

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION  
OPIATE LITIGATION

This document relates to:

*West Boca Medical Center, Inc. v.  
AmerisourceBergen Drug Corp., et al.*, No. 18-  
op-45530

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**MEMORANDUM OF LAW IN SUPPORT OF THE MANUFACTURER DEFENDANTS'  
JOINT MOTION TO DISMISS PLAINTIFF'S COMPLAINT**

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## **INTRODUCTION AND SUMMARY OF ISSUES AND ARGUMENT**<sup>1</sup>

West Boca Medical Center, Inc. (the “Hospital” or “Plaintiff”) seeks to hold a handful of manufacturers liable for the costs of treating patients unable to pay for opioid-related medical treatment. This is not the first time that a hospital has tried to pursue this type of legal theory. As described below, numerous courts have rejected similar claims brought by hospitals against tobacco companies to recover unreimbursed medical expenses. Those claims were dismissed with prejudice for lack of causation, because the hospitals’ alleged injuries were too far removed from any alleged fraud by cigarette manufacturers and the hospitals’ claims were merely derivative of the injuries to consumers who experienced tobacco-related illnesses. The same result should apply here.

Not only does the Hospital ignore this well-settled precedent, which forecloses its claims, but the Complaint also fails for many of the same reasons stated in the Manufacturer Defendants’ Joint Motion to Dismiss the Summit County, Ohio action (Dkt. No. 499-1 (“*Summit MTD*”)), and the Broward County, Florida action (Dkt. No. 593-1 (“*Broward MTD*”)). Indeed, the Complaint replicates many of the defective allegations in those cases verbatim. It too fails to plead a cognizable injury, actual or proximate causation, or any actionable misrepresentations, omissions, or other alleged misconduct tied to the Hospital’s alleged harms, and it too suffers from many additional claim-specific defects. The Complaint should be dismissed with prejudice.<sup>2</sup>

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<sup>1</sup> Pursuant to Case Management Order One (Dkt. No. 232) ¶ 2.g, the Manufacturer Defendants raise only certain key “issues common to all manufacturers” that warrant dismissal of the Hospital’s claims. Manufacturer Defendants do not raise, and expressly reserve the right to later raise, additional grounds for dismissal of all claims, including Defendant-specific challenges.

<sup>2</sup> This motion incorporates the definition of “Manufacturer Defendants” set forth in the *Summit MTD* at 1 n.2. Defendant Noramco, Inc. (“Noramco”), a company referenced in the Complaint as a former affiliate of Janssen (*see* Compl. ¶ 98), joins in this Motion to the extent applicable. Noramco does not (and did not at all material times relevant hereto) manufacture, package, brand, market, distribute, or sell the finished drug products at issue in this litigation, and

## LEGAL STANDARD

The Hospital's claims must meet the plausibility standard of *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and, because they sound in fraud, the particularity standard of Rule 9(b). *Summit MTD* at 5-6. The Complaint satisfies neither.

## ARGUMENT

### **I. COURTS HAVE REJECTED SIMILAR CLAIMS BROUGHT BY HOSPITALS SEEKING TO RECOVER UNREIMBURSED MEDICAL EXPENSES BASED UPON ALLEGED INDUSTRY-WIDE FRAUD.**

This is not the first time that a hospital has tried to bring fraud-based claims against manufacturers in an effort to recover unreimbursed medical expenses allegedly related to their products. In *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429 (3d Cir. 2000), for instance, several hospitals brought claims against tobacco manufacturers “seeking to recover unreimbursed costs of health care provided to nonpaying patients suffering from tobacco-related disease.” *Id.* at 432. The hospitals alleged that the manufacturers engaged in a “conspiracy lasting more than 40 years” that “deceived and misled the public about the addictive properties of nicotine and the health risks of smoking.” *Id.* at 433. As here, the hospitals also asserted RICO claims and common-law claims for, among other things, fraud, public nuisance, unjust enrichment, civil conspiracy, breach of duty, and negligence. *Id.* at 434.

The Third Circuit affirmed the dismissal of all claims. It held that the hospitals could not establish proximate causation as a matter of law because their alleged injuries were too “remote and indirect.” *Id.* at 444. The hospitals’ claims, for example, required inquiry into whether any “increased costs . . . resulted from the tobacco companies’ conspiracy to suppress health and safety

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it reserves all rights and defenses specific to it. In addition, although the arguments raised herein apply equally to Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc, these parties do not join this Motion for the same reasons stated in the *Summit MTD* at 1 n.2.



information, as opposed to smokers' other health problems, smokers' independent (i.e., separate from the fraud and conspiracy) decisions to smoke, smokers' ignoring of health and safety warnings, etc." *Id.* The hospitals' public nuisance claim failed because the hospitals "did not sufficiently allege that they suffered a harm different from and of greater magnitude than the harm suffered by the general public," given that the "Hospital's injuries are derivative of the nonpaying patients' injuries." *Id.* at 446. The Third Circuit further held that there was no "justice-based" exception to these causation requirements; to the contrary, the Court explained that permitting these types of claims would set a "dangerous" and flawed precedent that hospitals "have standing to sue any company that causes a nonpaying patient's disease illness." *Id.* at 445.

The Sixth Circuit and Ninth Circuit have followed the Third Circuit's *Allegheny General Hospital* decision in rejecting similar claims by hospitals and payors. *See, e.g., Ass'n of Washington Pub. Hosp. Dists. v. Philip Morris Inc.*, 241 F.3d 696, 704 (9th Cir. 2001) (applying *Allegheny Gen. Hosp.* to dismiss similar claims brought by association of hospitals against tobacco companies); *Perry v. Am. Tobacco Co.*, 324 F.3d 845, 849 (6th Cir. 2003) (citing *Allegheny Gen. Hosp.* with approval and relying upon that decision to dismiss claims brought by payor participant against the tobacco industry). The same logic compels dismissal here.

In fact, the Hospital's claims here are even more attenuated than the claims against tobacco manufacturers because, unlike cigarettes, the FDA-approved opioid medications at issue here serve a legitimate medical purpose and are lawfully obtained only from licensed prescribers who function as learned intermediaries. *See Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102 (Fla. 1989). The independent decision-making of prescribing physicians is yet another break in the causal chain. Like the Third, Sixth, and Ninth circuits, this Court should reject the Hospital's suggestion that there is a "justice-based" exception to the bedrock principles of proximate causation. Because

the Hospital’s alleged “injury is indirect, remote, and many steps away from the alleged cause,” *Allegheny Gen. Hosp.*, 228 F.3d at 445, this case should be dismissed with prejudice.

## **II. THE “FALSE NARRATIVE ENTERPRISE” RICO CLAIM FAILS (COUNT 1).**

The first count raises a claim under the federal Racketeer-Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §§ 1961 *et seq.* Plaintiff’s RICO allegations echo—nearly verbatim—those in previous complaints. *Compare* Compl. (Dkt. No. 385) ¶¶ 812-74 *with, e.g., Summit* Corrected 2AC (Dkt. No. 573) ¶¶ 814-77 and *Broward* 2AC (Dkt. No. 525) ¶¶ 741-804. The RICO count thus fails for all of the reasons set forth in the Manufacturer Defendants’ *Summit* MTD and *Broward* MTD—that is, there is no cognizable RICO injury, no actual or proximate causation, no plausible enterprise, and no actionable racketeering activity. *See Summit* MTD §§ II, III; *Broward* MTD §§ II., III.

In fact, the Hospital’s alleged injuries are even more attenuated than the municipalities’ alleged injuries in *Summit* and *Broward*. *See Summit* MTD §§ II.B.2, II.B.3; *Broward* MTD § II.. In *Summit* and *Broward*, both municipal plaintiffs claimed injuries stemming from public services provided in response to county residents using, abusing, or becoming addicted to opioids. Here, the Hospital claims an injury due to “unreimbursed charges for its treatment of patients with opioid conditions.” Compl. ¶ 55; *see id.* ¶¶ 56-58. In each case, the alleged injuries are entirely derivative of those suffered by third parties, here, the “patients with opioid conditions” who seek treatment from the Hospital—and who may have developed those “conditions” for any number of reasons wholly unrelated to the Manufacturer Defendants’ purported conduct. *See Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 460 (2006) (rejecting RICO claim because “[t]he direct victim” was not the plaintiff who alleged competitive harm due to alleged tax fraud by competitor); *cf. Jackson v. Sedgwick Claims Mgmt. Servs., Inc.*, 731 F.3d 556, 565 (6th Cir. 2013) (holding that economic losses derived from personal injury are not recoverable under § 1964(c)).

But the alleged injuries here are even further removed from the Manufacturer Defendants because the proposed causal chain assumes other steps not at issue in *Summit* or *Broward*, such as: (a) opioid users seeking care at the Hospital; (b) opioid users being unable to pay for that treatment (either out-of-pocket or through insurance); and (c) the Hospital's inability to recoup the treatment costs through other means. All of these intervening and independent causes make the RICO claim here even more untenable. *See Anza*, 547 U.S. at 460; *Allegheny Gen. Hosp.*, 228 F.3d at 443-44. In addition, unlike in *Summit* and *Broward*, the Hospital was *legally obligated* to provide at least some of the services at issue: federal law and state law require the Hospital to provide emergency medical services to all who demand them, regardless of cause. *See* Compl. ¶¶ 6, 41 (citing 42 U.S.C. §1395dd), ¶¶ 42-43 (citing Fla. Stat. § 395.1041), ¶ 44 (citing Fla. Stat. § 394.459). Thus, applicable federal and state law defeats causation because any alleged harm to the Hospital stems from these legislative public-policy decisions.

Finally, as in *Summit* and *Broward*, the Hospital has not pleaded any predicate act with the requisite particularity. *See Summit* MTD § II.B.4.; *Broward* MTD § II. The Hospital alleges predicate acts of federal mail and wire fraud under 18 U.S.C. §§1341 and 1343, respectively, and reporting violations under the Controlled Substances Act (“CSA”), 21 U.S.C. §§ 801 *et seq.* *See* Compl. ¶ 881. But reporting-based CSA violations cannot constitute predicate acts under RICO. *See Summit* MTD III.B.4. & n.31. And, as in *Summit* and *Broward*, the Hospital fails to plead a single misrepresentation or omission made to anyone at the Hospital or to any doctor that supposedly caused that doctor to write a medically inappropriate prescription for any patient who was eventually treated at the Hospital. The Hospital certainly fails to provide the critical details—i.e., the “who, what, when, and where”—of any such fraud required under Rule 9(b).

This failure is even more glaring here because the Hospital *operates a healthcare facility* that, according to the Complaint, “purchased opiates from the Defendants, and used them.” Compl. ¶ 63. Surely the Hospital knows which opiate medications it purchased, when they were purchased, whether its physician-employees were exposed to or relied on any alleged misrepresentations before deciding what medicine to prescribe, and whether any prescription was medically unnecessary or harmful to the patient. Yet the Complaint has no such allegations. The Hospital’s silence defeats its RICO and other claims.

### **III. THE HOSPITAL’S SECTION 1962(A) AND SECTION 1962(D) RICO CLAIMS FAIL (COUNT 2).**

Like its Section 1962(c) claim, the Hospital’s federal RICO claims under Sections 1962(a) and 1962(d) should be dismissed for failure to plead any actionable racketeering activity, an enterprise, or causation. *See* 18 U.S.C. § 1962(a) (requiring these elements); *Huff v. FirstEnergy Corp.*, 972 F. Supp. 2d 1018, 1039 (N.D. Ohio 2013) (to state a claim under Section 1962(d), plaintiffs “must successfully allege all the elements of a RICO violation” and an “illicit agreement to violate the substantive RICO provisions.”). The Hospital also fails to plead the *additional* elements required to state these federal RICO because it does not (and cannot) allege a cognizable investment injury under Section 1962(a) or an unlawful conspiracy under Section 1962(d).

#### **A. The Hospital Has Not Alleged An “Investment Injury” Under Section 1962(a).**

Section 1962(a) prohibits the use or investment of “any income derived . . . from a pattern of racketeering activity” in the acquisition, establishment, or operation of any enterprise that affects interstate commerce. 18 U.S.C. § 1962(a). To state a claim under Section 1962(a), the Hospital must allege it suffered an injury caused by the investment itself that is “*distinct from* any injuries caused by the predicate acts of racketeering.” *Vemco, Inc. v. Camardella*, 23 F.3d 129, 132 (6th Cir. 1994) (emphasis in original). In other words, it is not enough to allege the

Manufacturer Defendants used racketeering income to operate a purported enterprise, and that the enterprise harmed the Hospital. *Id.* at 133. Rather, the Hospital must allege separate and distinct “injuries *stemming directly* from the defendants’ alleged use or investment of their illegally obtained income.” *Craighead v. E.F. Hutton & Co.*, 899 F.2d 485, 494 (6th Cir. 1990).

Here, the Hospital does not (and cannot) identify any injuries stemming directly from investments purportedly made by the Manufacturer Defendants that are “distinct from injuries stemming from predicate acts.” *Vemco, Inc.*, 23 F.3d at 133. Indeed, the Hospital expressly alleges only that it was “injured . . . through the above-referenced *acts of racketeering*,” Compl. ¶ 894, and not through any specific investment itself. Under controlling Sixth Circuit precedent, this pleading deficiency alone defeats Plaintiff’s Section 1962(a) claim. *See Craighead*, 899 F.2d at 494 (dismissing Section 1962(a) claim because it requires “a separate and traceable injury and plaintiffs have alleged only injuries traceable to the alleged predicate acts.”); *Gotham Print, Inc. v. Am. Speedy Printing Ctrs., Inc.*, 863 F. Supp. 447, 461 (E.D. Mich. 1994) (same where “[t]he real source of Plaintiffs’ purported injury is that Defendants supposedly made certain misrepresentations and failed to disclose certain facts—not that they were injured by Defendants [sic] investment of money generated by those actions . . .”).

**B. The Hospital Has Not Alleged A RICO Conspiracy Under Section 1962(d).**

The Court also should dismiss Plaintiff’s RICO conspiracy claim under Section 1962(d) as derivative of Plaintiff’s failed RICO claims under Sections 1962(a) and (c). *See Craighead*, 899 F.2d at 495 (“Plaintiffs’ [RICO] conspiracy claim cannot stand in light of the dismissal of their other RICO counts.”).

Moreover, the conspiracy claim fails on its own terms because the Hospital has not alleged any conspiratorial *agreement* among the Manufacturer Defendants to violate RICO. *See, e.g., id.*; *Huff*, 972 F. Supp. 2d at 1039. Here, the Hospital makes only conclusory and unsupported

allegations that the Manufacturer Defendants “agreed, with knowledge and intent, to the overall objective of [their] fraudulent scheme.” Compl. ¶ 844(d). But the Hospital does not plead any specific facts to plausibly show any type of agreement between any of the Manufacturer Defendants—many of whom are direct competitors. Like in *Summit* and *Broward*, such a conclusory allegation fails to state a plausible conspiracy claim, let alone meet the particularity requirements of Rule 9(b) applicable to Plaintiff’s RICO claims. *Huff*, 972 F. Supp. 2d at 1040 (requiring plaintiff to specify “when, where, or between whom any alleged illicit agreement was made.”); *see also Summit* MTD § XIII.; *Broward* MTD, at § IX.

#### **IV. THE HOSPITAL’S STATE LAW CLAIMS ARE PREEMPTED BY FEDERAL LAW (COUNTS 3-12).**

As in *Summit* and *Broward*, federal law preempts the Hospital’s state law claims. The Hospital alleges the Manufacturer Defendants falsely represented opioids as safe and effective for the long-term treatment of chronic, non-cancer pain, even though FDA has approved most of the medications at issue here for exactly that purpose. *See, e.g.*, Compl. ¶¶ 15-16, 68-69, 72-73, 76, 131, 148, 155, 158-59, 161-63, 176. Moreover, “[t]he restrictions and guidelines placed upon pharmaceutical companies for off-label promotion are entirely dependent upon the statutory and regulatory scheme created by the FDCA,” which “does not provide a private right of action” to enforce its provisions. *Perdue v. Wyeth Pharm., Inc.*, 209 F. Supp. 3d 847, 851-52 (E.D.N.C. 2016), *appeal dismissed sub nom. Perdue v. Teva Pharm. USA, Inc.*, 2018 WL 994177 (4th Cir. Feb. 8, 2018). Therefore, because the Hospital’s claims conflict with FDA’s expert regulatory decisions regarding the approval and labeling of the Manufacturer Defendants’ medications, and thus they are preempted by federal law. *See Summit* MTD § IV.

**V. THE FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT CLAIM FAILS (COUNT 3).**

The Hospital's Florida Deceptive and Unfair Trade Practices Act ("FDUTPA") claim fails for the same reasons as the FDUTPA claim in *Broward*. See *Broward* MTD § VII. First, the FDUTPA safe-harbor provision applies because the FDA has approved most of the ER/LA opioid medications at issue here for the treatment of chronic pain and Florida law authorizes such use of opioids. *Id.* at § VII.A. (citing Fla. Stat. § 501.212(1) and Fla. Stat. § 456.44(2), (3)). Therefore, under the FDUTPA safe-harbor provision, the Hospital's FDUTPA claim based on advertising and promotion of these products fails as a matter of law. *Broward* MTD. at § VII.A.; see also *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234 (S.D. Fla. 2007) (applying safe-harbor where alleged advertisements "largely comport with[] the [FDA] approved label.").

*Second*, for the same reasons set forth in *Broward*, the Hospital fails to allege that it is a "consumer" authorized to bring a FDUTPA action. *Broward* MTD § VII.B. Although the Hospital seeks to recover the costs of providing unreimbursed services to patients addicted to opioids and the "operational costs" associated with such treatment, Compl. ¶¶ 55-58, the Hospital is not a "consumer" of any medicine sold by the Manufacturer Defendants. In addition, the Hospital pleads only conclusory allegations that it purchased opioids, *id.* ¶ 63, it does not identify a single prescription for which it purportedly paid, much less one written because of any Manufacturer Defendant's allegedly false or misleading statement. Nor would the Hospital's purchase of any such medicine in order to profit from that purchase render the Hospital a "consumer"; like a third-party payor, in this capacity, the Hospital acts only as an economic middleman—paying for

prescriptions used by actual consumers.<sup>3</sup> Accordingly, the Hospital cannot bring a claim under FDUTPA. *Broward* MTD § VII.B.

*Third*, the Hospital has not alleged *any* of the elements of a FDUTPA claim. As in *Broward* and described above, the Hospital does not plead the existence of an actionable misrepresentation or omission, or a causal link between any such statement and any unreimbursed medical service allegedly rendered. *See Broward* MTD § VII.C.; *Molina v. Aurora Loan Servs., LLC*, 635 F. App'x 618, 627 (11th Cir. 2015) (affirming dismissal of FDUTPA claim for lack of causation). Moreover, the Hospital's alleged damages, such as increased costs of providing healthcare to patients addicted to opioids, Compl. ¶ 55, are incidental or "consequential damages . . . not recoverable under FDUTPA." *Marketran, LLC v. Brooklyn Water Enters., Inc.*, 2017 WL 1292983, at \*4 (S.D. Fla. Jan. 31, 2017); *see also Hesterly v. Royal Caribbean Cruises, Ltd.*, 2008 WL 11406184, at \*7 (S.D. Fla. Aug. 6, 2008) (striking prayer for FDUTPA "damages associated with personal injury, pain and suffering, mental anguish, disability, past and future medical expenses, and other consequential damages"). The Hospital's FDUTPA claim must be dismissed.

#### **VI. THE MISLEADING ADVERTISING CLAIM FAILS (COUNT 4).**

To recover under Florida's misleading advertising statute, Fla. Stat. § 817.41, the Hospital must establish common law fraud in the inducement, including (1) an intentional misrepresentation and (2) reasonable and justifiable reliance. *Joseph v. Liberty Nat. Bank*, 873 So. 2d 384, 388 (Fla. Dist. Ct. App. 2004). Taken together, these elements require the Hospital to establish a "causal connection between the allegedly false advertisement and the injuries sustained." *Martino v. City*

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<sup>3</sup> Courts have dismissed claims brought by third-party payors against pharmaceutical manufacturers under consumer protection statutes that similarly impose a "consumer" requirement on the ground that a third-party payor is not a "consumer" of prescription medicines. *See, e.g., Cent. Reg'l Emps. Ben. Fund v. Cephalon, Inc.*, 2009 WL 3245485, at \*3 (D.N.J. Oct. 7, 2009); *In re Rezulin Prod. Liab. Litig.*, 392 F. Supp. 2d 597, 616-17 (S.D.N.Y. 2005).



*Furniture, Inc.*, 2006 WL 8431423, at \*4 (S.D. Fla. June 29, 2006); *see also Humana, Inc. v. Castillo*, 728 So. 2d 261, 265 (Fla. Dist. Ct. App. 1999); *Himes v. Brown & Co. Sec. Corp.*, 518 So. 2d 937, 938 (Fla. Dist. Ct. App. 1987). The Hospital fails to pleads facts that satisfy these elements.

First, as discussed above, the Hospital has failed to allege (1) any false or misleading statement by the Manufacture Defendants, much less with the specificity required by Rule 9(b), or (2) actual or proximate causation. *Allegheny Gen. Hosp.*, 228 F.3d at 444-46.

Second, the Hospital fails to allege that it was exposed to, and relied on, any alleged misrepresentations by the Manufacturing Defendants. *See Fla. Stat. § 817.41; Smith v. Mellon Bank*, 957 F.2d 856, 858 (11th Cir. 1992); *Vance v. Indian Hammock Hunt & Riding Club, Ltd.*, 403 So. 2d 1367, 1370 (Fla. Dist. Ct. App. 1981). Instead, the Hospital provides only conclusory allegations that various unspecified *physicians* heard and relied on the Manufacturing Defendants' various unspecified misrepresentations. *See, e.g.*, Compl. ¶¶ 161, 214, 237. Because the Hospital does not identify any statements that *it* received and relied upon, *id.* ¶¶ 438-39, the Hospital fails to state a viable claim. *See Samuels v. King Motor Co. of Fort Lauderdale*, 782 So. 2d 489, 496 (Fla. Dist. Ct. App. 2001); *see also Smith*, 957 F.2d at 858; *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 655 F. Supp. 2d 1270, 1289 (S.D. Fla. 2009).

## **VII. THE BREACH OF IMPLIED WARRANTY CLAIM FAILS (COUNT 5).**

The Hospital alleges that the Manufacturer Defendants breached an implied warranty of fitness for a particular purpose, Fla. Stat. § 672.315, by selling prescription opioids that were “not suitable” for the purpose of “provid[ing] pain relief.” Compl. ¶¶ 922-28.<sup>4</sup> Plaintiff’s implied

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<sup>4</sup> The Hospital also styles Count 5 as a cause of action under Fla. Stat. § “672.11, *et seq.*” Compl. at 923. No such statute(s) exists. Because Count 5 refers only to a “Breach of Implied Warranty of Fitness For a Particular Purpose,” *id.*, the Manufacturer Defendants construe Count 5 as alleging violation of only Fla. Stat. § 672.315.

warranty claim is procedurally and substantively defective.

*First*, the Hospital failed to provide the requisite notice of breach to the Manufacturer Defendants. *See Armadillo Distrib. Enters. v. Hai Yun Musical Instruments Manufacture Co., Ltd.*, 142 F. Supp. 3d 1245, 1254 (M.D. Fla. 2015) (“[T]he buyer must provide notice to the seller of the breach of warranty.”); Fla. Stat. § 672.607(3)(a) (“The buyer must within a reasonable time after he or she discovers or should have discovered any breach notify the seller of breach or be barred from any remedy.”). Under Florida law, “[t]he buyer bears the burden of showing that he gave the required notice within a reasonable time,” and “[t]he notice must be both timely and sufficient under the circumstances and is governed by the buyer’s obligation to act in good faith.” *Royal Typewriter Co., a Div. of Litton Bus. Sys. v. Xerographic Supplies Corp.*, 719 F.2d 1092, 1102 (11th Cir. 1983). Plaintiff nowhere alleges that it provided **any** such notice to any Manufacturer Defendant. *See* Compl. ¶¶ 922-28. This failure alone requires dismissal. *See* Fla. Stat. § 672.607(3)(a).

*Second*, in Florida, “to recover for the breach of a warranty . . . the plaintiff must be **in privity of contract** with the defendant.” *T.W.M. v. Am. Med. Sys., Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995). Privity exists only when the plaintiff “purchase[d] a product . . . **directly from the defendant.**” *Id.* The Hospital does not allege it purchased opioids directly from the Manufacturer Defendants. Nor could it. As the Complaint acknowledges, the Manufacturer Defendants sell directly to wholesale distributors rather than to hospitals or medical centers. *See, e.g.*, Compl. ¶ 730 (alleging that Mallinckrodt’s “direct customers” are “distributors”).<sup>5</sup> The

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<sup>5</sup> To the extent that the Hospital’s allegations could be construed as alleging the existence of a direct transaction with any of the Manufacturer Defendants, these allegations should be disregarded as vague and conclusory. *See, e.g.*, Compl. ¶¶ 52 (alleging that the Hospital “has purchased and continues to purchase” unspecified “opioids” that were “marketed and sold by”

Hospital's failure to allege privity is "dispositive [and the] claim of breach of implied warranty fails as a matter of law." *Bailey v. Monaco Coach Corp.*, 168 F. App'x 893, 894-95 (11th Cir. 2006) (per curiam).

*Third*, the Hospital must show that it purchased opioids for a "particular purpose" apart from the ordinary purpose of pain relief. *See Armadillo*, 142 F. Supp. 3d at 1255 (requiring plaintiff to show that "a seller has reason to know a particular purpose for which the goods are required"). A particular purpose "'envisages a specific use by the buyer which is *peculiar* to the nature of his business.'" *Id.* (quoting *Royal Typewriter Co.*, 719 F.2d at 1100). Here, however, as alleged by Plaintiff, the "ordinary" use of prescription opioids is "to provide pain relief in an appropriate way that [does] not unnecessarily endanger [the hospital's] patients." Compl. ¶ 924. Moreover, the Hospital does not allege facts to show that it purchased opioids for any "particular purpose" that is "peculiar to" a hospital, or that it communicated a particular purpose to any Manufacturer Defendant. This defeats the Hospital's implied warranty claim. *See Royal Typewriter Co.*, 719 F.2d at 1100 (rejecting implied warranty claim involving copier machines when "the contemplated use of the machines was as copiers—the ordinary purpose for which [the machine] was sold").

*Fourth*, the Hospital does not plead facts showing that any breach caused *its* alleged injuries. *See Dunham-Bush, Inc. v. Thermo-Air Serv., Inc.*, 351 So. 2d 351, 353 (Fla. Dist. Ct. App. 1977) (requiring a showing of "injuries *sustained by the buyer* as a result of the breach of warranty."). The Hospital's conclusory assertion that it "has been damaged" in unspecified amounts by the Manufacturer Defendants' purported breach, Compl. ¶ 928, is insufficient to make

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unspecified "Defendants"), *id.* ¶ 923 (alleging that the Hospital purchased unspecified "opioid products" from unspecified "Defendants").

this showing. *See Ashcroft v. Iqbal*, 556 U.S. 662, 677-79 (2009); *Dunham-Bush*, 351 So. 2d at 353. Indeed, despite its conclusory allegations, Compl. ¶¶ 923-24, the Hospital fails to identify any facts alleging that it did not get exactly what it bargained for: a prescription pain medicine with the properties, benefits, and risks identified in the FDA-approved label for that medicine. This, too, defeats the Hospital's breach of warranty claim.

### **VIII. THE HOSPITAL'S NEGLIGENCE CLAIMS FAIL (COUNTS 6-10).**

The Hospital asserts five types of negligence claims: Negligence (Count VI), Wanton Negligence (Count VII), Negligence Per Se (Count VIII), Negligent Marketing (Count IX), and Negligent Distribution (Count X). All fail because, as explained in *Summit* and *Broward County*: (1) the Complaint fails to plead any actionable conduct; (2) it fails to plead actual and proximate causation; and (3) the claims are preempted. *See Summit* MTD §§ IX., X.; *Broward* MTD §§ V., VI. They also fail for two additional reasons.

*First*, as an initial matter, Counts IX and X are not cognizable under Florida law. Indeed, courts have expressly held that “no Florida law exists supporting [a] claim for negligent marketing.” *Cabbage v. Novartis Pharm. Corp.*, 2016 WL 3595747 at \*9 (M.D. Fla. July 5, 2016) (dismissing claim on this ground). And the Manufacturer Defendants are unaware of any Florida authorities recognizing a claim for “negligent distribution” against a pharmaceutical manufacturer.

*Second*, as in *Broward*, the Hospital does not and cannot plead the threshold element of a negligence claim: that the Manufacturer Defendants owed a duty of care to Plaintiff. *Wallace v. Dean*, 3 So. 3d 1035, 1044 (Fla. 2009). Although the Complaint makes a generalized reference to the Manufacturer Defendants' duties with respect to the marketing and distribution of opioids, *see, e.g.*, Compl. ¶¶ 519-521, 971, 984, none of these vague allegations identifies any cognizable common law or statutory duty owed by the Manufacturer Defendants *to the Hospital*. Nor does the Hospital allege any special relationship with the Manufacturer Defendants. *See Estate of*

*Johnson ex rel. Johnson v. Badger Acquisition Of Tampa LLC*, 983 So. 2d 1175, 1182 (Fla. Dist. Ct. App. 2008). And although a statute may create a duty of care for negligence, that is true only where the statute includes a private right of action. *Owens-Benniefield v. Nationstar Mortg. LLC*, 258 F. Supp. 3d 1300, 1316 (M.D. Fla. 2017). Here, none of the cited statutes establish a private right of action. Indeed, Florida law bars recovery in negligence premised on purported federal FDCA, state FDCA, or CSA violations. *See, e.g., Markland v. Insys Therapeutics, Inc.*, 270 F. Supp. 3d 1318, 1331 (M.D. Fla. 2017); *Barrow v. Bristol-Myers Squibb*, 1998 WL 812318, at \*46 (M.D. Fla. Oct. 29, 1998), *aff'd sub nom* 190 F.3d 541 (11th Cir. 1999); *Labzda v. Purdue Pharma, L.P.*, 292 F. Supp. 2d 1346, 1355 (S.D. Fla. 2003). The Hospital cannot use common law theories to circumvent clear legislative intent not to create a private cause of action in these statutes. *See Buell v. Direct Gen. Ins. Agency, Inc.*, 267 F. App'x 907, 909 (11th Cir. 2008) (applying rule).

#### **IX. THE HOSPITAL'S PUBLIC NUISANCE CLAIM FAILS (COUNT 11).<sup>6</sup>**

The Hospital's public nuisance claim fails as a matter of law for the same reason stated in *Broward*: (1) Florida does not impose nuisance liability for the distribution and sale of lawful products, even those alleged to be defective; and (2) even if it did, the Hospital's injuries were not proximately caused by the Manufacturer Defendants' alleged conduct. *Broward* MTD § IV.

##### **A. The Hospital's Nuisance Claims are Barred Under Florida's Safe Harbor.**

Under Florida's safe harbor doctrine, "[p]ublic nuisance [liability] does not apply to the design, manufacture, and distribution of a lawful product." *Penelas v. Arms Tech., Inc.*, 1999 WL 1204353, at \*4 (Fla. Cir. Ct. Dec. 13, 1999), *aff'd*, 778 So. 2d 1042 (Fla. Dist. Ct. App. 2001).

Here, both federal and state law authorize and regulate the manufacture, marketing, labeling, sale,

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<sup>6</sup> The Hospital styles this claim simply as one for "nuisance," but states that "[t]he nuisance undermines public health, quality of life, and safety" (Compl. ¶ 997) and that it "[h]as harmed and will continue to harm the public health services of and public peace of Plaintiff" (*id.* ¶ 996(a)). Thus, Manufacturer Defendants construe this claim as one for public nuisance.

and use of the Manufacturer Defendants' opioid medications, including for the treatment of chronic pain, *see, e.g., Summit* MTD § VII.C.; *Broward* MTD §IV.B., and the Hospital has otherwise failed to allege any unlawful conduct by any Manufacturer Defendant. Florida's safe harbor thus bars the Hospital's public nuisance claim.

**B. The Hospital Cannot Plead Causation.**

The Hospital's public nuisance claim also fails because there is no causal connection between the Manufacturer Defendants' alleged actions and the Hospital's alleged harm. As explained in *Summit* and *Broward*, the chain of causation breaks when a link involves criminal acts of independent third parties. *See, e.g., Summit* MTD § VII.; *Broward* MTD § IV. The same applies here. Although the Hospital alleges that "[t]he nuisance is the over-saturation of opioids in the patient population of Plaintiff and in the geographic area served by Plaintiff for illegitimate purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use," Compl. ¶ 991, it also concedes that its injuries resulted from "widespread illegal opioid use," *id.* ¶ 991, the use of prescription opioids by "criminals," *id.* ¶ 993, and "theft, diversion and misuse of controlled substances," *id.* ¶ 994. This concession is fatal to the Hospital's attempt to establish proximate causation. *See Penelas*, 1999 WL 12043453 at \*4 ("Here, the nuisance is criminal or reckless misuse of [a product] by third parties who are beyond the control of the defendants. Because defendants have no ability to control the misconduct of these third parties, nuisance does not apply for that reason as well."). The Hospital's nuisance claim should be dismissed.<sup>7</sup>

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<sup>7</sup> In addition, as in *Allegheny Gen. Hosp.*, the Hospital's alleged harm is the same as the alleged harm to the general public, for its "injuries are derivative of the nonpaying patients' injuries" and it is "one of numerous parties in the public harmed by the alleged conspiracy." 228 F.3d at 446. Thus, "remedying the source of the [problem] is more properly a task for public officials." *Id.* The public nuisance claim fails for this reason, too.

**X. THE UNJUST ENRICHMENT CLAIM FAILS (COUNT 12).**

The Hospital's unjust enrichment claim is derivative of its other claims and thus falls with them. *Baptista v. JPMorgan Chase Bank, N.A.*, 640 F.3d 1194, 1197 (11th Cir. 2011).

The unjust enrichment claim also fails on its own terms. As explained in *Broward*, a plaintiff pleading unjust enrichment must allege that *the plaintiff* conferred a benefit on the defendant. *Broward* MTD § VIII. Here, however, the Hospital does not plausibly allege any such benefit. Although the Hospital asserts, with no supporting facts, that it “conferred a benefit on Defendants because Defendants should bear the expense of treating these patients’ opioid conditions,” Compl. ¶ 1006, this conclusory and illogical assertion is insufficient under *Iqbal* and *Twombly*. The Hospital’s view that Defendants should pay is not a benefit provided by the Plaintiff to Defendants. Indeed, the Hospital fails to allege any direct transaction with the Manufacturer Defendants in which a benefit was conferred, much less an unjust one, and any such benefit would have been conferred on patients, and not the Manufacturer Defendants. *See Allegheny Gen. Hosp.*, 228 F.3d at 447. Therefore, the Hospital’s unjust enrichment claim should be dismissed.

**XI. ALL CLAIMS SHOULD BE DISMISSED, IN PART, AS TIME-BARRED.**

**A. The Applicable Statutes of Limitations Bar The Hospital’s Claims.**

The Hospital’s claims rely largely on alleged acts or omissions that occurred as far back as the mid-1990s. *See, e.g.*, Compl. ¶¶ 172, 239, 284. But each claim is subject to a statute of limitations and the *longest* applicable limitations period is five years.<sup>8</sup> Because Plaintiff’s claims are “founded on fraud,” they accrued at “the time the facts giving rise to the cause of action were

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<sup>8</sup> Fla. Stat. § 772.17 (five-year period applies to Florida RICO claim). The remaining claims are subject to a four-year period. *Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 156 (1987) (federal RICO); Fla. Stat. § 95.11(3) (FDUTPA, nuisance, negligence, wanton negligence, negligent marketing, negligent distribution, unjust enrichment, misleading advertising, and breach of implied warranty claims).

discovered or should have been discovered with the exercise of due diligence.” Fla. Stat. § 95.031(2)(a). To the extent any claims are not fraud-based, they accrued “when the last element constituting the cause of action occur[red].” *Id.* § 95.031(1). Under either standard, at a minimum the Court should dismiss the Hospital’s claims to the extent they depend on alleged fraud-based conduct or any harm incurred before May 3, 2013—five years before the Hospital brought suit—and certain claims have ever shorter limitations periods.

Notwithstanding their labels, the Hospital’s claims are all premised on fraud-based conduct alleged to have begun roughly 20 years ago, *see* Compl. ¶¶ 168-83, 239, 251, 282, 284, 343, 351, 360, 495, 499, 827, including publications, advertisements, and third-party materials allegedly created and published before May 2013, *e.g., id.* at ¶¶ 192, 194, 203, 210, 218, 220, 224-25, 228, 230, 242, 254-55, 260-61, 263, 265-67, 269, 271, 276, 280, 293, 305, 352, 357, 361-62, 377-79, 399-400, 790-92. The Hospital cannot recover for any alleged injuries caused by this conduct, nor can they rely on more recent conduct as a “bootstrap to recover for injuries” caused by that time-barred conduct. *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 183 (1997) (applying rule to RICO claims). Even if its claims were not fraud-based, the Hospital still would not be able to recover under Florida law for alleged misconduct that purportedly caused it to incur any expenses prior to May 2013. The statutes of limitations thus preclude the vast majority, if not all, of the Hospital’s allegations with respect to each Manufacturer Defendant.

**B. No Exception to the Limitations Periods Applies.**

The Complaint cites three exceptions to the limitations period: fraudulent concealment, equitable estoppel, and continuing violation. *See* Compl. ¶¶ 769-80. As in *Summit* and *Broward*, none applies here.

**1. Fraudulent Concealment and Equitable Estoppel Do Not Apply.**

Both the fraudulent concealment and equitable estoppel doctrines require affirmative



conduct—apart from the underlying fraud—that constitutes “willful concealment of the cause of action” (in the case of fraudulent concealment), or that induces the plaintiff to believe that limitations would not be enforced (in the case of equitable estoppel). *Raie v. Cheminova, Inc.*, 336 F.3d 1278, 1282 n.1 (11th Cir. 2003) (fraudulent concealment); *Zainulabeddin v. Univ. of S. Fla. Bd. of Trs.*, 2017 WL 5202998, at \*11 (M.D. Fla. Apr. 19, 2017), *reconsideration denied*, 2017 WL 5202999 (M.D. Fla. May 3, 2017) (equitable estoppel). Plaintiff fails to plead facts sufficient to support either exception. To the contrary, the Complaint confirms that the Hospital knew, or reasonably should have known, of the alleged fraud long before May 3, 2013. Indeed, much of the information relied upon by the Hospital in its Complaint was publicly available before 2013. For example:

- Beginning in 2001, the FDA took public regulatory actions related to opioid medications, which the Hospital now claims show actionable misconduct on the part of the Manufacturer Defendants. *See* Compl. ¶¶ 90, 180, 251, 260, 276, 499(a), 785, 787, and 790; and
- The Hospital relies upon articles related to opioids and opioid addiction that were published as early as 2001. *See, e.g., id.* ¶¶ 222, 263, 343, 395, and 488.

The Hospital also necessarily knew of the alleged unreimbursed costs it spent for opioid-related treatment more than five years ago. And the Hospital has not alleged—indeed, it cannot allege—that any Manufacturer Defendant took affirmative steps to prevent the Hospital from bringing its claims or to induce the Hospital into believing that limitations would not be enforced. As a result, neither exception applies.

## **2. The Continuing Violation Doctrine Does Not Apply.**

“A continuing tort is ‘established by continual tortious *acts*, not by continual harmful effects from an original, completed act.’” *Suarez v. City of Tampa*, 987 So. 2d 681, 686 (Fla. Dist. Ct. App. 2008). Further, “[i]f an event or series of events should have alerted a reasonable person to act to assert his or her rights at the time of the violation, the victim cannot later rely on the

continuing violation doctrine[.]” *Weinberg v. Alley*, 2011 WL 1878129, at \*2 (N.D. Fla. Mar. 17, 2011), *report and recommendation approved sub nom. Weinberg v. Wakulla Cty. Bd. of Comm’rs*, 2011 WL 1877832 (N.D. Fla. May 17, 2011).

Just like the municipal plaintiffs in *Summit* and *Broward*, the Hospital alleges discrete acts that were themselves potentially actionable: that is, different Defendants, making different representations at distinct times to separate prescribers, who wrote different prescriptions that led to discrete alleged harms to different patients, and to discrete medical services to treat those alleged harms that, in some unidentified instances, went unreimbursed. *See, e.g.*, Compl. ¶¶ 165-84, 186-200, 202-08, 210-12, 215-20, 223-30, 233-35, 239-45, 249-59, 266-71, 274-84, 290, 295.<sup>9</sup> This is not a “continuing tort.” Moreover, the alleged public events for which the Hospital (a medical center) has sued, including alleged public misrepresentations about the safety and efficacy of opioids, should have alerted it to any claims it might have well before May 2013. *Weinberg*, 2011 WL 1878129, at \*2; *see also* Compl. ¶¶ 90, 180, 247, 251, 260, 276, 499(a), 785, 787, and 790. The continuing violation doctrine does not apply.

## **XII. THE HOSPITAL’S REQUEST FOR PUNITIVE DAMAGES SHOULD BE STRICKEN.**

The Court should strike the Hospital’s request for punitive damages on its false advertising and wanton negligence counts, *see* Compl. ¶¶ 921, 940, because the Complaint contains only conclusory allegations plainly insufficient to justify such extraordinary relief. *See Porter v. Ogden, Newell & Welch*, 241 F.3d 1334, 1341-42 (11th Cir. 2001) (plaintiff “must plead specific acts committed by a defendant” to support punitive damages). Indeed, the punitive damages allegations here—buried in a section on civil conspiracy—echo the same deficient allegations in

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<sup>9</sup> The Complaint also alleges that the Manufacturer Defendants used different channels to make their representations to prescribers. *See, e.g.*, Compl. ¶ 329.

*Broward* nearly verbatim. Compare Compl. ¶¶ 781-811 with *Broward* 2AC ¶¶ 708-710, 712-740.

The Hospital's punitive damages request fails for the same reasons.

**CONCLUSION**

For the foregoing reasons, the Complaint should be dismissed with prejudice.

Dated: June 29, 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, and L.R. 7.1(f).

Dated: June 29 2018

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 29, 2018, a copy of the foregoing **Memorandum of Law in Support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiff's Complaint** 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.

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