

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

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

The State of Alabama v. Purdue Pharma L.P.,
No. 1:18-op-45236-DAP

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 THE STATE OF ALABAMA'S FIRST AMENDED
COMPLAINT**

TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	iii
INTRODUCTION AND SUMMARY OF ISSUES AND ARGUMENT	1
LEGAL STANDARD.....	2
ARGUMENT	2
I. THE STATE’S CLAIMS FOR DAMAGES FAIL FOR SEVERAL REASONS	2
A. The Derivative-Injury Rule Bars the Claims	2
B. The State Has Failed to Plead Actual Causation	4
C. The State Cannot Establish Proximate Causation.....	6
II. THE STATE’S DRUG-LAW CLAIMS (COUNTS III & IV) FAIL.....	8
A. The State Has Not Pled a Violation of Federal or State Controlled Substances Acts by the Manufacturer Defendants.....	8
B. The Controlled Substances Acts Do Not Give the State a Right to the Relief It Seeks	10
C. The State Pleads No Violation of the Drug-Related Nuisance Statute Because That Statute Covers Only Drug-Related Activity at Specific Real Property.....	12
III. THE STATE’S CLAIM UNDER THE ALABAMA DECEPTIVE TRADE PRACTICES ACT (COUNT II) FAILS.....	13
A. The State is Not a “Consumer” That Can Recover Damages Under the ADTPA	13
B. The State Fails To Plead any False or Misleading Statements with Particularity.....	14
C. The State Has Failed To Plead an “Unconscionable Act”	15
IV. THE STATE’S STATUTORY PUBLIC NUISANCE CLAIM (COUNT I) FAILS.....	15
V. THE STATE’S COMMON LAW CLAIMS FAIL FOR ADDITIONAL CLAIM- SPECIFIC REASONS	17
A. The State’s Negligence Claim (Count V) Fails	17
B. Alabama’s Wantonness Claim (Count VII) Fails	19
C. The State’s Federal Common Law Unjust Enrichment Claim (Count VI) Fails.....	19
VI. THE STATE’S CLAIMS FOR MONETARY RELIEF ARE ENTIRELY OR PREDOMINATELY BARRED BY THE APPLICABLE STATUTES OF LIMITATIONS.....	20

A.	The State Cannot Recover Damages or Restitution Relating to Any Individual’s Opioid Use Beginning Before February 6, 2016.....	21
B.	The State’s ADTPA Claim for Civil Penalties Is Time Barred.....	25
	CONCLUSION.....	26

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Alabama Power Co. v. Gielle</i> , 373 So. 2d 851 (Ala. Civ. App. 1979)	25
<i>Auburn Univ. v. Int’l Bus. Mach., Corp.</i> , 716 F. Supp. 2d 1114 (M.D. Ala. 2010)	21
<i>Bell Atlantic Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	2, 4, 9
<i>Bennett v. Nationstar Mortgage, LLC</i> , No. 15-cv-165-KD-C, 2015 WL 5294321 (S.D. Ala. Sept. 8, 2015)	18
<i>In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.</i> , 2012 WL 3154957 (N.D. Cal. Aug. 2, 2012)	5
<i>In re Bextra and Celebrex Marketing Sales Practices and Prod. Liab. Litig.</i> , 495 F. Supp. 2d 1027 (N.D. Cal. 2007)	14
<i>Booker v. United Am. Ins. Co.</i> , 700 So.2d 1333 (Ala. 1997).....	21
<i>Boyce v. Cassese</i> , 941 So. 2d 932 (Ala. 2006).....	21
<i>Boyle & Co., Inc. v. Fasano</i> , No. 5:03cv47-V, 2006 WL 572183 (W.D.N.C. Mar. 3, 2006).....	21
<i>Ex parte Brian Nelson Excavating, LLC</i> , 25 So. 3d 1143, No. 1071473, 2009 WL 1643351 (Ala. June 12, 2009)	21
<i>Ex parte Capstone Bldg. Corp.</i> , 96 So.3d 77 (Ala. 2012).....	21
<i>City of Birmingham v. Crow</i> , 101 So. 2d 264 (Ala. 1958).....	2
<i>City of Chi. v. Purdue Pharma L.P.</i> , 211 F. Supp. 3d 1058, 1079-84 (N.D. Ill. 2016).....	6
<i>City of Chi. v. Purdue Pharma, L.P.</i> , No. 14-C-4361, 2015 WL 2208423 (N.D. Ill. May 8, 2015).....	5

City of Chicago v. Beretta,
821 N.E. 2d 1099 (Ill. 2004)16, 17

City of Miami v. Bank of Am. Corp.,
800 F.3d 1262 (11th Cir. 2015)20

City of Miami v. Bank of Am. Corp.,
137 S. Ct. 1296 (2017)20

City of Oakland v. BP P.L.C.,
No. C17-06011, 2018 WL 3109726 (N.D. Cal. June 25, 2018)16

City of San Francisco v. Philip Morris, Inc.,
957 F. Supp. 1130 (N.D. Cal. 1997)3

Colonial BancGroup, Inc. v. PricewaterhouseCoopers, LLP,
No. 2:11-cv-746-WKW, 2014 WL 4444148 (M.D. Ala. Sept. 9, 2014)8

Colonial Bank v. Ridley & Schweighert,
551 So. 2d 391 (Ala. 1989)18

Commodity Futures Trading Comm’n v. Wilshire Inv. Mgmt. Corp.,
531 F.3d 1339 (11th Cir. 2008)20

Cooper v. Bristol-Myers Squibb Co.,
No. 07-cv-885, 2009 WL 5206130 (D.N.J. Dec. 30, 2009)14

Craft v. Triumph Logistics, Inc.,
107 F. Supp. 3d 1218, 1221 (M.D. Ala. 2015)19

DGB, LLC v. Hinds,
55 So. 3d 218 (Ala. 2010)23

DiBiasi v. Joe Wheeler Elec. Membership Corp.,
988 So. 2d 454 (Ala. 2008)17

Doe v. Fulton-Dekalb Hosp. Authority,
628 F.3d 1325 (11th Cir. 2010)18

Durr v. Strickland,
602 F.3d 788 (6th Cir. 2010)19

Ex parte Essary,
992 So. 2d 5 (Ala. 2007)19

Flint City Nursing Home, Inc. v. Depreast,
406 So. 2d 356 (Ala. 1981)19

In re Ford Motor Co. E-350 Van Prods. Liab. Litig. (No. II),
 Civ. No. 03-4558 (HAA), MDL No. 1687, 2008 WL 4126264 (D.N.J. Sept. 2,
 2008)14

Gen. Motors Corp. v. Edwards,
 482 So. 2d 1176 (Ala. 1985),7

Holdbrooks v. Central Bank of Ala., N.A.,
 435 So. 2d 1250 (Ala. 1983).....23

Holmes v. Behr Process Corp.,
 No. 2:15-cv-0454, 2015 WL 7252662 (N.D. Ala. Nov. 17, 2015).....14, 26

Kentucky Laborers Dist. Council v. Hill & Knowlton, Inc.,
 24 F. Supp. 2d 755 (W.D. Ky. 1998).....3

Lady Corinne Trawlers, Inc. v. Zurich Ins. Co.,
 507 So. 2d 915 (Ala. 1987).....2

Moon v. Harco Drugs, Inc.,
 435 So. 2d 218 (Ala. 1983).....21, 22, 25

Morgan v. City of Tuscaloosa,
 108 So. 2d 342 (Ala. 1959).....8

Morguson v. 3M Co.,
 857 So. 2d 796 (Ala. 2003).....6

Moye v. A.G. Gaston Motels, Inc.,
 499 So. 2d 1368 (Ala. 1986).....8

Mut. Pharm. Co. v. Bartlett,
 570 U.S. 472 (2013).....6

Papastefan v. B & L Const. Co., Inc. of Mobile,
 385 So. 2d 966 (Ala. 1980).....24

Parker Bldg. Servs. Co., Inc. v. Lightsey ex rel. Lightsey,
 925 So. 2d 927 (Ala. 2005).....18

Perry v. Am. Tobacco Co.,
 324 F.3d 845 (6th Cir. 2003)3

Radcliff v. Tate & Lyle Sucralose, Inc.,
 No. 06-0345-CG-M, 2008 WL 3843446 (S.D. Ala. Aug. 14, 2008).....25

Reid v. Unilever U.S., Inc.,
 964 F. Supp. 2d 893 (N.D. Ill. 2013)14

In re Russell,
 181 B.R. 616 (M.D. Ala. 1995)15

S. Pac. Co. v. Darnell-Taenzer Lumber Co.,
 245 U.S. 531 (1918).....3

S.S. Silberblatt, Inc. v. E. Harlem Pilot Block-Building 1 Hous. Dev. Fund Co., Inc.,
 608 F.2d 28 (2d Cir. 1979)20

Safe Sts. Alliance v. Alternative Holistic Healing, LLC,
 No. 1:15-cv-00349-REB-CBS, 2016 WL 223815 (D. Colo. Jan. 19, 2016)19

Safe Sts. Alliance v. Alternative Holistic Healing, LLC,
 859 F.3d 865 (10th Cir. 2017)19

Sellers v. A.H. Robins Co., Inc.,
 715 F.2d 1559 (11th Cir. 1983)23, 24

Schwartz v. Volvo N. Am. Corp.,
 554 So. 2d 972 (Ala. 1989)7

Seybold v. Magnolia Land Co.,
 376 So. 2d 1083 (Ala. 1979).....23

Siegelman v. Ala. Ass’n of School Bds.,
 819 So. 2d 568 (Ala. 2001).....12

Spain v. Brown & Williamson Tobacco Corp.,
 872 So. 2d 101 (Ala. 2003).....25

Springhill Hosps., Inc. v. Larrimore,
 5 So. 3d 513 (Ala. 2008).....7

State v. Lead Indus. Ass’n, Inc.,
 951 A.2d 428 (R.I. 2008)16

Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.,
 171 F.3d 912 (3d Cir.1999).....4

Stone v. Smith, Kline & French Labs.,
 447 So. 2d 1301 (Ala. 1984).....7

Strayhorn v. Wyeth Pharm., Inc.,
 737 F.3d 378 (6th Cir. 2013)6

Tipler v. McKenzie Tank Lines
 547 So. 2d 438, 441 (Ala. 1989).....16, 17

<i>Travis v. Ziter</i> , 681 So. 2d 1348 (Ala. 1996).....	21
<i>U.S. v. Dekalb County</i> , 729 F.2d 738 (11th Cir. 1984)	19
<i>United Food & Commercial Workers Unions, Employers Health & Welfare Fund v. Philip Morris, Inc.</i> , 223 F.3d 1271 (11th Cir. 2000)	3, 4
<i>Waldrup v. Hartford Life Ins. Co.</i> , 598 F. Supp. 2d 1219 (N.D. Ala. 2008).....	23
<i>Weaver v. Firestone</i> , 155 So. 3d 952 (Ala. 2013).....	23
<i>Winberry v. United Collection Bureau, Inc.</i> , 697 F. Supp. 2d 1279 (M.D. Ala. 2010)	18
Statutes	
21 U.S.C. § 355(d).....	6
21 U.S.C. §§ 822, 823(a), (b) & (f).....	9
21 U.S.C. § 824.....	11
21 U.S.C. § 853.....	11
Ala. Code § 6-2-38(l).....	21
Ala. Code § 6-5-121.....	16
Ala. Code § 6-5-155(3).....	12
Ala. Code §§ 6-5-155 <i>et seq.</i>	8, 12
Ala. Code § 6-5-155.3(a)	12
Ala. Code § 6-5-155.3(b).....	13
Ala. Code § 6-5-155.3(c)	12
Ala. Code § 6-5-155.6.....	13
Ala. Code § 6-5-155.7.....	12
Ala. Code § 6-5-156.3(d).....	12

Ala. Code §§ 8-19-3(2).....	14
Ala. Code. §§ 8-19-5(2), (5), (7), and (9)	15
Ala. Code § 8-19-5(27).....	15
Ala. Code §§ 8-19-10(a)(1) & (2).....	13
Ala. Code § 8-19-10(e)	15
Ala. Code § 8-19-14.....	26
Ala. Code § 13A-12-212.....	17
Ala. Code §§ 20-2-51(a), 20-2-58(a)	10
Ala. Code § 20-2-52(a)(1).....	11
Ala. Code §§ 20-2-53, 20-2-54	11
Ala. Code §§ 20-2-71, 20-2-72.....	11
Ala. Code § 20-2-92.....	11
Ala. Code § 20-2-93.....	11
Alabama Deceptive Trade Practices Act	<i>passim</i>
Alabama Uniform Controlled Substances Act.....	<i>passim</i>
Controlled Substances Act.....	<i>passim</i>
Other Authorities	
21 C.F.R. § 841(b)	11
21 C.F.R. §§ 1301.71–1301.76.....	9
21 C.F.R. § 1301.71(a).....	11
21 C.F.R. § 1301.74	9, 11
Restatement (Second) of Torts § 821B cmt. g.....	16
Fed. R. Civ. P. 9(b)	2, 14, 23

INTRODUCTION AND SUMMARY OF ISSUES AND ARGUMENT¹

The State of Alabama brings this sweeping lawsuit seeking to hold manufacturers of certain lawful, FDA-approved opioid medications liable for the entire spectrum of public costs arising from the abuse and illegal trafficking of opioids throughout the State. The crux of the First Amended Complaint (“1AC”) is that the Manufacturer Defendants² should have to pay for all those societal and governmental costs—including lost taxes and expenditures related to law enforcement and emergency services—simply because they marketed certain prescription opioid medications for treatment for “long-term . . . chronic pain.” 1AC ¶ 6. The fundamental defect with the State’s entire action is that FDA—weighing the risks and benefits of those opioid medications—*expressly approved their use for precisely that purpose.*

At bottom, the State disagrees with FDA’s balancing of the documented benefits and risks of opioid medications for the treatment of chronic pain. But that is no basis for liability. Otherwise, any State, county, or municipality could unilaterally decide that it disagrees with a medication’s FDA approval and indications—and federal warning labels—and hold manufacturers liable for purported “fraud” for marketing the products for indications approved by FDA. That is at odds with state and federal law, as well as fundamental fairness.

¹ Pursuant to Case Management Order One (Dkt. 232) ¶ 2.g, the Manufacturer Defendants raise only certain key common issues that warrant dismissal of the State’s claims. These Defendants do not raise, and expressly reserve the right to later raise, additional grounds for dismissal of all claims, including Defendant-specific challenges.

² As used in this motion the term “Manufacturer Defendants” includes Purdue Pharma LP, Purdue Pharma Inc., and The Purdue Frederick Company Inc. (collectively, “Purdue”); Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. (collectively, “Endo”); and Rhodes Pharmaceuticals L.P. (“Rhodes”). However, Rhodes is not a manufacturer of opioid medications, and to the extent it is referred to in the State’s 1AC as a “manufacturer defendant” that is not accurate. Rhodes uses the State’s characterization here only for the sake of ease in joining this motion. The State also improperly categorizes Rhodes as a “Purdue” defendant (1AC ¶ 19). Rhodes is a separate legal entity from the Purdue defendants.

The State's theory of liability also disregards both the myriad socioeconomic reasons for opioid abuse and the many intervening links separating each company's marketing from the State's expenditures on public services, including: extensive federal regulations; individual doctor prescribing decisions; misuse and abuse of opioid medications by people who were never prescribed them; and criminal conduct, including drug trafficking and diversion. Those complexities preclude as a matter of law the State's effort to recover from a few companies who sold FDA-approved opioid medications all of the public spending and lost taxes it attributes to widespread abuse of prescription and illicit opioids.

This Court should dismiss this action in its entirety for a multitude of independent reasons discussed in detail below and in the Manufacturer Defendants' Joint Motion to Dismiss the Summit County, Ohio action (Dkt. 499-1) ("*Summit MTD*").

LEGAL STANDARD

To state a claim, the State's allegations must meet the plausibility standard of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and to the extent they sound in fraud, the particularity standard of Rule 9(b). *See Summit MTD* at 5-6. The 1AC satisfies neither standard.

ARGUMENT

I. The State's Claims for Damages Fail for Several Reasons

A. The Derivative-Injury Rule Bars the Claims

Ordinarily, a party who sustains damages because of injuries to a third party cannot directly sue the alleged wrongdoer for recovery. *See, e.g., Lady Corinne Trawlers, Inc. v. Zurich Ins. Co.*, 507 So. 2d 915, 918 (Ala. 1987) (insurer's claim is "dependent upon its liability to [the insured], which in turn is dependent upon [the tortfeasor's] liability to [the insured]"); *see also City of Birmingham v. Crow*, 101 So. 2d 264 (Ala. 1958) (government has no direct cause of

action against a defendant for the city's provision of health care to an injured third party); *see also Summit* MTD at 10.

This derivative injury rule is grounded in strong and long-standing administrative and due process concerns about duplicative recovery and redressing harms that by their nature are too remote as a matter of law. *See generally Kentucky Laborers Dist. Council v. Hill & Knowlton, Inc.*, 24 F. Supp. 2d 755, 763 (W.D. Ky. 1998) (“That a mega-lawsuit aggregating the claims of thousands may be more efficient or convenient is not a reason to jettison a time-tested legal doctrine.”). When a plaintiff's recovery is dependent on another person's injury, “[t]he general tendency of the law, in regard to damages at least,” is to allow only the directly harmed individual to recover. *See S. Pac. Co. v. Darnell-Taenzer Lumber Co.*, 245 U.S. 531, 533 (1918) (Holmes, J.); *see also Perry v. Am. Tobacco Co.*, 324 F.3d 845, 848-51 (6th Cir. 2003) (dismissing RICO claim); *City of San Francisco v. Philip Morris, Inc.*, 957 F. Supp. 1130, 1139 (N.D. Cal. 1997) (same).

United Food & Commercial Workers Unions, Employers Health & Welfare Fund v. Philip Morris, Inc., 223 F.3d 1271 (11th Cir. 2000), is particularly instructive. There, a health plan claimed that tobacco manufacturers' misrepresentations regarding the health effects of smoking caused a higher incidence of smoking and led to greater healthcare costs among its participants. Rejecting the claims, the court reasoned that the law “stops at the first link in the chain of causation.” *Id.* at 1273-74 (internal citations omitted). Accordingly, “absent subrogation—a health-care provider has no cause of action against a defendant who injures the health-care provider's ward, causing the health-care provider to incur increased expenses.” *Id.* at 1273 n.5. Indeed, the court noted that courts “uniformly have rejected” claims for such

derivative injuries. *Id.* at 1274 (citing, *e.g.*, *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912 (3d Cir.1999)).

Like the plaintiff in *United Food*, the State seeks to recover expenditures it made to address injuries derived from injuries to others. The State alleges that the Manufacturer Defendants made misrepresentations to unidentified doctors, which caused those doctors to provide patients with unnecessary, ineffective and harmful opioid prescriptions, which led to those patients experiencing addiction, overdose and other health problems, which in turn led to increased government expenditures. 1AC ¶¶ 158-161, 364, 376-77. Like the plan's alleged damages in *United Food*, the State's alleged injuries are purely derivative and not cognizable.

The derivative-injury rule also bars the State's efforts to recover amounts paid for opioid medication the State claims it would not have reimbursed were it not for Defendants' alleged misrepresentations. 1AC ¶ 441. Courts have found such reimbursement theories no more actionable than those for healthcare and other expenses derived from an injured person. *See Steamfitters*, 171 F.3d at 928 (rejecting argument that derivative injury rule would not bar a "case in which a defendant fraudulently induced health funds into reimbursing participants for a dangerous medical procedure that then harmed these participants"). The State's claims to recover for money it allegedly spent or lost as a result of prescriptions it asserts were improper are no less remote than the State's claims for other government expenditures that flow from harms sustained by third-party opioid abusers, and all claims should be dismissed.

B. The State Has Failed to Plead Actual Causation

The State must plead facts that, if true, could lead to a plausible conclusion that the State's injuries would not have occurred but for the Manufacturer Defendants' alleged conduct. *See* Ala. Pattern Jury Instruction 33.00 (defendant's "conduct caused the harm if . . . the harm would not have happened without the conduct"); *see generally Twombly*, 550 U.S. at 555-56.

Nowhere in the 459-paragraph 1AC does the State plead any facts that would causally link any alleged misrepresentation or other wrongful conduct by the Manufacturer Defendants to the State's alleged harm.

For example, the 1AC does not identify any specific instance of an improper statement by any of the Manufacturer Defendants that caused an Alabama physician to form a misimpression about the addictive nature of opioid medications and then write a particular ineffective and harmful prescription. Similarly, the 1AC does not identify a specific suspicious order that the Manufacturer Defendants supposedly had a duty, but failed, to report. Absent such allegations, the State has failed to plead even the first step in the causal chain necessary to plead a plausible claim that the alleged misconduct caused *any* harm,³ let alone the necessary links in the chain leading to the expansive harms the State alleges. *City of Chi. v. Purdue Pharma, L.P.*, No. 14-C-4361, 2015 WL 2208423, at *14 (N.D. Ill. May 8, 2015) (dismissing fraud-based claims because “the City d[id] not allege . . . the identities of doctors who, as a result of [the] alleged misrepresentations, prescribed opioids” that caused the resulting harm).

The failure of the State to properly plead causation is highlighted by the fact that the FDA has expressly determined that the Manufacturer Defendants are legally permitted to manufacture, promote, and sell their opioid medications to treat chronic pain. For instance, the FDA-approved label for Purdue's OxyContin provides: “OXYCONTIN is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate” Sean Morris Declaration (“Morris Decl.”) ¶ 2

³ *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 2012 WL 3154957, at *6-8 (N.D. Cal. Aug. 2, 2012) (dismissing damages claim because Plaintiffs failed to allege “specific” facts “that individual physicians actually relied on these misrepresentations in writing the challenged prescriptions”); *see also Summit MTD* at n.15.

& Ex. A (OxyContin label) at § 1.⁴ FDA’s approval means that the agency found “substantial evidence that the drug will have the effect it purports or is represented to have,” and that these medications are safe and effective for treating chronic pain long-term. 21 U.S.C. § 355(d). The manufacture, distribution, and promotion of the Manufacturer Defendants’ medications for the approved use of treating chronic pain is thus not only lawful, but expressly approved by the FDA; liability accordingly cannot rest on the sale or promotion of opioids for chronic pain. Indeed, federal law preempts any attempt to impose state-law liability on these activities. *See, e.g., Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 488-89 (2013); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013); *Summit MTD* § IV (full preemption argument, incorporated herein by reference). Further, even if the claims were permissible, the State has not pled the existence of any medically unnecessary prescriptions written as a result of a Manufacturer Defendant’s wrongful conduct, which then caused the State harm. Its claims should be dismissed. *City of Chi. v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058, 1079-84 (N.D. Ill. 2016).

C. The State Cannot Establish Proximate Causation

Even if the State could plead but-for causation, its claims would still fail, like those of other governmental entities (*Summit MTD* at 12-17, 29-30), because the State cannot establish that any alleged wrongful acts by the Manufacturer Defendants were the proximate cause of the State’s alleged injuries. “Proximate cause is an act or omission that in a natural and continuous sequence, unbroken by any new and independent causes, produces an injury or harm” *Morguson v. 3M Co.*, 857 So. 2d 796, 800 (Ala. 2003) (quoting *Dillard v. Pittway Corp.*, 719 So.

⁴ The label for Endo’s Opana ER contained a similar statement. *Id.* ¶ 3 & Ex. B at 1 (“Indications and Usage”). The Manufacturer Defendants request that the Court take judicial notice of these warning labels in their accompanying Request for Judicial Notice (“RJN”) ¶¶ 1, 2.

2d 188, 192 (Ala. 1998)). “[T]he word ‘proximate’ adds the requirement of *unbroken causation* between an act and an injury produced by that act.” *Gen. Motors Corp. v. Edwards*, 482 So. 2d 1176, 1194 (Ala. 1985), *overruled on other grounds by Schwartz v. Volvo N. Am. Corp.*, 554 So. 2d 972 (Ala. 1989) (emphasis added). “[A] cause not within the chain is said to be ‘remote’ and, thus, not actionable.” *Id.*

The causal chain here is far too attenuated to support the conclusion that conduct by the Manufacturer Defendants’ proximately caused the alleged harm. The State’s theory is (1) that each Manufacturer Defendant misleadingly marketed one or more opioid medications; (2) that some unidentified doctors heard or saw this marketing; (3) that marketing (as opposed to independent medical judgment) caused the doctors to write prescriptions that the doctors would not otherwise have written; (4) that those prescriptions led to addiction, overdose, or other injury for unidentified patients; (5) that first responders, law enforcement, or prisons had to assist or incarcerate these injured individuals; (6) that the State incurred lost tax revenue and social service costs associated with these services or incarceration. 1AC ¶ 363. That chain cannot bear the weight the State places on it. *Summit* MTD at 12-17.

Moreover, intervening events and actors break the chain. For one, the learned intermediary doctrine, which Alabama has long recognized, breaks the causal chain as a matter of law. *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304-05 (Ala. 1984); *Springhill Hosps., Inc. v. Larrimore*, 5 So. 3d 513, 518 (Ala. 2008). As explained in detail in other briefs (*see, e.g., Summit* MTD § II(B)(4)(a)), under that doctrine, a physician has a duty to know the qualities and characteristics of the medications he or she prescribes. That information is provided directly to the doctors through FDA-required labeling, which includes extensive and detailed information regarding the risks associated with the medication. For opioids, the risks

identified in the labeling include addiction, abuse and misuse, overdose, and death. Under the circumstances, the State cannot plausibly allege that the Manufacturer Defendants concealed or minimized risks prominently disclosed in the FDA-required labeling.

Beyond that, the chain is broken by the negligent or criminal acts of third parties. Under Alabama law, where some independent party or agent “has intervened and been the immediate cause of the injury, the party guilty of negligence, in the first instance, is not responsible.” *Morgan v. City of Tuscaloosa*, 108 So. 2d 342, 346 (Ala. 1959). Criminal acts of a third person that cause injury are “new independent causes” that intervene or break the chain of causation. *Colonial BancGroup, Inc. v. PricewaterhouseCoopers, LLP*, No. 2:11-cv-746-WKW, 2014 WL 4444148, at *5 (M.D. Ala. Sept. 9, 2014); *Moye v. A.G. Gaston Motels, Inc.*, 499 So. 2d 1368 (Ala. 1986). Here, as in *Summit*, the State’s claims fail because they depend on the intervening negligent and criminal conduct of others. *See Summit* MTD §§ II.B.2, VII.B, IX, X.

II. The State’s Drug-Law Claims (Counts III & IV) Fail

Counts III and IV assert violations of state and federal drug laws. Count IV alleges a violation of the federal Controlled Substances Act (“CSA”) and Alabama Uniform Controlled Substances Act (“ACSA”), and it is styled as a claim under the latter. Count III alleges violations of the Drug-Related Nuisance Statute, Ala. Code §§ 6-5-155 *et seq.*, but it is predicated on the same alleged violations of the CSA and ACSA. 1AC ¶¶ 390-92. Both counts fail because the State does not plead any violation of the controlled substances laws, and in any event, none of these laws gives the State a right of action for civil damages.

A. The State Has Not Pled a Violation of Federal or State Controlled Substances Acts by the Manufacturer Defendants

The State claims the Manufacturer Defendants each (separately) violated the CSA and ACSA by failing to monitor their respective distributor customers’ downstream sales and

reporting any suspicious orders to the DEA and Alabama’s Pharmacy Board.⁵ 1AC ¶¶ 302-22, 409. The State’s claims fail as a threshold matter because the CSA and ACSA do not impose such requirements on the Manufacturer Defendants.

The CSA creates a closed, three-tier distribution system. Opioid manufacturers, distributors, and pharmacies must be registered and may sell only to other registrants or patients with a lawful prescription. 21 U.S.C. §§ 822, 823(a), (b) & (f); 829(a); 841(a). The DEA requires each registrant to implement specific anti-diversion controls (21 C.F.R. §§ 1301.71–1301.76), including that when distributing opioids to another person within the system, each registrant must “make a good faith inquiry . . . to determine that the person is registered to possess the controlled substance” and use a “system to disclose to the registrant suspicious *orders*” 21 C.F.R. § 1301.74(a) & (b) (emphasis added). A manufacturer’s duty is to ensure that its sales are to registered *distributors*, and it must monitor *its orders from distributors* to assess whether any are suspicious. Each registered distributor is then obligated to monitor its own orders from its pharmacy customers, and each pharmacy in turn is required to monitor prescriptions it fills for its own customers, the patients. The system depends on registrants at each link in the distribution chain to monitor their own customers’ orders for signs

⁵ In Count IV, the State asserts various other conclusions—that Purdue and/or Endo failed to “properly register,” failed to provide accurate information in “applications, reports, records and other [required] documents,” and failed to “report suspicious activity” (1AC ¶¶ 409, 412-13)—none of which is alleged in the form of facts sufficient to state a claim for relief, *Twombly*, 550 U.S. at 555-56. The State also incorrectly (and highly improperly) asserts that Endo somehow has been found criminally liable for conduct related to its opioid medications. This is entirely false. The settlement the State references (*id.* ¶ 412) was civil in nature and the product at issue was fluoride. It had nothing to do with opioid medications at all. Morris Decl. ¶ 4 & Ex. C; RJN ¶ 3.

of diversion.⁶ *See also Summit* MTD at 32. The State makes no allegation that the Manufacturer Defendants received but failed to report suspicious orders from their distributor customers.

Similarly, the ACSA creates a parallel closed, three-tier distribution system within Alabama (Ala. Code §§ 20-2-51(a), 20-2-58(a); Ala. Admin. Code r. 680-X-3-.05(1)), and imposes the obligation to monitor pharmacy orders *only* on the distributors who sell to pharmacies. Under the regulations implementing the ACSA, opioid manufacturers and distributors in the state who “sell . . . to a registrant *other than another manufacture or wholesaler*” must submit “copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies within 30 days.” Ala. Admin. Code r. 680-X-3-.05(2) (emphasis added). The State makes no allegation that the Manufacturer Defendants made sales to customers other than registered distributors.

The State therefore fails to allege any CSA and ACSA violation by the Manufacturer Defendants.

B. The Controlled Substances Acts Do Not Give the State a Right to the Relief It Seeks

Even if the State had alleged violations of the CSA or ACSA by the Manufacturer Defendants, the statutes do not authorize the relief the State seeks. The relevant CSA regulations

⁶ The State relies on a 2017 settlement between Mallinckrodt, an opioid manufacturer not named in this action, and the Department of Justice (1AC ¶¶ 308-15) as support for its position that opioid manufacturers must monitor downstream sales under the CSA. But, as the DOJ recognized in a judicially noticeable press release, that settlement was “groundbreaking” because it rested on a compromise of allegations that Mallinckrodt had and breached a duty to “monitor and report to DEA suspicious sales of its oxycodone at the *next level in the supply chain . . .*” Morris Decl. ¶ 5 & Ex. D; RJN ¶ 4. The settlement did not rely on authority imposing a federal or state-law duty on a manufacturer to monitor downstream orders, and as it was not an adjudicated ruling, the settlement does not serve as authority for the idea that such a duty exists.

provide only that “[t]he registrant shall *inform the Field Division Office of the [DEA]* . . . of suspicious orders when discovered by the registrant.” 21 C.F.R. § 1301.74(b) (emphasis added). And it is solely “the *Administrator* [who] shall use the security requirements set forth [under federal law]” “[i]n order to determine whether a registrant has provided effective controls against diversion.” *Id.* § 1301.71(a) (emphasis added). Violations of the CSA empower the *United States Attorney General* to deny, revoke or suspend a manufacturer’s federal registration through administrative proceedings (21 U.S.C. § 824), obtain criminal penalties and fines (*id.* § 841(b) (found unconstitutional on other grounds)), and secure to the United States criminal forfeiture of proceeds from and property used in the violation (*id.* § 853). A state has no authority to enforce the CSA. *See infra* § V.A (no negligence per se).

While the ACSA creates a concurrent regulatory scheme under which the Alabama Attorney General has enforcement authority, it—like the federal statute—does not authorize enforcement through a civil claim for damages. The ACSA allows the State Board of Pharmacy to deny a registration application for lack of adequate controls against diversion. Ala. Code § 20-2-52(a)(1). And it provides for administrative proceedings under which the same board can revoke a registration. *Id.* §§ 20-2-53, 20-2-54. The statute also provides for enforcement by all prosecuting attorneys, but the only remedies it authorizes are criminal fines and penalties (*id.* §§ 20-2-71, 20-2-72), an injunction against violations (*id.* § 20-2-92), and forfeiture of the controlled substances, property, or money used in a violation (*id.* § 20-2-93). It does not provide for civil damages. *See also infra* § V.A (no negligence per se).

The State’s claim for damages is not authorized by the CSA or ACSA.

C. The State Pleads No Violation of the Drug-Related Nuisance Statute Because That Statute Covers Only Drug-Related Activity at Specific Real Property

Nor does Alabama’s Drug-Related Nuisance Statute, Ala. Code § 6-5-155, *et seq.*, permit the State to bring a civil damages claim against a manufacturer for alleged violations of the CSA or ACSA. The State suggests those violations are statutorily defined as a “Drug-Related Nuisance.” 1AC ¶ 390 (citing Ala. Code § 6-5-155.1(3)(b)). But this Court must consider the statutory scheme in its entirety. *Siegelman v. Ala. Ass’n of School Bds.*, 819 So. 2d 568, 582 (Ala. 2001) (courts “do[] not interpret provisions in isolation, but *consider[] them in the context of the entire statutory scheme*”). And the scheme here requires that CSA or ACSA violations *be linked to a specific piece of real property*.

When enacting the Drug-Related Nuisance Statute, the legislature expressly stated an intent to amplify the “inadequate incentives for *property owners* to take a more active role in preventing *the use of their property* for the manufacture, use, sale, storage, or distribution of drugs.” Ala. Code § 6-5-155(3) (emphasis added). Read as a whole, the statute addresses only conduct occurring at a specific piece of property. The statute requires the claimant to “describe the adverse impact associated with the drug-related nuisance upon the surrounding neighborhood.” *Id.* § 6-5-155.3(a). The statute identifies 18 examples of “adverse impact” that all evaluate a subject property; indeed, 15 of the 18 factors expressly use the term “property.” *Id.* Similarly, the statute requires that any complaint by a private citizen must “be supported by at least five residents residing or owning real property within 1,000 feet of the premises alleged to be a drug-related nuisance.” Ala. Code § 6-5-155.3(c). Even the civil penalty provision cited by the State, 1AC ¶ 398, does not apply without reference to a specific location, because that determines the fund into which penalties are paid. Ala. Code § 6-5-155.7; *see also id.* § 6-5-156.3(d) (multiple remedies for property, such as “clean up,” “repairs,” “installing secure locks

on doors,” or redirecting “all rental income”). The statute also requires a plaintiff to “notify the owner of the property on which the drug-related nuisance is situated” before suing, *id.* § 6-5-155.3(b), and contains numerous other property-related provisions.⁷

The State does not allege that the purported nuisance here is related to a given property. To the contrary, in an attempt to excuse its failure to provide the notice required under the statute, the State asserts that “the drug related nuisance is not confined to any single property.” 1AC ¶ 396. But the statute requires notice. The failure to give notice by itself dooms the State’s claims. Its concession that the alleged nuisance does not involve a given property also mandates dismissal.

III. The State’s Claim Under the Alabama Deceptive Trade Practices Act (Count II) Fails

A. The State is Not a “Consumer” That Can Recover Damages Under the ADTPA

The State is not a “consumer” as defined by the ADTPA, and therefore cannot recover compensatory damages for any alleged violation. The 1AC alleges that Defendants engaged in acts prohibited by five different subsections of Alabama Code Section 8-19-5: (2), (5), (7), (9) and (27). 1AC ¶ 384. Except for acts prohibited by subsections (19) and (20), which are not asserted here, the ADTPA makes damages available only to a “consumer.” Ala. Code §§ 8-19-10(a)(1) & (2). The ADTPA defines a “consumer” as “any natural person who buys goods or

⁷ See Ala. Code §§ 6-5-155.6 (providing for restraining orders regarding the “contents of the place where the drug-related nuisance is alleged to exist,” to be left at or posted at “the place” of the nuisance), 6-5-155.8 (authorizing protection of witnesses from “any defendant or other person using the property alleged to be a drug-related nuisance”); 6-5-156.1 (“evidence of the general reputation of the property” admissible); 6-5-156.3(a) (higher standard of proof required “to establish that the owner of the property who is not a resident or in actual possession of the property was criminally culpable”); 6-5-156.4(c), (d) (order of abatement may be suspended or cancelled if “owner of the property” meets certain conditions).

services for personal, family or household use.” *Id.* at 8-19-3(2). As neither a “natural” person nor a purchaser of goods for “personal, family or household use,” the State certainly is not a “consumer.” *See In re Ford Motor Co. E-350 Van Prods. Liab. Litig. (No. II)*, Civ. No. 03-4558 (HAA), MDL No. 1687, 2008 WL 4126264, at *22 (D.N.J. Sept. 2, 2008) (dismissing ADTPA claim because legal entities “are not natural persons”); *cf. In re Bextra and Celebrex Marketing Sales Practices and Prod. Liab. Litig.*, 495 F. Supp. 2d 1027, (N.D. Cal. 2007) (dismissing ADTPA claim against third-party payors in part because they are not “natural persons”).

B. The State Fails To Plead any False or Misleading Statements with Particularity

The State’s ADTPA claim alleges that the Manufacturer Defendants fraudulently misrepresented the characteristics of their products. 1AC ¶ 384 (citing Ala. Code. §§ 8-19-5(2), (5), (7), and (9)). “Claims brought pursuant to the . . . ADTPA are subject to the heightened pleading standards of Federal Rule of Civil Procedure 9(b).” *Reid v. Unilever U.S., Inc.*, 964 F. Supp. 2d 893, 916 (N.D. Ill. 2013); *Holmes v. Behr Process Corp.*, No. 2:15-cv-0454, 2015 WL 7252662, at *2 (N.D. Ala. Nov. 17, 2015). To make out an ADTPA claim, the State must identify specific misleading statements, the recipients of those statements, how the recipients were misled, how the statements affected the recipients’ behavior, and how the statements caused the State’s damages. *Cooper v. Bristol-Myers Squibb Co.*, No. 07-cv-885, 2009 WL 5206130, at *7 (D.N.J. Dec. 30, 2009) (applying Alabama law). The State fails to satisfy this heightened pleading requirement. The 1AC does not identify the who, what, when, where, and why of the purported fraud. The State describes broad categories of alleged misstatements, but it does not identify a single Alabama prescriber who received and was misled by them when prescribing an opioid medication for a patient. Because the State has failed to adequately plead

fraud with particularity, its claims under § 8-19-5(2), (5), (7) and (9) should be dismissed. (The State also failed to comply with Ala. Code § 8-19-10(e).)

C. The State Has Failed To Plead an “Unconscionable Act”

In addition to the ADTPA claims regarding misstatements, the State relies on the catch-all provision of the ADTPA, which prohibits “[e]ngaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.” 1AC ¶ 384(e) (citing Ala. Code. § 8-19-5(27)). But the State fails to adequately plead an unconscionable act by the Manufacturer Defendants. Under Alabama law, a party claiming unconscionability must allege that (1) one party to a transaction was unsophisticated or uneducated, (2) there was an “absence of meaningful choice on one party’s part,” (3) the “contractual terms [we]re unreasonably favorable to one party,” (4) there was “unequal bargaining power among the parties,” and/or (5) there were “oppressive, one-sided, or patently unfair terms in the contract.” *See In re Russell*, 181 B.R. 616, 623 (M.D. Ala. 1995) (citing *Layne v. Garner*, 612 So. 2d 404, 408 (Ala. 1992)). The State does not and cannot meet this standard here, where its claims involve alleged statements to sophisticated learned intermediaries, the State itself is a sophisticated entity, and the State has not, in any case, identified the circumstances of any alleged misrepresentation or omission to any physician or other person, much less a transaction that would meet Alabama’s unconscionability requirements. Accordingly, the alleged acts or omissions were not “unconscionable” within the meaning of the ADTPA, and the State’s claim under § 8-19-5(27) should be dismissed.

IV. The State’s Statutory Public Nuisance Claim (Count I) Fails

The State’s public nuisance claim fails for a least two reasons, in addition to the failure to establish causation (*supra* § I.B & C; *Summit* MTD at 41-42). *First*, the rights that the State alleges have been interfered with are not the kind of rights protected by a public nuisance claim.

Alabama law defines public nuisance as “one which damages *all persons* who come within the sphere of its operation, though it may vary in its effects on individuals.” Ala. Code § 6-5-121 (emphasis added). This definition is similar to the Second Restatement of Torts’ definition of a public nuisance as “an unreasonable interference with a public right,” which is “collective in nature and not like the individual right that everyone has not to be assaulted or defamed or defrauded or negligently injured.” Restatement (Second) of Torts § 821B cmt. g. The State’s public nuisance claim is premised on specific alleged interferences with the right not to be defrauded or negligently injured in the receipt of medical care. These are decidedly individual, not public, rights. *State v. Lead Indus. Ass’n, Inc.*, 951 A.2d 428, 454 (R.I. 2008) (“there is no common law public right to . . . a certain standard of medical care”); *see also Summit* MTD at 43-44; Distributors’ Joint MTD in *Summit County* at 26-29.

Second, this claim fails because Alabama does not impose liability on defendants when independent third-party conduct was essential to creating the public nuisance. As the Alabama Supreme Court found in *Tipler v. McKenzie Tank Lines*: “The problem is one of remoteness. . . . [The defendant] cannot be charged and held liable either for maintaining, or for failing to prevent, a chain of events and circumstances over which it had no reasonable means of control.” 547 So. 2d 438, 441 (Ala. 1989). Using this same reasoning, other courts have refused to impose liability for public nuisance where the purported nuisance arose at least in part from the conduct, including criminal conduct, of third parties over whom the defendant had no control, *see, e.g., City of Chicago v. Beretta*, 821 N.E. 2d 1099, 1109 (Ill. 2004), and where, as here, an alleged nuisance implicates multifaceted and complex activities extending far outside the parties and claims before the court, *see, e.g., City of Oakland v. BP P.L.C.*, No. C17-06011, 2018 WL 3109726, at *7-*9 (N.D. Cal. June 25, 2018).

Here, between the alleged misconduct by the Manufacturer Defendants and the social ills for which the State seeks recovery are numerous criminal acts of abuse and diversion by third parties over whom these Defendants have no control. *Supra* § II.A (federal law); Ala. Code § 13A-12-212 (unlawful possession or receipt of controlled substances); *id.* § 20-2-51 (requiring registration to distribute and dispense controlled substances); *id.* § 20-2-71 (criminal penalties for dispensing or distributing controlled substances unlawfully); *id.* §34-23-7 (criminal penalties for possession of drug without lawful prescription). Like the *Tipler* and *Beretta* defendants, the Manufacturer Defendants cannot control the criminal acts of third parties who divert their medications or misuse them, or who otherwise violate federal or state law.

V. The State’s Common Law Claims Fail for Additional Claim-Specific Reasons

A. The State’s Negligence Claim (Count V) Fails

The State has not alleged facts establishing any cognizable duty the Manufacturer Defendants owe to the State, so its common-law negligence claim (*id.* ¶¶ 431-35) fails. “In Alabama, the existence of a duty is a strictly legal question,” to be determined considering foreseeability of harm and “the nature of the defendant’s activity; [] the relationship between the parties; and [] the type of injury or harm threatened.” *DiBiasi v. Joe Wheeler Elec. Membership Corp.*, 988 So. 2d 454, 460-61 (Ala. 2008). Mere knowledge of a risk of harm is insufficient. *Id.* at 463. The State attempts to allege three breaches of a duty owed to it. Each fails.

The Misrepresentation Claim. The State alleges the Manufacturer Defendants breached a duty of due care by “failing to inform physicians and consumers [of the] nature of the drugs” because their “warnings to prescribing physicians were inadequate” and their alleged misstatements “ensured that prescribing physicians were unaware of the risks.” 1AC ¶¶ 431-32. But this duty was not owed to the State, and in any event, the Manufacturer Defendants satisfied it by providing FDA-approved warnings with the medications. The State has not pled any

circumstances that would warrant an exception to the rule that a defendant owes no duty to a third party in connection with its representations or warnings. *Colonial Bank v. Ridley & Schweighert*, 551 So. 2d 391, 395 (Ala. 1989).

The Promotion Claim. The State alleges the Manufacturer Defendants breached a duty of due care in the promotion of their opioids by “aggressively promoting them for chronic pain.” 1AC ¶ 431. But the FDA has approved those opioid medications to treat chronic pain. Federal law therefore preempts any claim seeking to impose state-law liability for the promotion of FDA-approved opioid medications for an FDA-approved use. *Summit County MTD* § IV.A.

The Reporting Claim. Finally, the State alleges the Manufacturing Defendants breached “a duty to prevent diversion and report and halt suspicious orders thereby failing to comply with its legal duties.” 1AC ¶ 433. The allegation implicitly relies on the State’s allegations that the Manufacturing Defendants violated the CSA and ACSA. As discussed, those statutes did not impose a duty as expansive as the State claims. *Supra* § II.A. Nor can these statutes be the basis for a claim of negligence per se because the CSA and ACSA were enacted to protect the public at large, and not “a class of persons, of which the plaintiff is a member.” *Parker Bldg. Servs. Co., Inc. v. Lightsey ex rel. Lightsey*, 925 So. 2d 927, 931-32 (Ala. 2005).⁸

⁸ See *id.* at 932 (no negligence per se claim based on Federal Debt Collection Practices Act); *Flint City Nursing Home, Inc. v. Depreast*, 406 So. 2d 356, 360 (Ala. 1981) (no negligence per se claim for violation of nursing home licensing requirements and health and safety codes); see also *Doe v. Fulton-Dekalb Hosp. Authority*, 628 F.3d 1325, 1340 (11th Cir. 2010) (holding that a regulation intended for licensing and inspection purposes cannot provide the basis for a negligence per se claim); *Winberry v. United Collection Bureau, Inc.*, 697 F. Supp. 2d 1279, 1293-94 (M.D. Ala. 2010) (holding Fair Debt Collection Practices Act enacted to protect consumers generally does not protect a “class of persons” and therefore does not support a negligence per se claim); cf. *Bennett v. Nationstar Mortgage, LLC*, No. 15-cv-165-KD-C, 2015 WL 5294321, at *6 (S.D. Ala. Sept. 8, 2015) (rejecting allegations of negligence per se based on violations of mortgage regulations).

Given the specific and limited enforcement provisions of the CSA and ACSA (*supra* II.B), and the strong presumption that criminal statutes to protect the general public do not create private rights of action, the controlled substances acts do not create a right of action for the State. *See Durr v. Strickland*, 602 F.3d 788, 789 (6th Cir. 2010) (“no private right of action exists under” the CSA); *Safe Sts. Alliance v. Alternative Holistic Healing, LLC*, No. 1:15-cv-00349-REB-CBS, 2016 WL 223815, at *3 (D. Colo. Jan. 19, 2016) (“federal courts uniformly have held that there are no private rights of action under the CSA”), *aff’d*, 859 F.3d 865 (10th Cir. 2017).

B. Alabama’s Wantonness Claim (Count VII) Fails

Alabama’s wantonness allegations are wholly indistinguishable from its negligence allegations. *Compare* 1AC ¶¶ 431-33 *with id.* ¶¶ 445-46. Alabama law is clear that “wantonness is not merely a higher degree of culpability than negligence. Negligence and wantonness, plainly and simply, are qualitatively different tort concepts.” *Ex parte Essary*, 992 So. 2d 5, 9 (Ala. 2007) (quoting *Tolbert v. Tolbert*, 903, So. 2d 103, 114-15 (Ala. 2004)). To support a claim of wantonness, a plaintiff must establish that “the defendant engaged in conduct conscious, or in knowing disregard, that it was likely to cause injury.” *Craft v. Triumph Logistics, Inc.*, 107 F. Supp. 3d 1218, 1221 (M.D. Ala. 2015). By failing to adequately allege even negligence, the State necessarily has failed to allege the required elements for the higher “wantonness” standard.

C. The State’s Federal Common Law Unjust Enrichment Claim (Count VI) Fails

To plead a federal common law unjust enrichment claim against the Manufacturer Defendants, the State must allege the manufacturer held money that belongs to or was improperly paid to it by the State because of mistake or fraud. *See U.S. v. Dekalb County*, 729 F.2d 738, 742 (11th Cir. 1984). Here, the State does not allege that it covered any opioid prescriptions based on a fraudulent statement that it received, as opposed to unidentified

physicians and consumers. 1AC ¶¶ 439, 441. Moreover, the only recovery available is restitution of the benefit conferred directly on the defendant as an ill-gotten gain, not the amount of the plaintiff's losses. *See Commodity Futures Trading Comm'n v. Wilshire Inv. Mgmt. Corp.*, 531 F.3d 1339, 1345 (11th Cir. 2008); *S.S. Silberblatt, Inc. v. E. Harlem Pilot Block-Building 1 Hous. Dev. Fund Co., Inc.*, 608 F.2d 28, 41 (2d Cir. 1979). Here, the State makes no effort to identify which opioid prescriptions that it reimbursed failed to provide effective pain relief and thus conferred an ill-gotten gain on anyone; the State paid pharmacies, not the Manufacturer Defendants, when covering prescriptions filled with their medications; the State did not even indirectly benefit the Manufacturer Defendants when providing reimbursement for any other "opioid prescriptions covered by the State" (1AC ¶ 441); and the State's alleged expenditures to address "opioid addiction, overdose, injury, and death" (*id.* ¶ 441) are services provided to its citizens and thus unrecoverable damages, *City of Miami v. Bank of Am. Corp.*, 800 F.3d 1262, 1288 (11th Cir. 2015), *vacated and remanded on other grounds*, 137 S. Ct. 1296 (2017). The State's unjust enrichment claim therefore must be dismissed.

VI. The State's Claims for Monetary Relief Are Entirely or Predominately Barred by the Applicable Statutes of Limitations

The State commenced this action on February 6, 2018, long after the alleged misconduct had been the focus of public scrutiny and the statute of limitations had lapsed. Recognizing this facial deficiency the Complaint attempts to get around the statute of limitations, but it fails to adequately allege tolling or any other doctrine that would allow these stale claims to proceed.

A. The State Cannot Recover Damages or Restitution Relating to Any Individual’s Opioid Use Beginning Before February 6, 2016

Alabama law imposes strict, conservative statutes of limitations, and disfavors the use of liberal tolling doctrines to spare stale claims. Claims for damages or restitution are subject to a two-year limitation period,⁹ which begins to run the day the plaintiff “could first maintain the action”—*i.e.* when the first actionable injury occurred, “regardless of whether the full amount of damage is apparent at the time of the first injury.” *Booker v. United Am. Ins. Co.*, 700 So.2d 1333, 1339-40 (Ala. 1997). The statute of limitations begins to run at this time regardless of whether the plaintiff discovered the alleged misconduct or injury. *Moon v. Harco Drugs, Inc.*, 435 So. 2d 218, 220 (Ala. 1983). The Alabama Supreme Court explained that this rule of accrual applies “be the actual damage (then apparent) however slight” and that:

[T]he statute will operate to bar a recovery not only for the present damages but for damages developing subsequently and not actionable at the time of the wrong done; for in such a case the subsequent increase in the damages resulting gives no new cause of action. *Nor does plaintiff’s ignorance of the tort or injury, at least if there is no fraudulent concealment by defendant, postpone the running of the statute until the tort or injury is discovered.*

Id. (emphasis in original) (internal quotations omitted). Alabama courts adhere to these substantive-law principles because they “advance[] the truth-seeking function of our justice system, promote[] efficiency by giving plaintiffs an incentive to timely pursue claims, and promote[] stability by protecting defendants from stale claims.” *Travis v. Ziter*, 681 So. 2d 1348,

⁹ See Ala. Code § 6-2-38(1) (“All actions for any injury to the . . . rights of another not arising from contract and not specifically enumerated in this section must be brought within two years); see also *Boyce v. Cassese*, 941 So. 2d 932, 945 (Ala. 2006) (negligence); *Ex parte Brian Nelson Excavating, LLC*, 25 So. 3d 1143, No. 1071473, 2009 WL 1643351, *2 (Ala. June 12, 2009) (nuisance claims); *Ex parte Capstone Bldg. Corp.*, 96 So.3d 77, 88 (Ala. 2012) (wantonness); *Auburn Univ. v. Int’l Bus. Mach., Corp.*, 716 F. Supp. 2d 1114, 1118 (M.D. Ala. 2010) (unjust enrichment); *Boyle & Co., Inc. v. Fasano*, No. 5:03cv47-V, 2006 WL 572183, at *7 (W.D.N.C. Mar. 3, 2006) (holding state statute of limitations applies to federal unjust enrichment claims).

1355 (Ala. 1996) (rejecting exception to date-of-injury rule of accrual for childhood sexual abuse victims who suffered from “an inability to comprehend a specific legal right, or to recall events that happened many years before”).

1. The State’s Claims for Damages or Restitution Are Entirely or at Least Predominately Barred Under the First-Injury Rule of Accrual

Under this accrual rule, the State’s causes of action for damages and restitution accrued entirely, or at least predominately, outside of the limitations period. The State rests its theories of liability on conduct that began as far back as the mid-1990s. 1AC ¶¶ 107, 133, 228. And the bulk of the alleged conduct occurred between 2007 and 2013. *Id.* ¶¶ 84-85, 91-94, 107-09, 113-14, 121-22, 133, 139, 160, 167-68, 173, 188-90, 197-98, 214-15, 218-19. Moreover, the State’s alleged injuries would have first occurred not long after the conduct. According to the State, misrepresentations regarding the risks and benefits of opioid analgesics for chronic pain followed by prescriptions that prescribers otherwise would not have written, *id.* ¶¶ 109-10, 124, 165, and failures to take steps to prevent diversion, *id.* ¶¶ 433-35, 445, caused the State injury. The State seeks recovery for payments made through its Medicaid program or employee benefits plans, *id.* ¶¶ 358, 441, and for expenses incurred when providing addiction and overdose services and law enforcement, *id.* ¶¶ 325, 363, 376-77. Under these allegations, a cause of action accrues under each formal “count” the first time the State covers an individual’s allegedly inappropriate prescription or incurs an expense in relation to a particular individual’s addiction. *See Moon*, 435 So. 2d at 220 (cause of action accrued as soon as plaintiff first became ill from product).

As a result, given the February 6, 2018 original filing date of this action, the State’s claims are barred as to any particular individual’s opioid use and resulting State expenses first incurred before February 6, 2016, irrespective of whether the State incurred additional expenses in relation to that patient’s addiction thereafter. *Id.*

2. The Fraudulent Concealment and Equitable Estoppel Doctrines Do Not Toll the Limitations Period

The State's tolling allegations (1AC ¶¶ 343-54) fail to provide the required particularity¹⁰ or even suggest the Manufacturer Defendants may have engaged in conduct that would toll the relevant statutes. The doctrines do not apply simply because a defendant is alleged to have engaged in fraud; rather, they require affirmative conduct by the defendant to conceal the fraud or other wrongful conduct or otherwise induce a plaintiff not to file suit. *See Sellers v. A.H. Robins Co., Inc.*, 715 F.2d 1559 (11th Cir. 1983) (rejecting under Alabama law a plaintiff's effort to invoke tolling doctrines because of the same alleged frauds on which her claims were based); *Holdbrooks v. Central Bank of Ala., N.A.*, 435 So. 2d 1250, 1252 (Ala. 1983) ("In the absence of a duty to disclose material facts, a person's mere silence is not actionable fraud."); *Seybold v. Magnolia Land Co.*, 376 So. 2d 1083, 1085 (Ala. 1979) ("[T]he type of conduct which is sufficient to give rise to an estoppel against pleading the statute of limitations must amount to an affirmative inducement to the claimant to delay bringing action."). The State's allegations here do not satisfy this strict factual requirement. 1AC ¶ 348.

The State also cannot avoid the time bars because it has been on at least inquiry notice of its potential claims since before February 6, 2016. The tolling doctrines apply only so long as the State lacked actual or constructive knowledge of the facts giving rise to its claims. *DGB, LLC v. Hinds*, 55 So. 3d 218, 225, n.3 (Ala. 2010) (quoting *City of Gadsden v. Harbin*, 398 So. 2d 707, 709 (Ala. Civ. App. 1981)) (fraudulent concealment); *Weaver v. Firestone*, 155 So. 3d 952, 962 (Ala. 2013) (equitable estoppel). The State had constructive knowledge as soon as it

¹⁰ The circumstances and events constituting fraudulent concealment must be averred with particularity, not in a generalized or conclusory manner. Fed. R. Civ. P. 9(b); *Waldrup v. Hartford Life Ins. Co.*, 598 F. Supp. 2d 1219, 1226-27 (N.D. Ala. 2008).

became aware of a fact that would cause a reasonable person to investigate and become aware of the facts giving rise to its claims. *Sellers*, 715 F.2d at 1561-62; *Papastefan v. B & L Const. Co., Inc. of Mobile*, 385 So. 2d 966, 968 (Ala. 1980).

As a matter of law, the State had at least constructive knowledge of its claims before the beginning of the limitations period, February 6, 2016. For example, the Alabama Drug Abuse Task Force's February 2013 Report to the Alabama Legislature, joined by the Alabama Attorney General, reports: "Alabama is among the highest in the country for numbers of persons with prescribed pain medication. There were 1.2 million prescriptions prescribed for painkilling narcotics per month for a total of 14 million per year." Morris Decl. ¶ 6 & Ex. E; RJN ¶ 5. Indeed, the State included an updated form of this statistic in the 1AC. 1AC ¶ 357.

Moreover, the facts on which the State now bases its claims were in no way concealed or hidden, and would easily have been discoverable by the State. The 1AC is premised on statements made as part of each manufacturer defendant's public marketing, 1AC ¶¶ 8, which allegedly used Internet websites, publications, advertisements, and third-party materials all created and published before February 6, 2016, *e.g., id.* ¶¶ 84-85, 90-94, 107-111, 113-14, 121-22, 126-28, 133, 160, 167-68, 173, 188-90, 194, 198-99, 202, 214, 219. And the State likewise relies on public regulatory actions that predate February 6, 2016. *E.g., id.* ¶¶ 56, 58, 72, 117, 133, 141, 147-48, 152, 175-77, 183. Finally, nearly *all* of the specifically or generally alleged misconduct by the Manufacturer Defendants was part of publicly filed complaints in high profile cases against the industry before February 6, 2016. *See, e.g.,* Second Amended Complaint Redacted, *City of Chicago v. Purdue et al.*, No. 14-cv-04361 (N.D. Ill. Nov. 5, 2015) ECF No. 395; Appendix A (detailed comparison of the 1AC and the Second Amended Complaint in the

City of Chicago). If other plaintiffs were in a position to assert claims before February 6, 2016, the State could have done so too. Its claims are time-barred.

3. The “Continuing Tort” Doctrine Does Not Alter This Result

The State’s effort to avoid the time bar by labeling the Manufacturer Defendants’ conduct a “continuing tort” (1AC ¶¶ 341-42) misapprehends that doctrine. The Alabama Supreme Court has explained that a “continuous tort” is “analogous to a continuing trespass in that the repeated actions of the defendants combined to create a single cause of action in tort.” *Moon*, 435 So. 2d at 220-21. Although damages for continuing trespass are considered a “single” cause of action under Alabama procedure, they are still limited to those “occurring within the statutory period.” *Alabama Power Co. v. Gielle*, 373 So. 2d 851, 854 (Ala. Civ. App. 1979). Thus, a “continuing tort” does not negate the statute of limitations or revive lost claims. Rather, it simply permits that, “[w]here multiple acts are involved, subsequent damages have been recognized as flowing from subsequent acts, and the fact that a limitations period may have expired as to an earlier act does not bar an action *for the subsequent injury*.” *Spain v. Brown & Williamson Tobacco Corp.*, 872 So. 2d 101, 114 (Ala. 2003) (plurality) (emphasis added). As a result, “[i]n Alabama, a plaintiff may only recover damages for the portion of a continuous tort that occurred within the statute of limitations that applies to the cause of action.” *Radcliff v. Tate & Lyle Sucralose, Inc.*, No. 06-0345-CG-M, 2008 WL 3843446, at *8 (S.D. Ala. Aug. 14, 2008). In other words, at most, the continuing tort doctrine means only that the State could assert claims for damages for harm first occurring within the limitations period.

B. The State’s ADTPA Claim for Civil Penalties Is Time Barred

The State’s ADTPA claim—its basis for civil penalties—is barred in its entirety by the statute’s limitation period. Under the ADTPA, “[n]o action may be brought under this chapter more than one year after the person bringing the action discovers or reasonably should have

discovered the *act or practice* which is the subject of the action” Ala. Code § 8-19-14 (emphasis added). As detailed above, the State knew or should have known of all the specifically alleged conduct more than two years, not just one year, before filing this action. *Supra* § VI.A.2; Appendix A; *Holmes v. Behr Process Corp.*, No. 2:15-cv-0454-WMA, 2015 WL 7252662, at *2 (N.D. Ala. Nov. 17, 2015) (holding that period runs when plaintiff “knew of facts that would have put a reasonable person on notice” of that conduct). The 1AC contains no specific allegations of deceptive conduct occurring in Alabama after February 6, 2017. Accordingly the ADTPA claim is time barred and should be dismissed.

CONCLUSION

For the foregoing reasons, the 1AC should be dismissed in its entirety.

Dated: June 29, 2018

Respectfully submitted,

By: /s/ Mark S. Cheffo

Mark S. Cheffo
Sheila L. Birnbaum
Hayden A. Coleman
DECHERT LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036
Tel: (212) 698-3500
Mark.Cheffo@dechert.com
Sheila.Birnbaum@dechert.com
Hayden.Coleman@dechert.com

*Attorneys for Defendants Purdue Pharma L.P.,
Purdue Pharma Inc., and The Purdue Frederick
Company*

By: /s/ Jonathan L. Stern (consent)

Jonathan L. Stern
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave. NW
Washington, DC 20001

Tel: (202) 942-5000
jonathan.stern@arnoldporter.com

Sean O. Morris
Arnold & Porter Kaye Scholer LLP
777 S. Figueroa St., Suite 4400
Los Angeles, CA 90017
Tel: (213) 243-4000
sean.morris@arnoldporter.com

*Attorneys for Defendants Endo Health Solutions
Inc. and Endo Pharmaceuticals Inc.*

By: /s/ Steven F. Napolitano (consent)

Steven F. Napolitano
Skarzynski Black
One Battery Park Plaza 32nd Floor
New York, New York 10004
Tel: (212) 820-7746
snapolitano@skarzynski.com
*Attorneys for Defendant Rhodes Pharmaceuticals
L.P.*

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

/s/ Mark S. Cheffo

APPENDIX A:**Alabama's Allegations of Manufacturer Misrepresentations in Chicago's 2015 Complaint**

2018 Ala	2015 Chi
¶ 79	¶ 153
¶ 83	¶ 627-628
¶ 84	¶¶ 225, 229(ee), 240(i), 596, 598-599
¶ 85	¶¶ 233, 238(d), 248(h), 575-576
¶ 86	¶¶ 224, 229(jj), 230, 482(c), 552(c), 627, 630(a), 630(f), 630(h), 630(l), 692
¶ 87	¶ 10
¶ 88	¶¶ 238(e-g), 627
¶ 89	¶¶ 575, 630(g)
¶ 90	¶¶ 148, 238(f), 618
¶ 91	¶¶ 238(e), 617
¶ 92a	¶¶ 239, 573, 599, 620
¶ 92b	¶¶ 240(f), 573
¶ 93	¶¶ 240(g), 578
¶ 94	¶ 240(h)
¶ 95	¶ 229(dd)
¶ 97	¶ N/A
¶ 107	¶ 165
¶ 108	¶ 166
¶ 109	¶ 167
¶ 111	¶ N/A
¶ 113	¶¶ 221(t), 221(s), 570
¶ 114	¶ 221(w)
¶ 119	¶¶ 249-250
¶ 120	¶¶ 213, 249
¶ 121	¶¶ 248(j), 252(n), 606
¶ 122	¶¶ 248(k), 252(o), 621
¶ 125	¶ N/A
¶ 126	¶ 248(h)
¶ 127	¶¶ 248(i), 600
¶ 128	¶¶ 248(k), 252(o), 621
¶ 131	¶¶ 216, 256, 558, 563, 564, 567, 627, 742(h)

2018 Ala	2015 Chi
¶ 133	¶ N/A
¶ 139	¶ N/A
¶ 142	¶ 627
¶ 143	¶ N/A
¶ 161	¶ 397
¶ 167	¶¶ 229(k), 449
¶ 168	¶ N/A
¶ 169	¶¶ 229(k), 449
¶ 170	¶ 229(l)
¶ 171a	¶ N/A
¶ 171b	¶¶ 229(o), 469
¶ 172	¶¶ 229(n), 409
¶ 173	¶ 252(g)
¶ 174	¶ 230
¶ 186	¶ 230
¶ 188	¶¶ 229(j), 404, 406, 408
¶ 189a	¶ N/A
¶ 189b	¶ 404
¶ 190	¶ 406
¶ 193	¶¶ 252(f), 418
¶ 194	¶ 419
¶ 195	¶ 412
¶ 196	¶¶ 221(k), 413
¶ 197	¶ 414
¶ 198	¶ 416
¶ 211	¶¶ 221(j), 229(m), 244(b), 445
¶ 214	¶ 448
¶ 215	¶¶ 229(k), 449
¶ 218	¶ 464
¶ 219	¶ 466
¶ 222	¶¶ 229(o), 469
¶ 223	¶¶ 248(f), 470
¶ 225	¶¶ 149, 240(c), 473
¶ 227	¶ 475

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 the State of Alabama's First Amended 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.

/s/ Mark S. Cheffo