material fact remain rendering summary judgment inappropriate.

b. Mallinckrodt Entities.

Plaintiffs draw the Court's attention to "Pocketcards" carried by Mallinckrodt sales representatives that made allegedly false representations about opioids generally, and not limited to any brand-name product. These Pocketcards stated in relevant part that: (1) "Risk of addiction [is] rare" or "low" when acute pain is managed with opioids (Doc. #: 2251, Ex. 26 at 3; Ex. 27 at 5); (2) "Addiction rarely occurs unless there is a hx [history] of abuse" (*id*., Ex. 4 at 2); (3) "Single-entity opioids have no maximum dose but may be limited by side effects" (*id*., Ex. 27 at 5); and (4) "Pseudoaddiction [is] Drug-seeking behavior focused on pain, due to undertreatment of pain." (*id*., Ex. 27 at 6.) None of these representations make any distinction between brand name or generic opioids.

Plaintiffs further assert the C.A.R.E.S. Alliance, an alleged front group created by Mallinckrodt, actively promoted the book *Defeat Chronic Pain Now!*, by Bradley Galer and Charles Argoff.[16]. (Doc #: 1466 at ¶¶ 223-225; Doc #: 1631 at ¶¶ 211-213.) The evidence presented shows that Mallinckrodt's documents specifically identified the booklet as an example of an "Education and Enabling Tool" for patients. (Doc. #: 2251, Ex. 23 at 2), which was also referenced in C.A.R.E.S.'s catalog. (*id*., Ex. 24 at 14.) Plaintiffs assert that the heavily-promoted book contains multiple misleading statements promoting opioid use for pain while minimizing the risk of addiction, including:

[16]Neither Generic Manufacturers' MSJ (Doc #: 1860) nor Mallinckrodt's separate MSJ (Doc #: 1907) challenge Plaintiffs' theory that the C.A.R.E.S. Alliance was a front group funded and directed by Mallinckrodt.

> "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy." (*id*., Ex. 25 at 22.)
>
> "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving." (*id*., Ex. 25 at 24.)
>
> "Sometimes chronic pain patients may develop something called *pseudoaddiction*, which is caused by their doctor not appropriately prescribing the opioid medication. Pseudoaddiction happens when a patient's opioid medication is not being prescribed in doses strong enough to provide good pain relief, or the drug is not being prescribed often enough throughout the day." *id*.
>
> "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance." (*id*., Ex. 25 at 25.)
>
> "The bottom line: Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction." *id*.
>
> "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain. Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction." (*id*., Ex. 25 at 26.)

Again, these alleged misrepresentations are not specific to a particular opioid product, branded or generic. Therefore, a genuine issue of material fact remains as to whether the Mallinckrodt entities falsely or fraudulently marketed all opioids, including generics.

c. Allergan/Actavis Entities[17]

Plaintiff's brief in opposition draws the Court's attention to the deposition testimony of Jinping McCormick, director of marketing of generic drugs for Actavis. (Doc #: 1966-19 at 25.) McCormick stated that when she was director, Actavis marketed the following generics: oxycodone

[17] Whether Actavis is properly classified as part of the Allergan family of companies or the Teva family of companies, or neither, is an issue not addressed in this Opinion and Order, as that is the subject of a separate motion for summary judgment. (Doc #: 1909 at 5.)

immediate-release tablets, oxycodone extended-release tablets (generic OxyContin); fentanyl patches, oxymorphone extended-release (generic Opana ER), and morphine sulfate extended release (generic Kadian). (Doc #: 1966-19 at 25, 27-28.) McCormick testified that ,while Actavis typically did not do "a lot of marketing for generics," the generic version of Opana ER was the subject of "more than so-called typical" marketing because they had to "make physicians and the pharmacists aware of the introduction of the generic alternative to the brand." *Id*. at 74-75.

Nathalie Leitch, head of Actavis's brand name marketing (Doc #: 1966-19 at 25), in an email to CEO Douglas Boothe on August 26, 2011, stated that an upcoming direct mail and email marketing campaign's "[m]ain messages … are long history of safe and efficicacious [sic] use, favorable formulary position and co-pay program." (Doc. #: 2251, Ex. 58 at 3.) In the very same email, Leitch concedes that:

> We have looked at speakers programs and every derivative thereof and have made the decision not to pursue. Legal and regulatory have been strongly opposed plus the cost-benefit very uncertain *given the complete lack of clinical data for Kadian*." (emphasis added).

Id.

A reasonable finder of fact could conclude, based on the above information, that Allergan/Actavis marketed both brand name and generic Kadian; and, based on the email, Allergan/Actavis falsely represented a long history of safe use despite the lack of any clinical data supporting the assertions. Thus, a genuine issue of material fact arises as to whether Allergan/Actavis engaged in false marketing, rendering summary judgment inappropriate.

d. Teva Entities.

Plaintiffs have presented evidence that can be construed as Teva actively seeking "partners" through which it could spread its so-called misrepresentations concerning the safety and efficacy of

opioids. (Doc. #: 2251, Ex. 72 & Ex. 73 at 12) (suggesting that at least one advocacy organization had "fewer resources that could be more receptive to a Teva partnership.") Plaintiffs assert that another organization, the American Pain Foundation ("APF"), was a front group funded by Teva, which misleadingly held itself out as an "independent, nonprofit organization serving people with pain through information, advocacy and support." (*id*., Ex. 80 at 3.)

Teva, through Cephalon, Inc.,[18] made the representation in its ESP Patient Tool Kit that: "*Opioid addiction is rare in people with chronic pain*." (Doc. # 2251, Ex. 86 at 3) (emphasis in original). Cephalon further represented that many symptoms that may look like opioid addiction are instead symptoms of "tolerance, physical dependence, and pseudo (or false) addiction." *Id*. at 3-4. During the deposition of Matthew Day, he acknowledged Teva's sales force was trained to assert that, "in patients without personal or family history of substance abuse, addiction resulting from exposure to opioid therapy is uncommon." (Doc #: 1976-11 at 154-155.) Day also explained that Teva's "Pain Matters" was an "unbranded campaign" for opioids that healthcare professionals and doctors could access through the internet. *Id*. at 87-89. By "unbranded," Day explained by contrasting it with branded campaigns that focus on a specific product. *Id*.

In a separate motion, Teva has argued that none of Plaintiffs' experts identified any false statements by them, and assert that neither Teva nor Cephalon should be held responsible for

[18] Teva's separate MSJ does not distinguish between itself and Cephalon, Inc., even noting in a footnote that "Cephalon and Teva USA are referred to as the 'Teva Defendants.'" (Doc #: 1891-2 at 1, n. 1.) Generic Manufacturers' reply disclaims any affiliation between Teva and Cephalon *prior to* October of 2011, but fails to set forth sufficient factual information that would allow the Court to determine whether Teva USA can be held liable for the representations of Cephalon. It bears noting that their joint corporate disclosure statement indicates that both Cephalon and Teva USA are owned by Teva Pharmaceuticals, Ltd. through a complex web of companies. (Doc #: 546.) To the extent the issue is briefed elsewhere in this MDL, it will be addressed in a different Order.

statements made by third parties—such as organizations that Plaintiffs label as front groups. (Doc #: 1891 at 3, 7.) Teva's separate motion concedes these third-party organizations received funding from Cephalon but not from any of the other moving defendants. (Doc #: 1891 at 3.) Teva asserts that "the uncontroverted evidence establishes that those third parties independently created their publications, and signed agreements specifying that Cephalon did not control the content of what they said or wrote." *Id*. at 3, 9. Nevertheless, an email from Stacey Beckhardt, who was responsible for Teva's Government Affairs and Advocacy Relations, references a "Teva – American Pain Foundation Meeting" scheduled for November 18, 2011, to be attended by the APF CEO and numerous members of Teva's pain marketing team. (Doc. #: 2251, Ex. 74 at 2.) The first item on the tentative agenda was "Overview of Transition to Teva Leadership." *Id*. Whether groups like APF were truly independent third parties or merely front groups, remains an issue of fact for the jury. Though Teva contends that funding to these third-party organizations was conditional on their independence (Doc #: 1891 at 9), it is the jury's province to decide whether third-party agreements requiring independence were actually followed; and this, to large extent, may depend on the credibility of the witnesses called. It is not the Court's province to weigh the credibility of witnesses at the summary judgment stage.

Finally, Plaintiffs also point to Teva/Cephalon's large network of CME speakers, and cite at least one example where the speaker suggested that addictive behaviors in patients who had been prescribed opioids could be the product of "pseudoaddiction, which indicates inadequate pain control." (Doc. # 2251, Ex. 94 at 24.)

A reasonable finder of fact could conclude, based on the above, that the Teva entities directly, as well as through front groups and CME programs, falsely represented the risk of opioid addiction,

and that these representations were not tied to specific brand names, but applied to opioids generally.

3. New or Undeveloped Arguments.

The Sixth Circuit Court of Appeals has repeatedly approved a district court's refusal to address arguments raised for the first time in a reply brief. *See,e.g., Barany-Snyder v. Weiner*, 539 F.3d 327 (6th Cir. 2008) ("When new submissions and/or arguments are included in a reply brief, and a nonmovant's ability to respond to the new evidence has been vitiated, a problem arises with respect to Federal Rule of Civil Procedure 56(c)."); *Scottsdale Ins. Co. v. Flowers*, 513 F.3d 546, 553 (6th Cir. 2008) ("[W]e have found issues to be waived when they are raised for the first time in motions requesting reconsideration or in replies to responses."). In addition, "issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived." *United States v. Layne*, 192 F.3d 556, 566 (6th Cir. 1999).

In their reply, Generic Manufacturers argue that causation is lacking with respect to Plaintiffs' false marketing claims. (Doc #: 2447 at 12-13.) Their initial brief in support, however, made only the most conclusory statement with respect to this issue: "[the Plaintiffs] have no evidence to support the other basic elements of their claims—causation or a cognizable injury. Plaintiffs simply have no evidence that any physician was misled by any such marketing into writing a prescription that caused harm to Plaintiffs." This statement, without more, does not amount to a developed argument. "It is not sufficient for a party to mention a possible argument in the most skeletal way, leaving the court to . . . put flesh on its bones." *Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 868 (6th Cir. 2006). Moreover, the Summit R & R, in reliance on the First Circuit's decision in *In re Neurontin Litigation*, 712 F.3d 21, 37 (1st Cir. 2013), already rejected the proposition that Plaintiffs must specifically identify physicians who were misled by the Defendants'

marketing claims in order to show causation. (Doc #: 1025 at 30-32.) It bears noting that the same Defendants who identify as Generic Manufacturers for the purposes of the present motion (Doc #: 1860) have separately moved for summary judgment on the issue of causation (Doc #: 1894), wherein they identify themselves simply as "Manufacturers." Thus, these causation arguments are addressed in a separate order. (Doc #: 2561).

Finally, the Generic Manufacturers' reply suggests that a number of statements Plaintiffs identify as false or misleading are "indeed true." (Doc #: 2447 at 9-10). This too is tantamount to a new argument that was not developed in the opening brief supporting the MSJ. The Plaintiffs' false marketing theories, revolving around the "nine categories" of falsehoods and misrepresentations, were clearly set forth in Summit and Cuyahoga complaints. If the moving Defendants assert that some or all of these nine categories of alleged misrepresentations are in fact true, it is their burden as the moving parties to establish that no genuine issue of material fact remains. Their attempt to raise the issue in a cursory manner in a reply brief is not well-taken.

The Generic Manufacturers' initial brief supporting their MSJ failed to develop any meaningful argument concerning causation. In addition, despite the Complaints' clear identification of the categories of statements Plaintiffs have maintained are false from the outset of this litigation, the moving defendants did not advance the argument that some or all of those statements are indeed true in the opening brief, waiting until the reply to make such an argument.[19] The Court deems these

[19] Though the moving defendants are correct that "statements are not rendered false or misleading simply by Plaintiffs' say so," (Doc. # 2447 at 9), neither are the statements rendered true simply by Defendants' say so. Furthermore, Generic Manufacturers' argument would fail on the merits. Generic Manufacturers would have this Court find that medical use of opioids rarely causes addiction is an indisputable fact, based on a single reading of a statement during a deposition of a statement attributed to the FDA, which in turn points to a statement by the National Institute of Health, which in turn points to studies that have not been identified by Defendants as part of the

belated or undeveloped arguments waived.

C. Pharmacies and Distributors' MSJ (Doc #: 1883).

Pharmacy and Distributor Defendants contend imposition of state tort liability would stand as an obstacle to DEA's ability to regulate and enforce the Controlled Substances Act ("CSA"). Congress struck a balance between the risk of diversion and the risk of access to important medications and vested DEA with the authority to implement that framework. The Court has previously rejected this obstacle preemption argument, albeit with respect to the FDA, and now does so with respect to the DEA.

D. Non-RICO Small Distributors' MSJ (Doc #: 1873).

These Defendants contend that Ohio does not recognize a claim for fraud on a federal agency, the CSA does not provide a private cause of action or a remedy, and Plaintiffs' claims are impliedly preempted under *Buckman*.

Plaintiffs have not alleged a claim for fraud on a federal agency, the Court agrees that the CSA does not provide a private cause of action and, for numerous reasons previously articulated, Plaintiffs' claims are not impliedly preempted under *Buckman*.

IV.

In conclusion, the Court finds that Plaintiffs' state law claims are not preempted and the RICO claims are not precluded. Generic Manufacturers' additional argument, that there is no evidence they engaged in the false marketing or promotion of their generics, is not well-taken. Accordingly, the pending summary judgment motions on the question of preemption (**Doc ##: 1873,**

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record. The Court declines to do so.

1883, 1926, and 1860) are hereby **DENIED**.

IT IS SO ORDERED.

/s/ Dan Aaron Polster ***September 3, 2019***
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE