IN THE CIRCUIT COURT FOR KNOX COUNTY
SIXTH JUDICIAL DISTRICT AT KNOXVILLE

STATE OF TENNESSEE,	)	
***ex rel.* HERBERT H. SLATERY III,**	)	
ATTORNEY GENERAL and REPORTER,	)	
	)	**JURY DEMAND**
Plaintiff,	)	
	)	
v.	)	**Case No. 1-173-18**
	)	
PURDUE PHARMA L.P.,	)	
a foreign limited partnership,	)	**Judge Kristi Davis**
	)	
Defendant.	)	

STATE OF TENNESSEE'S RESPONSE IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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INTRODUCTION

Defendant Purdue Pharma L.P. (Purdue) has moved to dismiss the State of Tennessee's Complaint on the grounds that it fails to state a claim upon which relief can be granted under Tennessee Rule of Civil Procedure 12.02(6). Defendant's Brief at 1. Purdue argues that the State (1) seeks to impose liability for Purdue's lawful promotion of medications approved by the United States Food and Drug Administration (FDA) for an FDA-approved use; (2) does not adequately plead causation; (3) does not plead its fraud-based allegations with particularity; and (4) that the State's public nuisance claim is barred by the derivative injury rule. Def. Br. at 4. Purdue's Motion contains few specifics and repeats many of the same arguments that have been rejected by other courts, including in the states of Washington (**Resp. Ex. A**), New York (**Resp. Ex. B**), and Alaska (**Resp. Ex. C**). Because Purdue has not met its burden, ignores the majority of the State's 271-page Complaint, mischaracterizes the State's allegations, and asserts invalid legal arguments, Purdue falls well short of the high burden for a motion to dismiss. Therefore, Purdue's Motion should be denied.

The State's Complaint alleges that Purdue engaged in an elaborate, long-running marketing campaign designed to reduce well-founded fears of the addictive nature and lack of safety of powerful narcotics, including OxyContin, by misrepresenting the risks and benefits of opioids to the public and the medical community. *See, e.g.*, Compl. ¶¶ 3, 18–57, 141-47, 192, 361, 399.

The Complaint details how Purdue's actions were guided by one principle: to sell more opioid pills and sell higher doses of these pills (*see, e.g.*, Compl. ¶¶ 20, 146–56); how Purdue substantially relied on continued users and high-dose opioids for its business model (*see, e.g.*, Compl. ¶¶ 20, 133–34, 141–42, 894–97); how Purdue targeted providers who wrote the most prescriptions for their opioids and providers who were untrained in pain management (*see, e.g.*,

Compl. ¶¶ 28–32, 896); and how Purdue saturated Tennessee with high dose OxyContin. *See, e.g.*, Compl. ¶¶ 144–45, 444–870, 872, 893–96.

The State's enforcement action further demonstrates how Purdue dramatically ramped up the number of calls made to providers in Tennessee despite the growing opioid epidemic and multiple investigations into Purdue's marketing practices (*see, e.g.,* Compl. ¶ 51); knew that more sales calls was "highly correlated" to more prescriptions of its opioids (*see, e.g.,* Compl. ¶¶ 23, 877); incentivized its sales representatives to continue calling upon problematic health care providers to obtain bonuses (*see, e.g.*, Compl. ¶¶ 33–35, 451, 469-71), and looked the other way when faced with red flags for abuse or diversion of its opioids. *See, e.g.*, Compl. ¶¶ 5, 444-870, 477, 522-31, 594-96.

The Complaint details how Purdue continued to make sales calls in spite of: internal reports of patient overdose deaths from OxyContin from providers with red flags; reports to Purdue from law enforcement about providers were responsible for significant interstate diversion of OxyContin; indictments of providers; adverse licensure actions of these providers; a provider admitting to a Purdue sales representative that he was addicted to heroin; a knife fight outside of a provider's office; a clinic that had no examination table or equipment, only took cash, performed no urine drug screens, and only took walk-in patients; an admission by a provider that he was running a pill mill; a provider changing the name of his practice shortly after he became aware of a state investigation into his practice; a patient being coached in the waiting room about how to fill out intake forms; armed guards in provider waiting rooms; high numbers of patients who purchased OxyContin in cash; high numbers of out-of-state or out-of-county car tags in providers' parking lots; accusations of insurance fraud; choreographed urine screenings and pill counts;

standing-room-only waiting rooms; and additional signs of problematic high volume practices. *See, e.g.*, Compl. ¶¶ 5, 450–52, 458–61, 477, 522-31, 594-96.

These well-pleaded allegations more than establish the basis for the State's three causes of action: violations of the Tennessee Consumer Protection Act (TCPA), violations of the 2007 Agreed Final Judgment between the State and Purdue, and public nuisance.

LEGAL STANDARD

Tennessee has a high bar for granting a motion to dismiss for failure to state a claim upon which relief can be granted. A Tenn. R. Civ. P. 12.02(6) motion only tests the legal sufficiency of the plaintiff's pleading, not the strength of its proof. *Highwoods Properties, Inc. v. City of Memphis*, 297 S.W.3d 695, 700 (Tenn. 2009). "[T]he motion contemplates that all relevant and material allegations in the complaint, even if true and correct, do not constitute a cause of action." *Lanier v. Rains*, 229 S.W.3d 656, 660 (Tenn. 2007). It is well-settled that "the motion cannot be sustained unless it appears that there are *no* facts warranting relief," *id.* (emphasis added), or when the complaint is *totally* lacking in clarity and specificity. *Dobbs v. Guenther*, 846 S.W.2d 270, 273 (Tenn. Ct. App. 1992) (emphasis added). The court "must construe the complaint liberally, presuming all factual allegations in the complaint to be true and giving the plaintiff the benefit of all reasonable inferences." *Tigg v. Pirelli Tire Corp.*, 232 S.W.3d 28, 31-32 (Tenn. 2007) (quoting *Trau-Med of Am. v. Allstate*, 71 S.W.3d 691, 696 (Tenn. 2002)). Moreover, the Court must look at the complaint's substance rather than its form. *Kaylor v. Bradley*, 912 S.W.2d 728, 731 (Tenn. Ct. App. 1995). Further, the movant under Rule 12.02(6) has the burden of showing that there are no facts warranting relief. *See Snyder v. First Tenn. Bank, N.A.*, 450 S.W.3d 515, 519 (Tenn. Ct. App. 2014).

ARGUMENT

I. THE FDA DID NOT APPROVE THE DECEPTIVE ADVERTISING CLAIMS AND OTHER CONDUCT IN THE STATE'S COMPLAINT.

Purdue moves for dismissal because the Complaint purportedly "hinges on a single improper premise[:]" that the State seeks to hold Purdue "liable for its promotion and sale of a medication for precisely the indication approved by the FDA—long-term treatment of chronic non-cancer pain." Def. Br. at 1, 5. However, the FDA's approval of OxyContin "for consumption by the general public does not mean that states . . . may not seek to protect their residents from the unlawful activities" concerning the drug. **Resp. Ex. B**, *In re Opioid Litig.*, No. 400000/2017, 2018 WL 3115102, at *8 (N.Y. Sup. June 18, 2018) (citing *English v. General Electric Co.*, 496 U.S. 72, 87 (1990)).

Within this overarching "single improper premise" argument, Purdue makes a series of related, sub-arguments that all collapse into whether the State alleges any conduct that has been approved by FDA action.[1] But the State's Complaint does not do this—as shown by an examination of the handful of claims Purdue actually identifies in its Motion.[2] These include claims relating to OxyContin's dose ceiling, pseudoaddiction, screening tools, failure to disclose

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[1] These sub-arguments include Purdue's incorrect assertions that (1) all of the State's claims are preempted because they conflict with the FDA's approved indications and labeling for opioids; (2) the State's TCPA and 2007 Agreed Final Judgment violation claims should be dismissed because statements that comport with FDA-approved labeling and promotion are not misleading as a matter of law; (3) the State's claims based on violations of the 2007 Agreed Final Judgment impermissibly seek to hold Purdue liable for conduct that the Judgment requires; and (4) the State's TCPA claims are barred by Tenn. Code Ann. § 47-18-111(a)(1), which exempts "[a]cts or transactions required or specifically authorized under the laws administered by, or rules and regulations promulgated by, any regulatory bodies or officers acting under the authority of this state or of the United States." Def. Br. at 5, 10.

[2] Purdue previously tried this argument and was unsuccessful. *See City of Chicago v. Purdue Pharma L.P.*, No. 14 C 4361, 2015 WL 2208423, *10 (N.D. Ill. May 8, 2015) (internal citation omitted) ("Defendants assert, for example, that the FAC's 'central allegation is that [they] falsely represented that opioid products are safe and effective for long-term treatment of chronic pain.' As discussed above, this is not what the City claims.").

the lack of substantiation for OxyContin beyond 12 weeks, and Purdue's abuse and diversion detection program. Def. Br. at 7.

Purdue also argues that "[t]he State's Complaint fails adequately to plead that Purdue made any statements inconsistent with the FDA's approval for Purdue's opioid medication." Def. Br. at 3. This statement is simply untrue. No less than one-third of the Complaint is devoted to describing, in detail, the numerous misleading or deceptive statements made by Purdue that were not approved by the FDA. Compl. ¶¶ 11, 57–443.

Purdue asserts that the State's enforcement action is preempted by federal law (Def. Br. at 5), but this is not the case. In our federal system, "States possess sovereignty concurrent with that of the Federal Government, subject only to the limitations imposed by the Supremacy Clause." *Tafflin v. Levitt*, 493 U.S. 455, 458 (1990). These limitations in the form of preemption are strongly disfavored—especially at the motion to dismiss stage where a court "may find a claim preempted only if the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted." *Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 444 (2d Cir. 2015). "In all preemption cases . . . [courts] 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quotations and citations omitted). The party arguing in favor of preemption "must overcome the presumption against finding pre-emption of state law in areas traditionally regulated by the States." *California v. ARC Am. Corp.*, 490 U.S. 93, 101 (1989) (citation omitted).

One of the historic police powers belonging to the states is the protection of consumers against deceptive business practices (*see id.*), and the United States Supreme Court recognizes that the FDA has "long maintained that state law offers an additional, and important, layer of consumer

protection that complements FDA regulation." *Wyeth*, 555 U.S. at 579. Importantly, a strong "presumption against preemption applies in consumer protection cases." *Langan v. Johnson & Johnson Consumer Cos., Inc.*, 95 F. Supp. 3d 284, 291 (D. Conn. 2015) (Specifically, the presumption against preemption applies to claims related to "[t]he advertising and labeling of consumer products" because it is a "field traditionally subject to state regulation" (citing *Altria Grp., Inc. v. Good*, 550 U.S. 70, 77 (2008)).

Purdue only asserts that conflict preemption[3] bars the State's claims. Def. Br. at 5-6. Conflict preemption occurs "where it is impossible for a private party to comply with both state and federal requirements" or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (quotations and citations omitted).

Purdue has no valid basis to assert conflict preemption based on impossibility. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011). State prohibitions on unfair and deceptive marketing do not conflict with federal law here. Misrepresentations about drugs violate the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 331(a), (b), 352(n), and its implementing regulations. No federal law allows Purdue to distribute deceptive material, to conduct aggressive in-person marketing to encourage high-prescribing in the face of widespread diversion and abuse, or to misrepresent how prescribers should assess and balance the risks and benefits its labels disclose. The State's Complaint describes Purdue's deceptive marketing strategies and materials not subject to FDA labeling

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[3] Under the Supremacy Clause (U.S. CONST. art. VI, cl. 2), there are three categories of preemption: express, field, and conflict. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992).

regulations or that did not have FDA approval. *See, e.g.*, Compl. ¶¶ 40–41, 43–50, 51–56, 57–443. The State does not challenge the content of FDA-approved labels; to the contrary, it is Purdue's *conduct* that is at issue. As a result, Purdue can comply with both federal and state law.

Accordingly, Purdue's preemption argument—which inaccurately recharacterizes the claims as grounded on inadequate FDA warnings—is irrelevant. Even if this were a failure to warn case, Purdue misidentifies the applicable standards governing conflict preemption. As a manufacturer of brand-name drugs, Purdue may add or strengthen its safety warnings without prior FDA approval. 21 C.F.R. §§ 314.70(c)(6)(iii)(A)–(C). Indeed, it must do so upon learning new information indicating that the existing warning is inadequate. 21 C.F.R. § 201.57(c)(6)(i). Congress made it clear that despite FDA oversight, manufacturers are "responsible for updating their labels" at all times and has charged them "both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth*, 555 U.S. at 568, 571. "[M]anufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." *Id.* at 578–79. While the State's action is not a tort-based or products liability action, the same principle applies. Even for failure to warn claims, Purdue can only prove conflict preemption by "clear evidence that the FDA would not have approved a change to [the drug's] label." *Wyeth*, 555 U.S. at 571. The "clear evidence" inquiry is "fact specific." *Seufert v. Merck Sharp & Dohme Corp.*, 187 F.Supp.3d 1163, 1170 (S.D. Cal. 2016). "[M]arkedly few cases have found the clear evidence standard satisfied." *Id.* at 1169. Purdue, which has the burden to establish preemption (*see Wyeth*, 555 U.S. at 569), cannot meet it here.

The State's suit is also not an obstacle to the accomplishment and execution of the full purposes and objectives of Congress—the other basis of conflict preemption. In evaluating this question, the court must consider whether Congress intended to set aside the laws of a state to achieve its objectives. *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 31 (1996). Congress had no such intent with the FDCA.[4] Further, the United States Supreme Court has "observed repeatedly that preemption is ordinarily not to be implied absent an actual conflict." *English*, 496 U.S. at 90 (quotations and citations omitted).

The State does not seek to compel Purdue to stop selling its opioids, does not seek to enforce FDA regulations, and does not allege any conduct in conflict with FDA regulatory activity.

A. The "Dose Ceiling" Allegations Do Not Conflict with FDA Approval.

Purdue argues that the FDA has "expressly declined to recommend a maximum . . . duration of use" and that the State's Complaint challenges the FDA's assessment. Def. Br. at 8 (quotations omitted). Purdue, however, mischaracterizes the text of the State's actual allegations, which expressly refer to Purdue's *unqualified* statements about maximum dose to providers that are inconsistent with the FDA's labeling. As referenced in the State's Complaint, the FDA approved a limited statement on OxyContin's labeling making clear that OxyContin's dose ceiling was imposed due to adverse reactions. Compl. ¶ 60. This statement is shown on

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[4] The 1962 amendments to the FDCA, which largely created the current version, added a savings clause, including that a provision of state law would only be invalidated upon a "direct and positive conflict" with the FDCA. Pub. L. 87-781, 76 Stat. 780, 793. When Congress enacted an express preemption provision for medical devices in 1976 (21 U.S.C. § 360k(a)), it declined to enact a provision for prescription drugs. And in 2007, when Congress again amended the FDCA (121 Stat. 823), it granted the FDA statutory authority to require a manufacturer to change its drug label based on safety information that becomes available after a drug's initial approval. § 901(a), *id.*, at 924–26. In doing so, however, Congress did *not* enact a provision in the Senate bill that would have required the FDA to preapprove all changes to drug labels. *See* S. 1082, 110th Cong., 1st Sess., § 208, pp. 107–14 (2007) *568 (as passed) (proposing new § 506D). Instead, it adopted a rule of construction to make it clear that manufacturers remain responsible for updating their labels. *See* 121 Stat. 925–26.

Purdue's OxyContin label, attached as Exhibit B to its Motion to Dismiss, which references the no ceiling effect to analgesia being limited by adverse reactions, including respiratory and Central Nervous System depression. Def. Ex. B, § 12.1. OxyContin's label contains numerous other statements concerning dosing that support the State's position.[5]

The Complaint's allegations concerning OxyContin's dose ceiling are wholly consistent with FDA regulatory action, including OxyContin product label and the FDA's 2013 response to a Citizen's Petition from Physicians for Responsible Opioid Prescribing (PROP Petition) (Def. Ex. C), which Purdue proffers as evidence that the FDA "expressly declined to recommend a 'maximum dose.'" Def. Br. at 8. A plain reading of the FDA PROP Petition response shows that it does not speak to the alleged unqualified dose ceiling claims at hand and was confined to the specific request of a 100 mg daily dose limit and studies cited by PROP. Def. Ex. C at 11. The New York state court rejected this dose ceiling argument from Purdue on similar grounds. **Resp. Ex. B**, *In re Opioid Litig.*, 2018 WL 3115102, at *9.

B. The "Pseudoaddiction" Allegations Do Not Conflict with FDA Approval.

The word "pseudoaddiction" does not appear on OxyContin's product label. *See* Def. Ex. B. It is a deceptive concept that Purdue delivered to Tennessee health care providers to make them willing to prescribe more, not fewer, opioids to patients who exhibited drug seeking or addictive behavior. Compl. ¶¶ 75–92. Purdue argues that the FDA's approved labeling "accepts the concept

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[5] *See* Def. Ex. B, § 9.2 (stating "[t]he high drug content in extended-release formulations adds to the risk of adverse outcomes from abuse and misuse"); § 2.1 (stating "us[ing] the lowest effective dosage for the shortest duration consistent with individual treatment goals"; Boxed Warning at 1 (stating to "[m]onitor closely, especially upon initiation or following a dose increase" and "[m]onitor for respiratory depression, especially during initiation of OXYCONTIN or following a dose increase"); and § 2.1 (stating "OxyContin 60 mg and 80 mg tablets, a single dose greater than 40 mg, or a total daily dose greater than 80 mg are only for use in patients in whom tolerance to an opioid of comparable potency has been established.")

of pseudoaddiction" and the State's allegations concerning pseudoaddiction are inconsistent. Def. Br. at 7–8 (citing Def. Ex. B, § 9.2). Purdue's argument is contrary to the FDA's own comments that the exact section in OxyContin labeling that Purdue cites is not intended as a discussion of pseudoaddiction.[6] A plain reading of OxyContin's label bears this out:

> "Drug-seeking" behavior is very common in persons with substance use disorders. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated "loss" of prescriptions, tampering with prescriptions, and reluctance to provide prior medical records or contact information for other treating healthcare provider(s). "Doctor shopping" (visiting multiple prescribers to obtain additional prescriptions) is common among drug abusers and people suffering from untreated addiction. Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control.

Def. Ex. B, § 9.2.

Purdue argues that the final sentence of the OxyContin label justifies its efforts to convince prescribers to disregard or be skeptical about drug-seeking or addictive behavior. The OxyContin label, however, confirms that drug-seeking behavior ought to raise suspicions, not allay them. By recharacterizing drug-seeking behavior as "pseudoaddiction" arising from inadequate pain relief and assuring prescribers they could disregard those behaviors, Purdue directly contradicted OxyContin's label when counseling prescribers. Likewise, Purdue's recommendation to providers to increase dosage strength in response to signs of abuse does not appear on the label. Purdue's misrepresentations conflict with OxyContin's label.

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[6] **Resp. Ex. D**, *Purdue Pharma Used Deceptive Sales Tactic for OxyContin after Settlement, Ex-Sales Rep Says*, CBS NEWS, June 21, 2018, https://www.cbsnews.com/news/oxycontin-purdue-pharma-former-sales-representative-deceptive-sales-psuedoaddiction/ (FDA spokesperson stating that OxyContin labeling including section 9.2 is not intended as a discussion of pseudoaddiction).

Purdue's argument regarding pseudoaddiction is not known to have been accepted by any court in the United States and has been rejected by a New York state court (**Resp. Ex. B**, *In re Opioid Litig.*, 2018 WL 3115102, at *9) and by an Alaska state court (*see* **Resp. Ex. C** at 5-6).

C. The "Overstating the Efficacy of Screening Tools" Allegations Do Not Conflict with FDA Approval.

Purdue also asserts that the "FDA-mandated Risk Evaluation and Mitigation Strategy ('REMS') program for [Extended Release/Long Acting] opioids advocates the use of the very screening tools that the State criticizes." Def. Br. at 8. But this argument also mischaracterizes the State's Complaint, which refers to *overstating* the efficacy of tools for providers to mitigate addiction and identify abuse, not the use of the tools themselves. Compl. ¶ 93. The excerpt of the REMS document Purdue cites only directs the provider to "understand and *appropriately use screening tools for addition or abus*e . . . [,]" which is not at all inconsistent with the State's allegations that Purdue overstated their efficacy. Def. Ex. D at 11 (emphasis added).

D. The "Failing to Disclose Lack of Substantiation" Allegations Do Not Conflict with FDA Approval.

Purdue asserts that the State takes issue with "claims relating to OxyContin's appropriateness for long-term treatment of chronic pain[.]" Def. Br. at 7. Again, Purdue's assertion mischaracterizes the State's allegations. The State's allegations do not challenge the FDA's indication for use with chronic pain, but instead assert that Purdue failed to disclose the lack of substantiation for opioid use beyond 12 weeks (Compl. ¶ 170), as the FDA has acknowledged, Def. Ex. C at 10. Even if these allegations are construed as similar to failure to warn claims, the United States Supreme Court has held that failure to warn claims are not preempted absent "clear evidence" that the FDA would have prohibited Purdue from adding this disclosure. *Wyeth*, 555 U.S. at 571.

Purdue's reliance on the FDA's response to the PROP Petition (Def. Ex. C) does not provide this clear evidence. The PROP Petition requested that the FDA (1) strike the term "moderate" from the indication of opioids for non-cancer pain, (2) add a maximum daily dose, equivalent to 100 mg of morphine for non-cancer pain, and (3) add a maximum duration of 90-days for continuous daily use for non-cancer pain. Def. Ex. C at 1. The PROP Petition did not seek disclosure of the lack of substantiation for opioid use beyond 12 weeks and was limited to the specific studies cited. In fact, in response to the PROP Citizen's Petition, the FDA stated that it "is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks" (Def. Ex. C at 10), also stated that the "FDA has also determined that more data are needed about the safety of long-term use of opioids," (Def. Ex. C at 1) and required "ER/LA opioid drug sponsors to conduct [post-market studies] to assess the known serious risks of misuse, abuse, hyperalagesia, addiction, overdose, and death associated with the *long-term use* of opioid analgesics." Def. Ex. C at 10 (emphasis added).

The New York state court expressly rejected this argument from Purdue noting that the opioid manufacturers, including Purdue, failed to establish clear evidence that the FDA would have prohibited this disclosure. **Resp. Ex. B**, *In re Opioid Litig.*, 2018 WL 3115102, at *9. A similar argument by the opioid manufacturers was likewise rejected by the Northern District of Illinois. *City of Chicago v. Purdue Pharma L.P.*, No. 14 C 4361, 2015 WL 2208423, at *10 (N.D. Ill. May 8, 2015).

E. The "Abuse and Diversion Detection Program" Allegations Do Not Conflict with FDA Approval.

The State's Complaint asserts that Purdue violated an injunctive provision contained in paragraph 13 of the 2007 Agreed Final Judgment, which required the company to (1) establish, implement, and follow an OxyContin abuse and diversion detection (ADD) program and (2) to

take appropriate steps when Purdue became aware of red flags for abuse or diversion of OxyContin prescribed by the providers its sales representatives called upon. Compl. ¶¶ 444–870; Def. Ex. A ¶ 13.

Instead of addressing its agreed upon obligations under paragraph 13, Purdue created a strawman. According to Purdue, the State alleges Purdue made misrepresentations that were permitted or required under the 2007 Agreed Final Judgment and that the State should be judicially estopped from taking contrary positions. Def. Br. at 10. But the State has not taken an inconsistent position. As set forth above, the State does not challenge the promotion of Purdue's opioids that are consistent with FDA labeling and indications; likewise, the State does not challenge the promotion of Purdue's opioids that are consistent with the 2007 Agreed Final Judgment.

Purdue argues the State "wrongly believes the 2007 Agreed [Final] Judgment requires Purdue to stop promoting opioid medications for long-term treatment of chronic pain." Def. Br. at 10. This contradicts not only what is in the Complaint, but also what is in the Agreed Final Judgment itself. The Agreed Final Judgment specifies that Purdue was to cease off-label promotion, or, marketing and promotions of an off-label use. A plain reading of paragraph 13 of the Agreed Final Judgment shows that Purdue was required to implement and follow its ADD program and to stop promoting to providers whose practices showed red flags for abuse or diversion of OxyContin if warranted.[7]

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[7] Def. Ex. A ¶ 13 states "Purdue *shall,* no later than thirty (30) business days after the Effective Date of this Judgment, *establish, implement, and follow an OxyContin abuse and diversion detection program* consisting of internal procedures designed to identify potential abuse or diversion of OxyContin in certain settings . . . Upon identification of potential abuse or diversion involving a Health Care Professional with whom Purdue employees . . . interact, Purdue . . . *shall take such further steps as may be appropriate based on the facts and circumstances*, which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." (emphasis added).

II. THE STATE HAS ADEQUATELY PLEADED ITS COMPLAINT.

Purdue's Motion makes a series of arguments that the State has not adequately pleaded the elements of the causes of action it asserts. All are inapposite.

A. The State has adequately pleaded its 2007 Agreed Final Judgment claims.

Purdue argues that the State has not pleaded any diversion-based violation of the 2007 Agreed Judgment. Def. Br. at 5, 11. Purdue's argument is incorrect for two reasons. First, the Agreed Final Judgment does not require the State to prove that diversion occurred. It only requires the State to show that Purdue failed to implement or follow its ADD program or failed to take appropriate steps when the company became aware of red flags for abuse or diversion of OxyContin related to the providers it called upon. Def. Ex. A ¶ 13. Second, the State's Complaint is replete with examples where Purdue knew or should have known that OxyContin diversion or abuse was taking place. Compl. ¶¶ 444–870. While the State was not required to do so to show a violation of the 2007 Agreed Final Judgment, it *did* plead specific facts showing that Purdue knew or should have known about actual diversion of Purdue's opioids prescribed by specific providers its sales representatives called upon. For example, paragraphs 534–39 of the Complaint allege that Purdue knew or should have known about diversion or abuse of OxyContin at the practice of Dr. James Pogue. For example, paragraph 538 alleges:

> Purdue knew through savings card data that it collected of other examples of many other high quantity/high dose prescriptions from Dr. Pogue that were extremely likely to have been diverted. Purdue compiled savings card data showing that Dr. Pogue wrote a 24 year-old male a 12-day prescription for 150 tablets of 80 mg Oxycontin-equivalent to 1,000 mg or 1,500 [Morphine Milligram Equivalents] a day. Dr. Pogue also wrote a 12-day prescription for 180 tablets of 80 mg OxyContin, which equals 16 tablets per day, or 1,920 MMEs per day, over 21 times the [Centers for Disease and Control and Prevention]'s 90 MME cautionary limit.

The Complaint contains numerous other allegations of Purdue's knowledge of actual diversion.[8]

B. The State has adequately pleaded its TCPA claims.

Purdue makes a series of unpersuasive arguments that the State did not adequately plead its TCPA claims. Purdue's arguments are incorrect both as a matter of law and fact.

The State's burden to prove a violation of the TCPA is minimal. The TCPA is to be "interpreted and construed consistently with the interpretations given by the federal trade commission and the federal courts" under the comparable provision of the FTC Act that prohibits unfair or deceptive acts or practices. Tenn. Code Ann. §§ 47-18-102(1), -115. A governmental enforcement action is not a private or common law fraud action designed to remedy a singular harm, but an action to deter deceptive acts or practices and provide remediation. *See FTC v. Affiliate Strategies, Inc.*, No. 09-4104-JAR-KGS, 2010 WL 11470099 (D. Kan. June 4, 2010) (citing *FTC v. Freecom Commc'ns., Inc.*, 401 F.3d 1192, 1202–03, n. 7 (10th Cir. 2005)). Unlike the elements of common law fraud, the State need not prove scienter, reliance, or injury to establish a violation. *See Freecom Commc'ns, Inc.*, 401 F.3d at 1203, n. 7 (citation omitted); Tenn. Code Ann. §§ 47-18-102(1), -115.

Purdue incorrectly asserts that the State must establish under the TCPA that its conduct caused an "ascertainable loss of money or property"[9] and did not. Def. Br. at 12. The State is not

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[8] *See, e.g.*, Compl. ¶¶ 734 ("Despite Purdue's knowledge of abuse and diversion associated with the clinic's providers, Purdue failed to ever place the actual Pain Clinic B on cease calling status."); 785 ("As of December 2016, Purdue had not placed Dr. Mohamed in cease calling status despite being told that abuse and diversion were taking place outside of his clinic, that he was overprescribing controlled substances, about his suspect conversions from an opioid use disorder treatment to OxyContin, and that his office was standing room only or very busy on multiple occasions. . ."); and 965 ("[Purdue] continued sales targeting of providers and pharmacies with practices that had actual abuse or diversion or signs indicative of abuse or diversion of opioids . . .").

[9] Ascertainable loss is not limited to money or property. It is defined as "[a]n identifiable deprivation, detriment or injury arising from . . . any unfair, misleading, or deceptive act or practice even when the precise amount of the loss is not known[.]" Tenn. Code Ann. § 47-18-2102(1).

required to demonstrate an ascertainable loss as part of its TCPA burden. Purdue exclusively cites cases for this proposition under the TCPA's *private* right-of-action provision, Def. Br. at 12,[10] but the State has not brought suit under this provision. Compl. ¶ 1. Unlike the TCPA's private right-of-action provision, Tenn. Code Ann. § 47-18-109, the State's TCPA enforcement provision, Tenn. Code Ann. § 47-18-*108*, contains *no* requirement that a person suffer an ascertainable loss for the State to bring suit.[11] Instead, the TCPA's state enforcement provision affords the State a menu of remedies, including a permanent injunction, civil penalties, license or certificate revocation, and attorney's fees and costs that are available upon a showing of a violation of the TCPA regardless of whether a person has suffered an ascertainable loss. Tenn. Code Ann. §§ 47-18-108(a)(1), (a)(5), (b)(2), (b)(3), and (b)(4).

The State's burden to show a violation based on deception is also minimal. "A deceptive act or practice is one that causes or tends to cause a consumer to believe what is false or that misleads or tends to mislead a consumer as to a matter of fact." *Tucker*, 180 S.W.3d at 116. "Thus, for the purposes of the TCPA and other little FTC acts, the essence of deception is misleading consumers by a merchant's statements, silence, or actions." *Id.* Through Tenn. Code Ann. § 47-18-104(b)(27), deception is also actionable if it occurs to "any other person."

While not part of its minimal burden to prove a violation, the State does seek recovery of ascertainable losses as a remedy under Tenn. Code Ann. § 47-18-108(b)(1). Compl. p. 271. Unlike

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[10] Citing *Audio Visual Artistry v. Tanzer*, 403 S.W.3d 789, 810 (Tenn. Ct. App. 2012); *Tucker v. Sierra Builders*, 180 S.W.3d 109, 115 (Tenn. Ct. App. 2005); *Harvey v. Ford Motor Credit. Co.*, No. 03A01-9807-CV-00235, 1999 WL 486894 (Tenn. Ct. App. July 13, 1999).

[11] *Cf.* Tenn. Code Ann. § 47-18-108(a)(1) ("Whenever the division has reason to believe that any person has engaged in [or] is engaging in ... any act or practice declared unlawful by this part." with Tenn. Code Ann. § 47-18-109(a)(1) (which limits the private right of action to"[a]ny person who suffers an ascertainable loss . . . as a result of the use or employment by another person of an unfair or deceptive act or practice described in § 47-18-104(b) and declared unlawful by this part.").

its burden to establish a TCPA violation or to establish other remedies, a showing of reliance is required to establish restitution for ascertainable losses. This is the only portion of the State's TCPA action that approaches a traditional proximate cause analysis within tort law. Consistent with the FTC Act, to raise a presumption of reliance for restitution, the State need only show (1) the business entity made material misrepresentations likely to deceive, (2) those misrepresentations were widely disseminated, and (3) persons[12] purchased the business entity's products. *Freecom Commc'ns., Inc.*, 401 F.3d at 1205–06. A governmental enforcer is not required to show that any particular purchaser *actually* relied on or was injured by the unlawful misrepresentations and is not required to present a parade of witnesses. *Id.* at 1205. Under binding FTC case law, express claims,[13] health and safety information,[14] and financial connections[15] are all presumptively material.

The State's Complaint makes allegations satisfying the State's burden for pleading ascertainable losses. The Complaint alleges Purdue made widely-disseminated, deceptive, and express health and safety claims,[16] material omissions of health and safety information,[17] and material omissions of Purdue's financial connections to third-party groups it substantially

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[12] *Freecom* refers to consumers, but Tenn. Code Ann. § 47-18-108(b)(1) is broader and includes a "person." *See* Tenn. Code Ann. § 47-18-103(13).

[13] *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095–96 (9th Cir. 1994), *cert. denied*, 115 S. Ct. 1794 (1995); *Thompson Medical Co.*, 104 F.T.C. 648, *102 (1984), *aff'd* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 107 S.Ct. 1289 (1987).

[14] *See, e.g., FTC v. QT*, 448 F. Supp. 2d 908, 960 (N.D. Ill. 2006) (citing *Kraft, Inc. v. FTC*, 970 F.2d 321, 322 (7th Cir. 1992)); *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1190 (N.D. Ga. 2008).

[15] 16 C.F.R. § 255.5.

[16] Compl. ¶¶ 58–74 (unqualified no dose ceiling), ¶¶ 75–92 (pseudoaddiction), ¶¶ 93–137 (overstating the efficacy of tools to mitigate addiction), ¶¶ 180–88 (general safety claims), ¶¶ 189–360 (comparative claims with other opioid products), ¶¶ 362–71 (quality of life), ¶¶ 372–86 (improved function), ¶¶ 387–98 (sleep aid), ¶¶ 399–416 (use in the elderly).

[17] Compl. ¶¶ 138–69, 170–79.

funded,[18] and that persons purchased Purdue's opioid products.[19] Elsewhere, the Complaint asserts that Purdue's deceptive conduct caused economic loss. Compl. ¶¶ 874, 965, p. 271.

Next, Purdue asserts that the State's Complaint is deficient because it "does not identify a Tennessee physician who allegedly prescribed one of Purdue's opioid medications because of Purdue's marketing." Def. Br. at 13–14. The State does not have this burden under the TCPA. Tennessee Code Annotated § 47-18-104(b)(27), the "catch-all" deception provision which the State alleges for every misrepresentation and omission, declares that it is unlawful to "engag[e] in any other act or practice which is deceptive to the consumer *or to any other person*[.]" (emphasis added); *see also* Tenn. Code Ann.§ 47-18-103(13). Aside from the numerous other materials that were available to consumers and others directly (*see, e.g.*, Compl. ¶¶ 85, 426–27), the misrepresentations that Purdue made to Tennessee health care providers are actionable as violations under the TCPA under the catch-all provision, which only the State can assert.

And while not required as part of its showing, the State's Complaint *does* allege that Purdue's material misrepresentations and omissions were passed on from deceived prescribers to patients (Compl. ¶ 37), that Purdue "was aware at least by 2014 that prescribers often relied upon the company as 'someone [sic] they can look to for the information they need to make prescribing decisions" (Compl. ¶ 32), that Purdue made widely disseminated material misrepresentations and omissions through sales calls and other marketing vehicles about its opioid products (*see supra* n. 16-17), that Purdue made sales calls to two providers whose practice Purdue was specifically told by law enforcement had questionable OxyContin prescribing practices (Compl. ¶¶ 594–96), and

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[18] Compl. ¶¶ 417–43.

[19] *See, e.g.*, Compl. ¶¶ 5, 314, 458, 470, 474, 532, 533, 537, 545, 548, 559, 576, 587, 588, 593, 608, 643, 798, 880, 886, 892.

that the number of prescriptions "is Highly Correlated to [Sales] Call Activity." Compl. ¶ 877. Additionally, the State's Complaint does definitively specify how Purdue's marketing influenced more OxyContin prescriptions (Compl. ¶¶ 536, 882–85) and references specific prescriptions that were obtained through Purdue's marketing vehicles. Compl. ¶¶ 536–39.

Purdue next argues that the State has not pleaded its TCPA claims with specificity[20] and cites two cases in support. But neither case cited by Purdue involved a state plaintiff or was analogous to this action.[21] Even so, in the present case, the State has pleaded with specificity and other courts have upheld far less detailed complaints than the one at issue here against Purdue's Rule 9 objection. *See, e.g.,* **Resp. Ex. C**, Alaska Or. at 16. Purdue fails to acknowledge in its argument, let alone address, paragraphs 57 through 443 in the State's Complaint, which detail specific misrepresentations, made by specific Purdue employees, to specific health care providers, on specific dates, in specific counties—all based upon internal Purdue documents cited to in the

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[20] Cases under the TCPA's private-right-of-action provision state that TCPA actions must be pleaded with specificity under Tenn. R. Civ. P. 9 (*see Harvey v. Ford Motor Credit Co.*, 8 S.W.3d 273, 275 (Tenn. Ct. App. 1999)), but FTC cases interpreting section 5's differences with common law fraud hold that compliance with Rule 9 is not required for FTC actions under section 5, which are analogous to the State's TCPA provision. *See, e.g., FTC v. Affiliate Strategies, Inc.*, No. 09-4104-JAR-KGS, 2010 WL 11470099 (D. Kan. June 4, 2010) (citing *Freecom*, 401 F.3d at 1202–03, n.7); *FTC v. Nat'l Testing Servs., LLC*, No. 3:05–0613, 2005 WL 2000634, at *2 (M.D. Tenn. Aug. 18, 2005).

[21] First, Purdue claims that the court in *City of Chicago v. Purdue Pharma L.P.*, No. 14 C 4361, 2015 WL 2208423 (N.D. Ill. May 8, 2015), "dismissed similar fraud-based claims" because the city failed to allege 'the identities of doctors who, as a result of one or more of defendants' alleged misrepresentations, prescribed opioids for chronic pain to a City-insured patient." Def. Br. at 14. However, the city's *consumer protection* claims were expressly preserved, *id.* at *12, and the "fraud-based claims" that were dismissed *without prejudice* in the cited order were counts of false claims, insurance fraud, common law fraud, and false statements made to the government or under oath. *City of Chicago*, 2015 WL 2208423 at *13–14. Even these claims survived a subsequent motion to dismiss when they were amended. *City of Chicago*, 211 F. Supp. 3d 1058, 1074, 1076 (N.D. Ill. 2016). Second, Purdue cites *Bunting v. Bristol-Myers Squibb Company*, in which one of the claims brought by a private plaintiff was under the Colorado Consumer Protection Act (CCPA). No. 3:06-cv-6052 (FLW), 2009 WL 5216981 (D.N.J. Dec. 30, 2009). The complaint was one of at least twenty-three virtually identical other complaints filed by personal injury Plavix plaintiffs in that district. *Id.* at *6. The court found the complaint to be "woefully deficient" because it contained "boilerplate allegations" which "amount[ed] to nothing more than a mechanical recitation of the elements of a cause of action under the CCPA." *Id.* Indeed, the plaintiff's complaint in *Bunting* only contained a single paragraph with specific details, and "not one of those details concern[ed] the CCPA claim." *Id.* Next, the court also found that, "[s]ignificantly, the facts necessary to satisfy Rule 9(b) are not facts which are in Defendants' control." *Id.*

Complaint. The State also provides allegations that recite specific misleading statements made by specific sales representatives to specific health care providers who were known to be suspicious prescribers of OxyContin, such as paragraphs 511 (discussing patient selection and documentation with Dr. Rhodes), 528 (Dr. Rhodes stated he was getting out of pain management and Purdue's sales representative refocused him on proper patient selection for OxyContin) 774 (conversion guide for switching patient from Suboxone to OxyContin), and 802 ("[d]iscussed that diversion could happen with all products [provider] agreed that could happen with any scheduled drug.").

Finally, according to Purdue, the State's allegations "undermine any plausible causal link" because the Complaint makes the "contradictory claim" that physicians and clinics that improperly or unnecessarily prescribed opioid medications did so for financial gain, "not because of anything Purdue said or did." Def. Br. at 15. Purdue fails to articulate why Purdue's deceptive conduct and a provider's profit motivation are mutually exclusive and undermine a causal link. Further, Purdue's argument is flawed because it ignores allegations in the State's Complaint demonstrating that Purdue's sales calls to providers *did* impact prescription rates for Purdue's opioids. Compl. ¶¶ 27–37, 877–79. In addition, Purdue ignores the representative examples set forth in Complaint paragraphs 533, 561, and 590 that explicitly allege the profit Purdue was earning from the OxyContin prescriptions written by several suspicious providers who were marketed by Purdue's sales representatives.

C. The State has adequately pleaded its public nuisance claim.

Purdue's multiple arguments that the State has not adequately pleaded its public nuisance claim are also all without merit.

1. The State alleges interference with a public right.

Purdue first argues that the State has not sufficiently pleaded the elements of public nuisance because the State has not alleged any right that is common to the public. Def. Br. at 22–23. Purdue unsuccessfully raised this argument before. **Resp. Ex. B**, *In re Opioid Litig.*, 2018 WL 3115102, at *27-28; **Resp. Ex. C,** Alaska Or. at 9.

Purdue argues that a public right for nuisance purposes is restricted in scope and includes rights common to the public such as clean air and water. Def. Br. at 22. Purdue also asserts that "[c]onduct does not become a public nuisance merely because it interferes with the use and enjoyment of land by a large number of persons[,]" (Def. Br. at 22–23 (citing Restatement (Second) of Torts § 821B cmt. g (1979)), or by spending taxpayer money. Def. Br. at 23. Purdue's arguments are without merit, ignore the action's broad application under Tennessee and common law, ignore the State's allegations, and rely on distinguishable case law from other jurisdictions.

The Tennessee Supreme Court has defined the common law nuisance cause of action expansively. Nuisance "extends to everything that endangers life or health" as the Tennessee Supreme Court recognized in a nuisance case brought by the State that did not involve clean air or water. *State ex. rel. Swann v. Pack*, 527 S.W.2d 99, 113 (Tenn. 1975). As the court in *Pack* recognized,

> Our state and nation have an interest in having a strong, healthy, robust, taxpaying citizenry capable of self-support and of bearing arms and adding to the resources and reserves of manpower. We, therefore, have a substantial and compelling state interest in the face of a clear and present danger so grave as to endanger paramount public interests.

Id.

While a nuisance action is often used in the context of a specific property,[22] it is not limited to this context in Tennessee. *See Pack*, 527 S.W.2d at 114; *see also State v. Graham*, 35 Tenn. (3 Sneed) 134 (1855) (holding unlawful utterance constituted a nuisance). In *Pack*, which involved a church group's handling of deadly snakes and consumption of poison, the Tennessee Supreme Court expanded the trial court's injunction of the respondents to prohibit the act of handling deadly snakes or consuming poison not just to Cocke County where the church was located, *but throughout the entire state*. *Id.* at 114. The Tennessee Supreme Court also held that the creation and maintenance of the public nuisance extended not just to those who "publicly handle snakes in the presence of other persons" but also to "those who are present aiding and abetting." *Id.* at 113. Thus, it is clear that in Tennessee common law nuisance extends broadly to actions or omissions and is not limited to those involving land.[23] *Id.*; *see also Wayne County v. Tenn. Solid Waste Disposal Bd.*, 756 S.W.2d 274, 283 (Tenn. Ct. App. 1988) (defining nuisance as "an act or omission that unreasonably interferes with or obstructs rights common to the public").

The State alleges interference with public health and the marketplace on an immense scale. *See, e.g.*, Compl. ¶¶ 956, 959. Instead of actions by an isolated church group, the State's Complaint alleges statewide harm on a massive scale by the largest branded opioid market participant that has affected a significant portion of the State's population. The State's basis for its nuisance action comes from Purdue's own conduct which interferes with the public health and the commercial

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[22] The State has also included allegations in its Complaint that tie Purdue's conduct to specific pieces of property in Tennessee. *See* Compl. ¶¶ 444–870, 889–892, 960.

[23] Purdue's reliance on *City of Chicago v. Beretta U.S.A. Corporation.*, 821 N.E. 2d 1099 (Ill. 2004) in support of its public right argument is misplaced because it was exclusively based on Illinois case law, which only recognizes nuisance involving "use of land" or in violation of a statute. *Id.* at 1117. These restrictions do not exist in Tennessee.

marketplace.[24] Eight hundred and sixty-five paragraphs (Compl. ¶¶ 57–922) of the State's Complaint set forth detailed descriptions of Purdue's own conduct that interfered with the commercial marketplace and the public health. Even Purdue's cited authority supports the State's position by making clear that freedom from interference with public health and operation of the public market have long been recognized as public rights. RESTATEMENT (SECOND) OF TORTS § 821B, cmts. a, b.

2. The State has adequately pleaded causation in fact.

The State has adequately pleaded that Purdue was the cause in fact of the nuisance. The Complaint plainly asserts causation in paragraphs 962 and 964.[25] These paragraphs summarize the preceding allegations that detail how Purdue: aggressively marketed its opioid products (Compl. ¶¶ 2–6, 18–56) by making material misrepresentations and omissions about the safety, efficacy, and comparative benefits of its opioid products (Compl. ¶¶ 57–443), continued to market its products deceptively to providers, clinics, and pharmacies that the company knew to have red flags for abuse and diversion or outright abuse or diversion (Compl. ¶¶ 444–870), distributed promotional material and savings cards that it knew or should have known were vehicles for OxyContin diversion (Compl. ¶¶ 535–38, 880–86), and adversely impacted the State by saturating the marketplace with OxyContin and other opioids. (Compl ¶¶ 871–971).

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[24] Purdue remained in control of its own marketing, promotional materials, sales force, and other conduct that form the basis of the State's nuisance claim, thus Purdue's reliance on *Johnson County, Tennessee v. U.S. Gypsum Co.*, 580 F. Supp. 284, 294 (E.D. Tenn. 1984), *order set aside in part sub. nom. Johnson County, Tennessee v. U.S. Gypsum Co.*, 664 F. Supp. 1127 (E.D. Tenn. 1985), is misplaced.

[25] Compl. ¶¶ 962 (stating "[e]xpanding the market for prescription opioids by making misrepresentations and omissions to health care providers, especially to general practitioners, nurse practitioners, and physician assistants, as well as targeting providers and pharmacies with practices that had actual abuse or diversion or signs indicated of abuse or diversion has created an abundance of opioids available for criminal use and fueled a wave of addiction, abuse, injury, and death) and 964 (stating "[b]ut for Purdue's actions, opioid use would not have become so widespread, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists would have been averted. Purdue's actions have and will continue to injure and harm many residents throughout Tennessee.").

Among other things, the State's Complaint alleges that:

- Purdue continued to make marketing calls to a prescriber who had previously shown red flags for abuse or diversion of OxyContin after knowing that one of his patients died from an OxyContin overdose and after being told that the prescriber had given the deceased 90 80 mg OxyContin tablets while knowing he had an opioid addiction problem, among other things (Compl. ¶¶ 501; 498–512);

- Purdue continued to make sales calls in spite of credible reports of OxyContin diversion, patient overdoses, indictments, adverse licensure actions, a provider admitting he was addicted to heroin, a knife fight outside a provider's office, muggings over controlled substances outside of a pharmacy linked to a specific provider, a clinic that had no examination tables or equipment, an admission by a provider that he was running a pill mill, a provider changing the name of his practice shortly after he was notified of a state investigation into his practice, a patient being coached in the waiting room about how to fill out intake forms, armed guards in provider waiting rooms, high numbers of patients who purchased OxyContin in cash, high numbers of out-of-state or out-of-county car tags in providers' parking lots, accusations of insurance fraud, choreographed urine screenings and pill counts, standing-room-only waiting rooms, and additional signs of problematic high volume practices (Compl. ¶¶ 5, 450–52, 458–61, 477, 522–31, 594–96);

- Purdue ignored red flags for abuse or diversion at Tennessee pharmacies and continued to push OxyContin (Compl. ¶¶ 890–92);

- Purdue fueled the opioid epidemic through its heavy promotion and use of OxyContin savings cards, which served as vehicles for abuse and diversion of OxyContin (Compl. ¶¶ 880–86);

- Purdue created a sales structure that led to and fostered the proliferation of unlawful marketing claims, which was compounded by trainings in which Purdue instructed sales representatives to make select prohibited claims, lax compliance enforcement, a heavy emphasis on sales performance for compensation and otherwise inadequate instruction (Compl. ¶ 21);

- Purdue's sales representatives misrepresented the safety, efficacy, and benefits of its opioid products and those of its competitors to providers in Tennessee, did not provide adequate warnings to these providers, and marketed the company's opioid products to providers who were not experienced in prescribing them (Compl. ¶ 36);

- Purdue spent significant money to call on providers to promote its opioid products because it had evidence that increased sales calls were "highly

correlated" with more prescriptions for its products—particularly among the top prescribers of those products (Compl. ¶ 23);

- Purdue understated the addictive potential of OxyContin and other opioid products (Compl. ¶¶ 133–37), misrepresented the dose ceiling of OxyContin which can cause serious adverse effects to patients taking increased doses of the drug including overdose, respiratory depression, somnolence, and addiction (Compl. ¶¶ 58–59), and omitted the increased risk of addiction at higher doses of OxyContin (Compl ¶¶ 138–69);

- Out of the 104,340,382 total OxyContin tablets prescribed in Tennessee from 2008 to 2017, 53.7% of them were 40 mg or higher. If 40 mg OxyContin is taken twice a day as directed, that amount equals 120 morphine milligram equivalents (MMEs) per day, which exceeds the 90 MMEs daily amount of opioids the CDC warns against by over 33% (Compl ¶¶ 20, 894);

- The large number of OxyContin prescriptions especially at high doses has equated to a substantial number of residents who have become addicted in Tennessee. A 2015 meta-analysis of 38 studies evaluating opioid misuse, abuse, and addiction in chronic pain patients found rates of addiction averaging between 8-12% though the actual percentage is most likely higher because of those misclassified as physically tolerant (Compl. ¶ 897);

- OxyContin's addictive qualities and easy manipulation led to a subset of addicted individuals to turn to and die from heroin, which was cheaper, when the old formulation of OxyContin was removed from the market on August 5, 2010, and replaced with the reformulated version beginning on August 9, 2010 (Compl. ¶¶ 903–08);

- Evidence showing the heroin death rate, including in Tennessee, was caused by the reformulated OxyContin (Compl. ¶¶ 904–09); and

- Patients taking opioids manufactured by Purdue died from overdoses; (Compl ¶¶ 479, 501, 503, 507, 647).

These allegations if taken as true are more than enough to establish causation in fact.

3. The State has adequately pleaded proximate causation.

Purdue next argues that the State's action does not adequately plead that Purdue's conduct was the proximate cause of the alleged harm. Def. Br. at 15. This argument is without merit.

At the outset, nuisance actions brought by the sovereign are distinct from nuisance actions brought by individuals based on tort. *Philadelphia Elec. Co. v. Hercules, Inc.*, 762 F.2d 303, 315

(3d Cir. 1985) (citation omitted). At common law, nuisance actions brought by the sovereign were "an entirely separate principle." W. Prosser, THE LAW OF TORTS 572 (4th ed. 1971). Other courts have recognized that:

> The absence of facts supporting concepts of negligence, foreseeability, or unlawful conduct is not in the least fatal to a finding of the existence of a common law public nuisance. The assumption that such might be the case is 'based upon an entirely mistaken emphasis upon what the defendant has done rather than the result which has followed, and forgets completely the well established fact that negligence is merely one type of conduct which may give rise to a nuisance.

Com. v. Barnes & Tucker Co., 319 A.2d 871, 883 (Pa. 1974) (citing W. Prosser, LAW OF TORTS, § 88 at 595 (3d ed. 1964)).

Even if a tort-based analysis applies, the State has alleged proximate cause. In Tennessee, conduct constitutes proximate cause of an injury it if it was a substantial factor in bringing about the injury, if no rule or policy relieves the actor from liability because of the manner in which the conduct resulted in the harm, and if injury could have been reasonably foreseen or anticipated by a reasonable person of ordinary intelligence. *McClenahan v. Cooley*, 806 S.W.2d 767, 775 (Tenn. 1991) (citations omitted). All are met here even if this analysis applies.

The State has alleged that Purdue's conduct was a substantial factor in causing the statewide opioid epidemic (Compl. ¶ 874) and has provided detailed allegations in support thereof. Compl. ¶¶ 57-922. If these allegations are taken as true, the State adequately alleged Purdue was a substantial factor in bringing about the injury.

Proximate cause reflects a policy decision made by the Legislature or the courts to deny liability for otherwise actionable conduct. *Snyder v. LTG Lufttechnische GmbH*, 955 S.W.2d 252, 256, n. 6 (Tenn. 1997) (citation omitted). Both the Legislature and state courts have recognized the converse, namely the broad universe of actionable conduct available to the State in enforcement

actions.[26] And while Purdue argues that a series of intervening and superseding acts break the causal link (Def. Br. at 15-16), this argument fails because the State's Complaint alleges that Purdue had knowledge about and could have foreseen these acts. Compl. ¶¶ 444-870. As the court in *McClenahan* stated:

> There is no requirement that a cause, to be regarded as the proximate cause of an injury, be the sole cause, the last act, or the one nearest to the injury, provided it is a substantial factor in producing the end result. An intervening act ... is not a superseding, intervening cause so as to relieve the original wrongdoer of liability, provided the intervening act could have reasonably been foreseen and the conduct was a substantial factor in bringing about the harm. An intervening act will not exculpate the original wrongdoer unless it appears that the negligent intervening act could not have been reasonably anticipated.

806 S.W.2d at 775 (citations omitted). No rule or policy relieves Purdue from liability.

Likewise, other rules Purdue asserts do not apply. Purdue argues that the learned intermediary doctrine and intervening actions by third-parties break the causal link. Def. Br. at 16–17. But this argument also misses the mark. First, the learned intermediary doctrine applies only when intermediaries have received adequate warnings, which is normally a question of fact. *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) (citation omitted). Here, the State has made a series of allegations that Purdue made material misrepresentations and omissions to providers about the safety, efficacy, and comparative benefits of its opioid products (Compl. ¶¶ 57–443) and asserts that these material misrepresentations and omissions were passed on from

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[26] The State as a sovereign has broad common law and statutory authority to address injury to the general welfare. *See State v. Heath*, 806 S.W.2d 535, 537 (Tenn. Ct. App. 1990). The State is the only actor that may assert violations under the deception catch-all, which applies to those acts or practices that tend to cause a person to believe what is false or misleads or tends to mislead a person as to matter of fact. Tenn. Code Ann. § 47-18-104(b)(27) (prohibiting any act or practice "which is deceptive to the consumer *or to any other person*") (emphasis added); *see Morrison v. Allen*, 338 S.W.3d 417, 439 (Tenn. 2011) (citation omitted). The State may also bring suit for "directly or *indirectly* . . . advertising, promoting, selling or *offering for sale* any good or service that is illegal or *unlawful* to sell in the state"); Tenn. Code Ann. § 47-18-104(b)(43)(C) (emphasis added). The State brought suit under both of these TCPA provisions in this action. *See* Compl. ¶¶ 926-51.

deceived providers to patients. Compl. ¶ 37. The defense is inapplicable if the allegations are to be taken as true.

Second, the State's Complaint makes a host of allegations that do not involve an intervening act—superseding or otherwise, including that Purdue's own promotional material was used as a vehicle for abuse and diversion of OxyContin about which Purdue knew or should have known. Compl. ¶¶ 535–38, 880–86.

Third, the actions by third parties were reasonably anticipated or known. The State alleges that Purdue knew that its own marketing efforts increased prescription rates among Purdue's highest prescribers—even to those who it knew or should have known had practices where abuse or diversion was taking place. Compl. ¶¶ 5, 23, 877–78, 882. Purdue's argument that the intervening diversion of highly dangerous narcotics was not somehow reasonably anticipated taxes basic logic—particularly when the label for OxyContin, Purdue's best-selling drug, contains the warning: "Opioids are sought by drug abusers and people with addiction disorders and are subject to criminal diversion." Def. Ex. B. at 5, 17.

The involvement of third parties, even criminals, was reasonably foreseeable given the extensive facts of Purdue's knowledge detailed in the State's Complaint that show the wealth of information Purdue had regarding these suspicious providers, clinics and pharmacies, including reports identifying OxyContin as the cause of death for a patient of a provider Purdue called upon that Purdue knew showed red flags for abuse or diversion of OxyContin,[27] reports of concern

[27] Compl. ¶¶ 498–504 (¶ 501 states "The patient died on 08JAN2009 from the toxic effects of OxyContin. . .").

submitted by Purdue's sales representatives,[28] sales representative call notes,[29] reports from law enforcement,[30] prescription savings card data,[31] commercial sales data about prescribers,[32] field reports,[33] disciplinary action reports,[34] and news or media reports.[35] *See generally*, Compl. ¶¶ 444–870, 876–92. Among other things, the State's Complaint asserts that:

- Purdue had direct knowledge from highly credible sources that the practice of two of Purdue's top customers in Tennessee, Drs. Mireille Lalanne and Visuvalingam Vilvarajah, were the source of diversion of large amounts of OxyContin. Nevertheless, Purdue persisted to call on the providers to encourage them to prescribe even more of their narcotics. Compl. ¶ 596.

- Purdue had knowledge that a significant number of providers at Pain Clinic A were problematic (Compl. ¶¶ 633–34) and of credible reports of additional red flags, such as the clinic being raided by federal authorities, these providers prescribing the highest volume of OxyContin in the entire State and at the highest dose strengths, employees having to be escorted to work because the parking lot was unsafe and because of death threats, the clinic being packed with young, out of town patients who frequently paid cash, and providers losing their DEA licenses due to overprescribing. Compl. ¶¶ 632–62.

- Purdue had knowledge that the owners and providers at Breakthrough Pain Therapy Center were being investigated and later indicted for charges related to diversion and conspiracy, that the clinic had no examination tables or gloves, no appointments, no urine drug screens, no providers who performed independent pain diagnoses, had prewritten prescriptions, and had providers who worked there were or had been on Purdue's suspicious prescriber list. Compl. ¶¶ 663–84, 692.

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[28] *E.g.*, Compl. ¶¶ 449, 471, 478, 483–86, 489–91, 493, 495, 530, 548, 550, 553–54, 579, 581–82, 584–85, 628, 641, 648, 650–51, 656–57, 660, 672, 674–75, 723, 730–32, 754, 775–76, 788, 790, 794, 797, 799, 812, 828, 847, 851–52, 855, 857, 863.

[29] *E.g.*, Compl. ¶¶ 51, 543–44, 598–99, 605–06, 645, 677, 708, 721, 725–28, 755–56, 778–84, 801–03, 816; *see generally*, Compl. ¶¶ 57–870.

[30] *E.g.* Compl. ¶¶ 5, 454, 458, 594–95, 619, 630; *see also*, Compl. ¶¶ 625, 669–70, 679.

[31] *E.g.* Compl. ¶¶ 470, 534–39, 643, 719, 880–86, 892.

[32] *E.g* Compl. ¶¶ 450, 474, 533, 545, 560, 575, 587–88, 608–09, 638, 685, 735, 744, 760, 769.

[33] *E.g.*, Compl. ¶¶ 595, 604, 619–20.

[34] *E.g.* Compl. ¶¶ 459, 557, 613-17.

[35] Compl. ¶¶ 458, 498–99, 551, 553, 556, 597, 624–25, 678, 683, 710, 718, 729, 799, 820, 825, 832–33; *see also*, Compl. ¶¶ 512, 669.

Fourth, as the Alaska court observed in rejecting Purdue's causation argument:

> The State alleges a very sophisticated fraudulent and deceptive marketing scheme to influence the medical community, which included direct marketing of its products to doctors. The State alleges Purdue helped to change the perception of opioid risk and benefit and promoted its use to general practitioners through marketing materials, medical literature, articles, symposia, and direct approach to doctors. It is sufficient that the complaint alleges there is a connection between Purdue's marketing of its opioid products and the injuries to the State.

Resp. Ex. C, Alaska Or. at 17. The same is true of the allegations in the Tennessee Complaint.

In any event, "[j]ust as in the case of proximate causation, the question of superseding intervening cause is a matter peculiarly for the jury because of foreseeability considerations." *McClenahan*, 806 S.W.2d at 775–76 (citations omitted). Even if proximate cause applies to the State's nuisance action, the State's allegations if taken as true establish it.

4. The State's nuisance action is not subject to the derivative injury rule or remoteness.

As part of its proximate cause argument, Purdue asserts that the State's public nuisance claim seeks recovery for wholly derivative harm to third parties and is too remote to be actionable. Def. Br. at 21. This argument is also without merit and has been rejected by other courts. *See, e.g.*, **Resp. Ex. B**, *In re Opioid Litig.*, 2018 WL 3115102, at *27-28; **Resp. Ex. C** at 17.

Even assuming that proximate cause is applicable in a public nuisance action brought by the sovereign, the derivative injury rule and remoteness do not apply because the State seeks compensation *for its own injuries*, ones that are distinct from an individual citizen's injuries. The State brings its claims as a sovereign protecting the public health and the integrity of the marketplace, not as an aggregation of individual claimants. The State seeks multiple avenues of monetary relief: TCPA civil penalties, restitution/disgorgement, equitable costs of abating the nuisance, and damages. The only monetary remedy that approaches being derivative of a third party is restitution under the TCPA, but this is specifically authorized as a state enforcement

remedy by statute (Tenn. Code Ann. § 47-18-108(b)(1)) and prevails over a common law defense. *See Hodge v. Craig*, 382 S.W.3d 325, 338 (Tenn. 2012).

Purdue cites to only one case involving a state sovereign in support of its argument: *People ex rel. Spitzer v. Sturm, Ruger & Co., Inc.*, 309 A.D.2d 91 (N.Y. 2003), but it was not decided under Tennessee law. In that case, the New York Attorney General brought suit against firearm manufacturers and distributors under common law public nuisance. *Id.* The New York appellate court affirmed dismissal by the trial court based on the facts presented in that complaint. *Id.* at 106. The New York appellate court found that the Attorney General's complaint was defective because it relied *as a "central" part of its claim* on trace requests from the Bureau of Alcohol Tobacco and Firearms to show defendants' notice when New York's highest court had already found that the trace requests did not provide enough detail and involved conduct that was "far removed" from the unlawful use of handguns that constituted the nuisance. *Id.* at 93–94, 99. The New York court reiterated that common law public nuisance may be an appropriate legal tool to address consequential harm from other commercial activity. *Id.* at 97.

Because derivative injury and remoteness are fact-specific inquiries,[36] *Sturm*, *Steamfitters*, and the other cases Purdue cites that involve third party payors (Def. Br. at 20-21) are distinguishable based on the facts presented.[37]

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[36] *See Steamfitters Local Union 614 Health and Welfare Fund v. Philip Morris, Inc.*, No. W1999-01061-COA-R9-CV, 2000 WL 1390171, at *4 (Tenn. Ct. App. Sept. 26, 2000) (citing *McClung v. Delta Square Ltd P'ship*, 937 S.W.2d 891, 905 (Tenn. 1996)).

[37] The State does not assert comparable legal theories or damages to the plaintiff in *Steamfitters* or the other cited cases. In *Steamfitters,* the plaintiff sought damages based on *its own fraudulently induced inaction* and had to prove the effect education or smoking cessation programs would have had on the physical injuries suffered by plan participants, who the court noted, determined whether to continue smoking and, if so, how frequently to smoke. *Steamfitters*, 2000 WL 1390171, at *6. The State has not asserted a damages theory based on its fraudulently induced inaction and individual patients on Purdue's opioids, unlike cigarettes, do not independently decide whether to continue using opioids or how frequently to use opioids without a prescription from a provider. Unlike the *Steamfitters*

The State's Complaint details harm based not only on the illegal use of opioids, but also *by their legal use* consistent with Purdue's deceptive marketing and promoting. Unlike in *Sturm*, the State's Complaint here describes how Purdue itself collected a plethora of data points showing direct knowledge about red flags or actual abuse or diversion of OxyContin and other opioids prescribed by the providers its sales representatives called upon and yet continued to market its opioid products in spite of this knowledge. *See, e.g.*, Compl. ¶¶ 5, 444–870. For example, the State's Complaint details how Purdue's prescription savings cards were used as the vehicles for abuse or diversion of OxyContin with Purdue's knowledge. *E.g.* Compl. ¶¶ 535–38, 880–86. And unlike the firearm defendants in *Sturm*, Purdue had an affirmative legal duty to take appropriate action. Purdue had a duty under the TCPA to disseminate non-misleading promotional material, had a duty under the TCPA to disclose material facts (Tenn. Code Ann. § 47-18-104(b)(27), had a duty under the 2007 Agreed Final Judgment to effectively establish, implement, and follow an abuse and diversion detection program (Def. Ex. B ¶ 13), and had a duty not to indirectly offer or sell an unlawful product. Tenn. Code Ann. § 47-18-104(b)(43)(C); Compl. ¶ 957. Purdue violated these duties. Compl. ¶ 957.

The State's action is also distinguishable based on the monetary relief sought. Aside from the statutorily-authorized civil penalties and restitution/disgorgement discussed above, the State seeks the equitable costs of abating the nuisance Purdue substantially created and damages for its own injuries which are distinct from any injuries suffered by individuals. Compl. ¶¶ 910, 955–71.

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plaintiff, Purdue's own documents show that its sales calls to these providers, in which the State alleges Purdue made material misrepresentations and omissions (Compl. ¶¶ 57–443), were "highly correlated" to increased prescriptions of its opioid products, Compl. ¶ 23, 877, and that it continued to make sales calls to providers whose practices Purdue knew to have red flags for abuse or diversion of opioids. Compl. ¶¶ 5, 444–870.

Purdue relies on *Steamfitters*, 2000 WL 1390171, at *4, for the proposition that the State's asserted injuries are wholly derivative of third parties and too remote to be actionable. Def. Br. at 20. But the State's equitable costs of abatement and damages remedies do not raise the problems the court identified in *Steamfitters* because they assert the State's own damages, do not create a risk of multiple recoveries, and are not best asserted by others. *See Steamfitters*, 2000 WL 1390171, at *4–6.

While it is true that most of the State's damages would not exist but for Tennesseans being injured by Purdue's bad conduct, those private citizens do not have standing to recover the *public* monies and remedy the *public* epidemic at issue here. Among other things, the State seeks recovery for Purdue's conduct with respect to fostering the illegal abuse and diversion of OxyContin and other opioids. The State has alleged it has been harmed by diversion of prescription opioids to illicit channels as a result of Purdue's conduct, including through increased law enforcement costs, corrections, and other expenses only the state could incur. Compl. ¶¶ 910, 961-63, 955-71. Private citizens do not have standing to recover for these public harms.

The State's Complaint sufficiently alleges that there is a connection between Purdue's marketing of its opioid products and the relief the State seeks. *See, e.g.*, Compl. ¶¶ 874-922. Further, dismissal is inappropriate because determining proximate cause and related questions is a question for the jury "unless the uncontroverted facts and inferences to be drawn from them make it so clear that all reasonable persons would agree on the outcome." *McClung v. Delta Square Ltd. P'ship*, 937 S.W.2d 891, 905 (Tenn. 1996). Purdue, which bears the burden, has not met this high threshold.

III. PURDUE HAS NOT MET ITS BURDEN.

Purdue fails to address most of the independently-actionable deception claims identified in the State's Complaint,[38] fails to show that its acts or practices were approved by the FDA, and fails to even reference its opioid products besides OxyContin (Hysingla ER, Butrans, and Ryzolt) whose marketing claims are also the subject of the State's lawsuit.

Because Purdue does not address these claims, it has failed to meet its Rule 12.06(2) burden of proof. *Snyder*, 450 S.W.3d at 519. Thus, the Court cannot dismiss these portions of the State's Complaint. And while it is not the State's burden to show how claims not addressed in Purdue's Motion are actionable, these claims, which must be taken as true, *Highwoods Prop., Inc.*, 297 S.W.3d at 700, establish the State's minimal showing for deception under the TCPA.[39]

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[38] Deception claims not addressed by Purdue's Motion to Dismiss include Compl. ¶¶ 114–22 (misrepresentations about peaks and valleys), ¶¶ 123–32 (misrepresentations about abuse deterrence), ¶¶ 133–37 (understating the risk of addiction), ¶¶ 138–69 (omissions about increased risk of addiction at higher doses), ¶¶ 180–88 (general misrepresentations as to safety), ¶¶ 193-200 (misrepresentations about OxyContin's superiority or equivalence to other products (generally), ¶¶ 201–13 (misrepresentations as to OxyContin's superiority or equivalence to Opana), ¶¶ 214–28 (misrepresentations as to OxyContin's superiority or equivalence to Duragesic), ¶¶ 229–35 (misrepresentations as to OxyContin's superiority or equivalence to methadone), ¶¶ 236–47 (misrepresentations as to OxyContin's superiority or equivalence to Avinza), ¶¶ 248–64 (misrepresentations as to OxyContin's superiority or equivalence to immediate-release opioids), ¶¶ 265–68 (misrepresentations as to OxyContin's superiority or equivalence to Dilaudid), ¶¶ 269–80 (misrepresentations as to OxyContin's superiority or equivalence to hydrocodone), ¶¶ 281–97 (misrepresentations as to OxyContin's superiority to opioid products containing acetaminophen), ¶¶ 298–306 (misrepresentations as to OxyContin's superiority to hydrocodone combination products), ¶¶ 307–12 (misrepresentations as to OxyContin's superiority to Lortab or Vicodin), ¶¶ 313–23 (misrepresentations as to OxyContin's superiority or equivalence to Percocet), ¶¶ 324–25 (misrepresentations as to OxyContin's superiority or equivalence to non-opioids), ¶¶ 326–39 (misrepresentations as to Butrans's superiority or equivalence to hydrocodone or hydrocodone combinations), ¶¶ 340–43 (misrepresentations as to Butrans's superiority or equivalence to Darvocet or Tramadol), ¶¶ 344–46 (misrepresentations as to Butrans's superiority or equivalence to Lortab), ¶¶ 347–52 (misrepresentations as to Ryzolt's superiority or equivalence to immediate release opioids), ¶¶ 353–56 (misrepresentations as to Ryzolt's superiority or equivalence to other Tramadol products), ¶¶ 357–60 (misrepresentations as to Hysingla ER's superiority or equivalence to acetaminophen and hydrocodone combination products), ¶¶ 362–71 (misrepresentations as to improved quality of life), ¶¶ 372–86 (misrepresentations as to improved function), ¶¶ 387–98 (misrepresentations as to sleep aid), ¶¶ 399–416 (misrepresentations about opioid use in the elderly), and ¶¶ 417–43 (omissions as to Purdue's material connections to third party groups).

[39] To prove deception under the TCPA's state enforcement provisions, Tenn. Code Ann. §§ 47-18-108(a)(1) and (b)(3), the State must show that Purdue caused or tends to cause a consumer or other person to believe what is false or that misleads or tends to mislead a consumer or other persons as to a matter of fact. *Tucker v. Sierra Builders*, 180 S.W.3d 109, 116 (Tenn. Ct. App. 2005); Tenn. Code Ann. § 47-18-104(b)(27) (applying deception to "the consumer *or to any other person.*") (emphasis added).

CONCLUSION

Because Purdue fails to meet its burden, mischaracterizes the State's Complaint, and asserts invalid defenses, its Motion to Dismiss should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

On this the 22nd day of August, 2018, I, BRANT HARRELL, certify that the above-referenced document was served via U.S. Mail, First Class and e-mail as follows:

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