STATE OF RHODE ISLAND

PROVIDENCE, SC. **SUPERIOR COURT**

(FILED: February 18, 2022)

STATE OF RHODE ISLAND, by and through, PETER NERONHA, ATTORNEY GENERAL,
Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC; RHODES PHARMACEUTICALS L.P.; RHODES TECHNOLOGIES; RHODES TECHNOLOGIES INC; RICHARD S. SACKLER; TEVA PHARMACEUTICALS USA, INC; CEPHALON, INC.; WATSON LABORATORIES, INC.; WARNER CHILCOTT COMPANY, LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; ACTAVIS SOUTH ATLANTIC LLC; ACTAVIS ELIZABETH LLC; ACTAVIS MID ATLANTIC LLC; ACTAVIS TOTOWA LLC; ACTAVIS LLC; ACTAVIS KADIAN LLC; ACTAVIS LABORATORIES UT, INC, F/K/A WATSON LABORATORIES, INC.-SALT LAKE CITY; ACTAVIS LABORATORIES FL, INC, F/K/A WATSON LABORATORIES, INC.-FLORIDA; MALLINCKRODT PLC; MALLINCKRODT, LLC; SPECGX, LLC; CARDINAL HEALTH, INC; MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY; and AMERISOURCEBERGEN DRUG CORPORATION,
***Defendants*.**

C.A. No. PC-2018-4555

DECISION

I

Introduction

LICHT, J. For nearly a quarter of a century, our nation has faced a scourge that has been labeled "the Opioid Crisis." The National Institute on Drug Abuse provides a recent snapshot of the crisis:

> " In 2019, nearly 50,000 people in the United States died from opioid-involved overdoses.[1] The misuse of and addiction to opioids—including prescription pain relievers, heroin, and synthetic opioids such as fentanyl—is a serious national crisis that affects public health as well as social and economic welfare. The Centers for Disease Control and Prevention estimates that the total 'economic burden' of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement."[2] *https://www.nida.nih.gov/drug-topics/opioids/opioid-overdose-crisis* 1/20/22.

Rhode Island has not escaped this plague. Quite the opposite, in 2020 over 384 Rhode Islanders died from accidental overdose on drugs, including opioids. This makes 2020 the deadliest year for accidental overdose deaths in the state's history,[3] and while the final total for 2021 is still being tabulated, it is on pace to shatter that record.[4]

As of 2018, Rhode Island had the ninth highest ranked overdose rate in the country.[5] The toll exacted by this epidemic has been devastating, not only for those lost, but on family, friends, the medical community, law enforcement, and providers of social services.

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[1] *National Vital Statistics, Drug Overdose Deaths,* CDC WONDER, https://www.cdc.gov/nchs/nvss/drug-overdose-deaths.htm.

[2] Florence C.S., Zhou C., Luo F., Xu L., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States,* 54 Med Care 901-906 (2013).

[3] Brian Amaral, *Fentanyl is Killing People. It's Thinning the Streets,* Boston Globe (February 2, 2022), https://www.bostonglobe.com/2022/02/02/metro/fentanyl-is-killing-people-its-thinning-streets.

[4] *Id.*

[5] Erick Trickey, *How the Smallest State is Defeating America's Biggest Addiction Crisis,* Politico Magazine (August 25, 2018), https://www.politico.com/magazine/story/2018/08/25/rhode-island-opioids-inmates-219594.

As one consequence of this epidemic, states, counties, cities, large employers, and health insurers have brought over 3,000 suits seeking to hold pharmaceutical manufacturers, distributors, and even large pharmacy chains responsible for this epidemic.

In our state, the Attorney General, as Plaintiff, who is referred to as the State, brought the instant action against numerous defendants, who are (or were) pharmaceutical manufacturers or distributors claiming that they "created, perpetuated, [and] maintained"[6] the opioid epidemic through deceptive marketing practices and by shipping opioids into Rhode Island without adequate systems to detect and prevent diversion of those drugs.

More specifically, the State has filed a 143-page Second Amended Complaint (the Complaint or SAC) with its allegations embodied in 432 paragraphs. The causes of action are (1) Public Nuisance; (2) Fraud and Fraudulent Misrepresentation; (3) Negligence; and (4) Unjust Enrichment.

This case has been vigorously litigated with extensive discovery and a vibrant motion practice. Over the last several years, the number of extant defendants has dwindled through bankruptcy and/or settlement. The remaining fourteen defendants are (1) Teva Pharmaceutical USA, Inc. (Teva USA); (2) Cephalon (Cephalon), an affiliated company to Teva USA; (3)Warner Chilcott Company, LLC, another affiliated company to Teva USA; and eleven other corporations[7] which are subsidiaries of Teva USA. These eleven corporations, along with Warner Chilcott, are manufacturers of generic medications and are referred to as the "Actavis Entities." All fourteen

[6] Am. Comp. ¶ 357.

[7] Actavis Pharma, Inc.; Actavis LLC; Watson Laboratories, Inc.; Actavis South Atlantic, LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Laboratories UT, Inc.; Actavis Laboratories FL, Inc.; Actavis Kadian LLC; and Actavis Totowa LLC.

defendants are owned (either directly or indirectly through a subsidiary) by a non-party, Teva Pharmaceuticals Industries, Ltd. (Teva Parent).

The State refers to these fourteen defendants as the "Teva Defendants" who object to this characterization because they argue that each defendant is a separate legal entity. Therefore, for purposes of convenience and simplicity, the Court will use the term "Defendants" when referring to *all* named defendants in the aggregate. By doing so, the Court is not resolving any issue Defendants raise on motion.[8] Rather, it will address that issue at the appropriate time.

Teva USA, Cephalon, and the Actavis Entities have each moved separately for Summary Judgment. The State has objected and responded with one memorandum[9] opposing all three motions (the State's Opposition or Opposition). Since most issues are similar and, in some cases, identical in each motion, the Court will endeavor to decide all three motions in one Decision. Where it is necessary to distinguish between and among the various defendants, the Court will do so.

II

Facts & Travel Relative to the Motion

In 1971, Congress passed the Controlled Substances Act (CSA) to "reduce the widespread diversion of [controlled substances] out of legitimate channels into the illicit market[.]" (H.R. Rep. No. 91-1444 (1970) U.S.C.C.A.N. 4566, 4572). Congress expressly designed the CSA to "**combat diversion by providing for a closed system of drug distribution**, in which all legitimate handlers

[8] *See* Defendants' Joint Motion in Limine to exclude reference to "Defendants" generally without distinguishing, and to exclude references to the absence of a corporate representative at trial; Omnibus Motion in Limine by Cephalon, Inc., Teva Pharmaceuticals USA, Inc., and the Actavis Generic Defendants (MIL 8 — The State Should Be Precluded from Arguing that a Defendant is Liable Based Upon the Actions of Its Affiliate).

[9] *See* the State's Combined Memorandum of Law in Opposition to Motions for Summary Judgment by Cephalon, Inc.; Teva Pharmaceuticals USA, Inc.; and Actavis Generic Entities.

of controlled substances . . . **must take reasonable steps to ensure**" they are not acting "as a source for diversion." (Emphasis added.)[10] Both manufacturers (i.e., the makers of opioid prescriptions) and distributors (i.e., the "middlemen") must register with the DEA in order to sell opioids. As a condition of registration, manufacturers and distributors must undertake duties prescribed by the CSA to ensure they are not acting as a source of diversion. *See* 21 U.S.C. § 822.

As it relates to these motions, the "heyday" of opioid prescription writing and marketing lasted roughly from the mid-1990s through 2012, when a confluence of factors led to a precipitous drop in opioid prescribing.[11]

In 2012, defendants Watson Pharmaceuticals, Inc. and Actavis, Inc. merged.[12] Prior to that merger, Actavis produced twelve different generic opioids, including generic OxyContin (Oxycodone I hydrochloride tablet), generic Opana ER (Oxymorphone tablet) and generic Duragesic (a fentanyl transdermal patch).[13]

Ultimately, the State offers two theories of wrongful conduct by the Defendants: (1) falsely marketing the risks and benefits of opioid medicines; and (2) failing to identify, report, and stop shipments of "suspicious [opioid] orders."[14] These two theories undergird each of the four common law claims alleged by the State.

For their part, the Defendants counter that every single one of the State's claims fails for: (i) lack of evidence of fraudulent marketing; (ii) lack of evidence that the Defendants failed to maintain effective, CSA-mandated suspicious order monitoring (SOM) controls; and (iii) absence of proof that the Defendants *caused* any injury whatsoever in Rhode Island, legally or proximally.

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[10] H.R. Rep. No. 91-1444 (1970) U.S.C.C.A.N. 4566, 4572.
[11] *See* Def. Teva's Mem. at 1-2.
[12] *See* Pl.'s Mem. for Partial Summ. J. at 8.
[13] *Id.* at Pl.'s Ex. R.
[14] Pl.'s Mem. for Partial Summ. J. at 8.

The Actavis Entities bring additional defenses reflecting their unique position as manufacturers of *solely* generic prescriptions (i.e., non-branded medication); namely, that (a) generic manufacturers do *not* market to the general, opioid-consuming public; (b) the federal "sameness" requirement mandates that they must label and/or market *exactly* like their branded equivalents; and (c) federal case law preempts state law tort claims against generic pharmaceutical manufacturers.[15]

III

Standard of Review

"Summary judgment is a drastic remedy, and a motion for summary judgment should be dealt with cautiously." *Employers Mutual Casualty Co. v. Arbella Protection Insurance Co.*, 24 A.3d 544, 553 (R.I. 2011) (internal quotations omitted). "[S]ummary judgment is appropriate when, viewing the facts and all reasonable inferences therefrom in the light most favorable to the nonmoving party, the Court determines that there are no issues of material fact in dispute, and the moving party is entitled to judgment as a matter of law." *Quest Diagnostics, LLC v. Pinnacle Consortium of Higher Education*, 93 A.3d 949, 951 (R.I. 2014) (internal quotations omitted).

The moving party bears the initial burden of establishing that no such issues exist. *Heflin v. Koszela*, 774 A.2d 25, 29 (R.I. 2001). If the moving party can sustain its burden, then the "litigant opposing a motion for summary judgment has the burden of proving by competent evidence the existence of a disputed issue of material fact and cannot rest upon mere allegations or denials in the pleadings, mere conclusions or mere legal opinions." *American Express Bank, FSB v. Johnson*, 945 A.2d 297, 299 (R.I. 2008) (internal quotations omitted).

[15] *See Pliva, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (holding that federal law preempts state laws imposing on generic drug manufacturers a duty to alter a drug's label).

"The motion justice must refrain from weighing the evidence or passing upon issues of credibility [as] . . . [u]ltimately, **the purpose of the summary judgment procedure is issue finding, not issue determination**." *DeMaio v. Ciccone*, 59 A.3d 125, 130 (R.I. 2013) (internal quotations omitted) (emphasis added). Further, "[i]t is clear from our precedent that '[o]rdinarily the determination of proximate cause . . . is a question of fact that should not be decided by summary judgment.'" *Belmore v. Petterutti*, 253 A.3d 864, 868 (R.I. 2021) (quoting *Splendorio v. Bilray Demolition Co., Inc.*, 682 A.2d 461, 467 (R.I. 1996)).

IV
Analysis
A
The State's Claims

The State argues that all four common law tort claims brought against Defendants (public nuisance, negligence, fraud, and unjust enrichment) are substantiated by Defendants' participation in two discrete courses of conduct: (i) false and misleading marketing of opioids and (ii) failure to identify, report, and stop suspicious orders of opioids. Expectedly, Defendants contest each of the four claims as well as the viability of the two theories they rest upon. Since these two theories form the evidentiary basis of the four named causes of action, it makes conceptual sense for the Court to analyze the viability of those theories first[16] before transitioning to the respective elements of each claim. The order in which the Court will assess Defendants' arguments for summary judgment, therefore, will proceed as follows: evidence of *fraudulent marketing* against each Defendant; evidence of *failure to identify and report suspicious opioid orders* against each Defendant; *causation issues* with respect to both legal theories against all Defendants; the State's *public nuisance* claim; the State's *common law fraud* claim; the State's *general negligence* claim;

[16] As, in this action, no viable legal theories *necessarily equal* no cause of action!

and the State's *unjust enrichment* claim. The Court will conclude by assessing Defendants' arguments in support of dismissing the State's request for *punitive damages* at the summary judgment stage.

However, before embarking on the State's two theories, the Court will provide a brief primer on *how*, exactly, each common law tort claim is legally and factually derivative of these two foundational theories. Much of this groundwork was laid by Presiding Justice Gibney, who in 2019 authored a substantial and didactic decision at the 12(b)(6) stage of the proceedings.[17]

(1) Public Nuisance

In *State v. Lead Industries Association, Inc.*, 951 A.2d 428 (R.I. 2008), our Supreme Court recognized the elements of a public nuisance as "(1) an unreasonable interference; (2) with a right common to the general public; (3) by a person or people with control over the instrumentality alleged to have created the nuisance when the damage occurred." *Lead Industries*, 951 A.2d at 446-47. Since this Court, by way of a decision of Presiding Justice Gibney on the Defendants' Motion to Dismiss the Complaint, has already recognized that "freedom from an overabundance of prescription opioids" is the **common public right** at issue, misleading marketing constitutes one of the two "**instrumentalit[ies]" controlled** by the Defendants which eventually will create the nuisance. *State v. Purdue Pharma L.P.*, No. PC-2018-4555, 2019 WL 3991963, at *9-10. (R.I. Super. Aug. 16, 2019) (emphasis added). The State alleges the **unreasonable interference** resulted from misleading marketing and the Defendants intentionally neglecting their statutorily mandated suspicious order monitoring requirements, knowing that doing so would lead to a flood of diverted opioids.

[17] *See State v. Purdue Pharma L.P.*, No. PC-2018-4555, 2019 WL 3991963 (R.I. Super. Ct. R.I. Aug. 16, 2019).

(2) Fraud

To establish a prima facie fraud claim, "the plaintiff must prove that the defendant made a false representation intending thereby to induce [the] plaintiff to rely thereon and that the plaintiff justifiably relied thereon to [their] damage." *McNulty v. Chip*, 116 A.3d 173, 182-83 (R.I. 2015) (citations omitted). In the present matter, the intentional "false representation[s]" are incidents of the Defendants generating and sending out knowingly misleading or fraudulent marketing material. *See Purdue Pharma L.P.*, 2019 WL 3991963, at *14.

(3) Negligence

To maintain a cause of action for **negligence**, "the plaintiff must establish four elements: (1) a legally cognizable duty owed by defendant to plaintiff; (2) breach of that duty; (3) that the conduct proximately caused the injury; and (4) actual loss or damage." *Rhode Island Resource Recovery Corp. v. Restivo Monacelli LLP*, 189 A.3d 539, 546 (R.I. 2018) (internal citations omitted). In her decision referenced above, Presiding Justice Gibney found for the State's theory that the manufacturers owed a duty to the State to "exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs," as well as a "duty to exercise reasonable care . . . not to cause foreseeable harm to others." *Purdue Pharma L.P.*, 2019 WL 3991963, at *15-16. She also recognized the State's theory that the Defendants owed statutory duties, including those set forth under G.L. 1956 §§ 21-28-3.04, 21-28-3.28, and 216-RICR-20-20-4.7. *Id.* at *15. However, in a subsequent motion for partial summary judgment brought by the State, Presiding Justice Gibney was quick to "shut the door" on any notion that, under Rhode Island law, a violation of the federal or state CSA statute could somehow constitute negligence *per se*: "Establishment and violation of a statutory duty does not resolve the duty element of a common law negligence claim[;] [and l]ikewise, statutory violations are not *de facto* evidence of a public

nuisance." *Purdue Pharma L.P.*, No. PC-2018-4555, May 5, 2020 Decision Denying State's Motion for Summary Judgment at *6 (Gibney, P.J.); *see also* Restatement (Second) Torts § 821B (clarifying that whether conduct is proscribed by a statute, ordinance, or administrative regulation is one circumstance, among others, that "may sustain a holding that an interference with a public right is unreasonable[.]").

(4) Unjust Enrichment

Under Rhode Island law, "unjust enrichment is not simply a remedy in contract and tort but can stand alone as a cause of action in its own right." *Dellagrotta v. Dellagrotta*, 873 A.2d 101, 113 (R.I. 2005) (citing *Toupin v. Laverdiere*, 729 A.2d 1286 (R.I. 1999)). To recover for a claim of unjust enrichment, a plaintiff must prove: "(1) that he or she conferred a benefit upon the party from whom relief is sought; (2) that the recipient appreciated the benefit; and (3) that the recipient accepted the benefit under such circumstances 'that it would be inequitable for [the recipient] to retain the benefit without paying the value thereof.'" *Dellagrotta*, 873 A.2d at 113 (quoting *Bouchard v. Price*, 694 A.2d 670, 673 (R.I. 1997)). In its Amended Complaint, the State alleged that Defendants committed conscious wrongdoings in furtherance of their deceptive and illegal campaigns to promote, distribute, and sell opioids in Rhode Island[18] and, further, that it "expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct."[19]

Accepting those allegations as true, Presiding Justice Gibney ruled in favor of the State's theory that it fronted the treatment and social costs of opioid-related disease derived from the

[18] *See* Am. Compl. ¶¶ 432-35.
[19] Am. Compl. ¶ 437.

conduct of Manufacturer Defendants. (i.e., their false and misleading marketing). *See Purdue Pharma L.P.*, 2019 WL 3991963, at *17-18.

B

Fraudulent Marketing Claims

(1) Teva USA

Both the State as well as Teva USA concede that *all* the State's claims rest in some form on allegations of false marketing and/or misleading promotion: "[b]y identifying false statements, aggregate harms from opioid marketing, and a link between the marketing of opioids and these harms, the State can establish a *prima facie* case on its consumer fraud, public nuisance, and negligence claims."[20] As such, Teva USA argues that *all* claims necessarily fail against it for want of evidence that: (a) Teva USA ever marketed any opioid other than *Fentora* (and that branded opioid was only ever promoted objectively) and (b) Teva USA exercised control over third-party organizations, individual influencers, and corresponding publications that it admittingly funded.[21] For its part, the State counters that it possesses competent evidence that Defendant: (i) marketed *Fentora*, and generic opioids more generally, in a misleading fashion and (ii) exercised "both direct and indirect control over [third-party, sponsored] messages[] sufficient to present a question of fact" for the trier.[22]

(a) Teva USA's Direct Marketing

Even assuming, *arguendo*, that Teva USA promoted no opioids until its October 2011 "affiliation" with Cephalon (which brought *Actiq* and *Fentora* into Teva USA's opioid portfolio),[23]

[20] Pl.'s Opp'n Mem. at 16-17; *see also* Def. Teva's Mem. at 19.
[21] *See* Def. Teva's Mem. at 19-21.
[22] Pl.'s Opp'n Mem. at 18.
[23] *See* Def. Teva's Mem. at 19.

it would still fail in its burden to establish that no issues of material fact exist. This shortfall pertains particularly to *Fentora*, a branded fentanyl product with a documented history of being marketed, prescribed, and, ultimately, consumed off-label.[24] Teva USA has not addressed its off-label promotion of branded *Fentora*.

For example, the State proffers a December 2011 "Special Report" on *Fentora* and *Actiq* risk evaluation and mitigation strategies.[25] This "Special Report" features studies on fentanyl tablet efficacy in chronic pain patients with and, more importantly, *without* cancer (a non-FDA-approved use of fentanyl by default).[26] Further, the title page of the report opens by noting that "[i]t is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain." *Id.* Teva USA, in contrast, strenuously argues that the "Special Report" does not constitute

[24] *See* Pl.'s Ex. 49, Gopu Tr. 212:20-213:23; Pl.'s Ex. 50, Rollman, Jeffrey Eric, et al. "*Assessment of the FDA Risk Evaluation and Mitigation Strategy for Transmucosal Immediate-Release Fentanyl Products*." *Jama* 321.7 (2019): 676-685 ("**Conclusions and Relevance**[.] In this review of FDA documents pertaining to the TIRF REMS, surveys of pharmacists, prescribers, and patients reflected generally high levels of knowledge regarding proper TIRF prescribing**, yet some survey items as well as claims-based analyses indicated substantial rates of inappropriate TIRF use.**") (emphasis added).

[25] *See* Pl.'s Ex. 15. The Court notes that while it is Cephalon, Inc.'s name (and affiliates) listed throughout the document, the December 2011 document publication date places it chronologically *after* Cephalon, Inc. was acquired by Teva Parent. At hearing on Defendants' Motion for Summary Judgment, counsel for Teva USA maintained that "Special Report" should be treated as a Cephalon publication, not Teva's. Resolution of this question, however, is clearly a factual issue, and it will be up to the trier to determine whether the "Special Report" "belongs" to Cephalon, Teva USA, or both entities.

[26] *See* Pl.'s Ex. 15, "*Breakthrough Pain in Cancer and Noncancer Patients: An Overview*," Teva_MDL_A_01208121. *HIGHLIGHTS OF PRESCRIBING INFORMATION*, U.S. Food & Drug Administration (last revised December, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021947s024s025lbl.pdf. ("FENTORA is an opioid agonist indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.").

marketing: "this [Special Report] … is not marketing[] [and] [o]n its face it is about '*Risk Evaluation and Mitigation,*' which is not a promotional message."[27]

Teva USA would see this Court judge a report by its cover. On summary judgment, it is not for this Court to so decide whether such "promotional material" constitutes marketing. Nor is it the Court's responsibility to determine whether such material crosses the line from "objective" to "misleading." The jury, rather, is uniquely suited to resolving such material disputes.

Evidence offered by the State appears to show that Teva USA promoted off-label use of fentanyl drugs through at least 2015. For example, at hearing on Defendants' Motion for Summary Judgment,[28] counsel for the State proffered a 2014 internal training document given to Teva USA's prescriber-facing sales team—PAIN PRODUCTS LEARNING SYSTEM: *LESSON 5. Misuse, Abuse, Addiction, Overdose, Diversion, and Serious Complications* (Lesson 5). Among the potentially misleading material offered by Lesson 5 includes claims that: (i) "in general, patients in pain do not become addicted to opioids[;]"[29] (ii) "clinicians often overestimate the risk of [opioid] addiction;[30] (iii) "'Relief-seeking' behavior" for cancer patients "generally ceases when an effective level of analgesia is achieved[;]"[31] and (iv) "opiophobia"[32] leads to the "undertreatment of patients who are suffering from pain but," according to unreferenced statistics, "does not seem

[27] Def. Teva's Reply Mem. at 6.
[28] For another example, *see* Pl.'s Ex. 30, "2013 FENTORA Marketing Mix Planning: *Preliminary Marketing Mix Recommendation,*" at TEVA_MDL_A_00755344 (outsourced marketing presentation delivered to Teva USA suggesting that TIRF-REMS was used as a Trojan horse to promote branded *Fentora* ("Brand may pursue a "piggyback" strategy to allow competitors to drive TIRF-REMS enrollments and subsequently *pull through* with FENTORA detailing.") (emphasis added)).
[29] *Id.* at 58 (TEVA_MDL_A_00405057).
[30] Citing to unnamed "surveys." *Id.*
[31] *Id.*
[32] I.e., The fear of prescribing opiate painkillers.

to be reducing misuse, abuse, and diversion."[33] Counsel for Teva USA objected to the inclusion of Lesson 5 on causation grounds, stressing that "talking points" provided by Teva USA management to its sales staff are *not necessarily* relayed by the sales staff to prescribers. While undeniably true, the Court finds that a reasonable jury could weigh causation and infer that a salesperson—trained to use certain allegedly misleading "talking points"—will ultimately go out and use those very talking points.

As another example, the State points to the Teva-sponsored 2015 *Pain Matters* program which, viewed in the light most favorable to the Plaintiff, could be characterized as both (i) glorifying the increased dissemination of opioids[34] and (ii) overstating the role of opioids as an integral and safe component of *many* pain treatment protocols.[35] Indeed, not only was the *Pain Matters* program featured on the Discovery Channel in 2015, but a Teva USA employee, at deposition, referred to it as "an unbranded *campaign* that healthcare professionals and doctors could access."[36] Teva USA is free to argue its interpretation before the jury—as it does in its Memoranda[37]—that this admission constitutes a mere "snippet" of the larger deposition transcript that does not even feature the word "promotion" (which, by Teva USA's at-times pharisaic logic, means it could *never* be confused for promotional marketing). However, it must indeed do so before the trier of fact, not before the Court on pretrial motion. *See Steinberg v. State*, 427 A.2d 338, 340 (R.I. 1981) ("The process of factfinding includes the drawing of inferences. Only when

[33] *Id.* at 57 (TEVA_MDL_A_00405056).
[34] In particular, the "BE THE VOICE THAT INSPIRES CHANGE" subheading appears notably egregious. Pl's Ex. 41, at 1/5.
[35] "Prescription opioid medications are an important part of a treatment plan for many people living with chronic pain . . ." *Id.* at 1/4.
[36] Pl.'s Ex. 40, Day Tr. 87:11-18 (emphasis added).
[37] *See* Def.'s Reply Mem. at 8.

facts that are undisputably or reliably found point to a single permissible inference can this process be treated as a matter of law.").

The Court finds that the State has countered with sufficient competent evidence placing the existence of post-October 2011 misleading marketing claims made by Teva USA in dispute.

(b) Teva USA's Control of Third-Party Entities

Teva USA argues that it did not exercise control over opioid-promoting third-party entities, Continuing Medical Education (CME) programs, or the content of publications that it funded.[38] Moreover, Teva USA highlights that such funding was expressly conditioned on third-party independence from their influence.[39] As such, Teva USA argues that it would be a clear violation of agency law principles to hold it liable for any misleading third-party statements. *See General Building Contractors Association, Inc. v. Pennsylvania*, 458 U.S. 375, 395 (1982) (funding alone is insufficient to make organization an agent of funder).[40]

As a preliminary matter, Teva USA concedes that it has provided "unrestricted" funding to certain third-party organizations and key opinion leaders.[41] Additionally, our Supreme Court tells us that the finding of an agency relationship's existence "is essentially a factual determination[.]" *American Underwriting Corp. v. Rhode Island Hospital Trust Co.*, 111 R.I. 415,

[38] Def. Teva's Mem. at 12.
[39] *See e.g.*, Def. Teva's Ex. 20, US Policy 205 — Independent Medical Education Grants, dated August 2013, TEVA_MDL_A_01090487 ("Independent medical education activities must remain independent from Teva and no Teva personnel or Teva agent may control any aspect of an independent education activity."); Def.'s Ex. 21, US Policy 101 — US Specialty Medicines Compliance Policy Manual dated 8/24/15, TEVA_MDL_A_01090318 at 390.
[40] *See also Rosati v. Kuzman*, 660 A.2d 263, 265 (R.I. 1995) ("The essence of an agency relationship is the principal's right to control the work of the agent, whose actions must primarily benefit the principal.") (citation omitted).
[41] *See* Def. Teva's Mem. at 20 ("And while Teva USA provided funding to certain organizations . . ."); *id.* at 21. *See also* Def. Teva's Reply Mem. at n.10 (admitting that the *Pain Matters* program could constitute a third-party publication or statement attributable to Teva USA).

420, 303 A.2d 121, 124 (1973). Therefore, while Defendants' counsel may wish the Court to decide whether *the State has presented enough evidence to show that Teva USA*[42] *had and/or exerted "control" over these third-party entities*—such consideration is both (a) premature and (b) simply not the Court's role. *See Toledo v. Van Waters & Rogers, Inc.*, 92 F. Supp. 2d 44, 53 (D.R.I. 2000) (finding that genuine issue of material fact as to whether shipper was agent of distributor of chemicals *precluded* summary judgment in truck driver's action against distributor to recover for injuries sustained at distributor's place of business).

For now, the Court abstains in considering whether the weight of available evidence could sustain an agency relationship. Instead, the Court finds a genuine issue of material fact over whether the State's proffered evidence (e.g., the *Pain Matters* program, Dr. Perri's testimony on "soft control,"[43] etc.) demonstrates the requisite control necessary to establish an agency relationship between Teva USA and any of its affiliated third-party entities. *See Toledo*, 92 F. Supp. 2d at 55 ("Again, control is the linchpin of an agency relationship.") (citation omitted). Indeed, it is not some sort of novel allegation that a supposedly "independent," front-facing entity could double as the nonprofit promoter for manufacturers of a dangerous product.[44] The Court finds no reason to take this determination away from the capable hands of the trier of fact.

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[42] As opposed to, say, Cephalon, Inc. or the Actavis Generic Entities.

[43] Pl.'s Ex. 32, Perri Tr. at 207:8-18 ("Well, I think my report discusses this, and, you know, it's a subtle point, but you may or may not control the actual content, but you absolutely get to decide who you fund and who you don't fund, and that is a subtle form of control over the content, as well as when you do or don't use a speaker that may or may not be more sympathetic or less sympathetic to your product. So you get to pick who you hire, and you get to pick - - to decide what programs you fund. So, to a degree, they do have a level of control.").

[44] As one example, *see* "The [Foundation for a Smokefree World]'s 2019 tax return filed on 15 May 2020 shows that more than two years after its creation, the Foundation remains solely funded by Philip Morris International." https://tobaccotactics.org/wiki/foundation-for-a-smoke-free-world (last edited, Oct. 6, 2021).

Furthermore, an argument can be presented that even if formal agency does not apply, the Defendants, through their strategic funding, engaged in tortious conduct vis-à-vis enabling third parties to disseminate false and misleading information. Such false and misleading information, in turn, could be found to have ultimately contributed to the inordinate increase in opioid prescriptions and supply in the community.

(2) Cephalon

Similar to Teva USA, Cephalon argues that *all* claims necessarily fail against it for want of evidence that: (a) Cephalon ever marketed *Actiq* or *Fentora* outside of the then-prevailing medical consensus toward opioids for pain management (and certainly never *falsely*);[45] (b) Cephalon exercised requisite control over third-party organizations, individual influencers, and corresponding publications that it (admittingly) funded;[46] and (c) that the stringent prescribing requirements designed to facilitate awareness of the hazards of transmucosal immediate release fentanyl (TIRF) medications were not followed or understood by prescribers and patients (more specifically, the FDA-mandated[47] TIRF Risk Evaluation and Mitigation Strategies Program (TIRF-REMS)).[48]

The State counters that it possesses competent evidence that Defendant Cephalon: (i) has a well-documented history of falsely marketing *Actiq* and *Fentora*, both against its FDA-approved indications and running counter to prevailing medical trends (which Cephalon was attempting to influence at all times material);[49] (ii) that Cephalon exercised "both direct and indirect control over

[45] Def. Cephalon's Mem. at 5-7, 11.
[46] *Id.* at 13.
[47] *See* 21 U.S.C. § 355-1 (governing REMS programs).
[48] Def. Cephalon's Mem. at 10.
[49] *See* Pl.'s Opp'n Mem. at 4-8.

[third-party, sponsored] messages[] sufficient to present a question of fact" for the jury;[50] and (iii) that TIRF-REMS and other similarly situated programs functioned as a "Trojan Horse" (as Cephalon intended) through which to further promote both branded and generic opioids as a class.[51]

The Court will deal with the (i) "prevailing medical consensus" marketing and (iii) TIRF-REMS sub-issues first before considering the more conceptual matter of (ii) third-party entity control. In doing so, the Court will determine whether a disputed issue of material fact exists as to the State's claim of false marketing against Cephalon that can, if proven at trial, undergird the State's common law tort claims.

(a) Cephalon's Direct Marketing

(i) *Cephalon's Marketing in Light of the Scientific Consensus*

In each of their respective motions for summary judgment, the Defendant Manufacturers insist that they could not have engaged in false or misleading marketing based upon *when* they came to the branded opioid marketing "game." For example, Teva USA argues that they came *too late* to the game to incur liability: "[o]nly evidence from post-October 2011 is potentially relevant to Teva USA's marketing[.]"[52] The Actavis Entities, by contrast, argue that their status as manufacturers of generics means they *never actually participated* in the game.[53] And finally, Cephalon makes the novel argument that it came to the game *too early* (or, alternatively, at *just*

[50] *Id.* at 18.
[51] *Id.* at 18-19.
[52] Def. Teva's Mem. at 2. *See also id.* at 1 ("Nor was it associated with any corporation that had such products until October 2011—well after the wrongful conduct heyday alleged by the State would have occurred.").
[53] *See* Def. Actavis's Mem. at 5 ("Because a prescriber has no control over which medicine of any Actavis Generic Entity is substituted for the more expensive brand-name medicine at the pharmacy, Actavis Generic Entities do not market the safety or efficacy of their medicines to prescribers.").

the right time) to have misled prescribers and patients: "Clearly, Cephalon cannot be held responsible for statements that were consistent at the time with the prevailing view of opioids taught in medical school and espoused by . . . medical professionals across the country[.]"[54]

Such "Goldilocks" argument aside, Cephalon highlights that their post-2001 marketing of *Actiq* and *Fentora* comported not only with the consensus view of the medical and pain treatment establishment at the time, but also with the (then-) view of the State's own expert, Dr. Ballantyne.[55] Further, Cephalon's post-2001 marketing also aligned with the official view of the State of Rhode Island itself![56] Finally, Cephalon argues that, under Rhode Island law, the determination of a statement's "falsity" can only be properly accessed when viewed in full context. In other words, when viewed in light of the scientific consensus at the time. *See Cruz v. DaimlerChrysler Motors Corp.*, 66 A.3d 446, 453 (R.I. 2013) (affirming grant of summary judgment because no evidence that statements about vehicle "were false ***when they were made***") (emphasis added).[57]

To begin, the Court makes two observations which will anchor its analysis. First, Cephalon contends that the medical consensus during the period it engaged in fentanyl marketing (2001 to October 2011) was so in chorus regarding high-strength opioid use for breakthrough pain in non-cancer patients that it obviates any possible inference of wrongdoing. This argument strikes the Court as self-serving and circular. Whether Cephalon's opioid marketing was "true" in accordance with the prevailing medical consensus for over a decade is a determination of *reasonableness*. In

[54] Def. Cephalon's Mem. at 19.
[55] *See* Def. Cephalon's Mem. at 6; Def. Cephalon's Ex. 4, Ballantyne Tr. at 76:15-19, 73:4-20, 93:6-19, 105:10-13, 111:10-2, 112:5-22, 113:9-18, 114:1-13, 242:19-243:11, 252:12-254:17.
[56] *See* G.L. 1956 § 5-37.4-3*; see also* 216-R.I.C.R.-20-20-4.4(D).
[57] *See also Swerdlick v. Koch*, 721 A.2d 849, 862 (R.I. 1998) ("Upon examination of these statements **in the context in which they were made**, we agree with the trial justice's conclusion that plaintiffs failed to prove that defendant published false or fictitious facts as to the appearance of ongoing business activities at plaintiffs' residence.") (emphasis added).

tort, determination of reasonableness traditionally belongs to the trier of fact. Hence, the Court is already wary of granting summary judgment on Cephalon's very context-specific labelling of its own marketing as "reasonable." *See Barreiro Lopez v. Universal Insurance Co.*, 98 F. Supp. 3d 349, 357 (D.P.R. 2015) ("In negligence cases, determinations of foreseeability and of whether a defendant acted reasonably fall within the province of the jury. Hence, a court should be cautious in using the summary judgment device to dispose of such cases.") (internal quotation omitted). Second, Cephalon's characterization of the nationwide medical and pain management consensus during the 2000s paints them as a passive—almost reluctant—participant in an otherwise inexorable process. Considering the evidentiary record, such a characterization belies the extent to which Cephalon *participated* in shaping that consensus through its targeted marketing, sponsored CMEs, sales representatives, and third-party publications.

Ultimately, the State has proffered sufficient competent evidence to place the "falsity" of Cephalon's branded opioid marketing from 2001 to 2011 in dispute. Such evidence includes:

> (1) testimony from a Cephalon/Teva salesperson (who started in the Boston region in 2005, later expanding to Rhode Island) that "improve[d] functionality" and "improved quality of life" was part of the company's approved sales messages;[58]
>
> (2) testimony from another Cephalon sales representative discussing "proper titration strategies" with a "top Fentora prescrib[ing] [physician]";[59]
>
> (3) a 2004 approved patient brochure from Cephalon entitled "**Breakthrough Pain: Do you *still* have pain?**" which facially appears to (i) downplay the risk of addiction while (ii) increasing patient agency to ask their physician for additional opioids. It also contains these bullet points: "Asking for pain medicine is NOT a sign of weakness . . . Concerns about addiction should NOT prevent proper pain management." (Emphasis in original.)[60]

[58] Pl.'s Ex. 18, Collins Tr. 91:4-20.
[59] Pl.'s Ex. 19, McMahon Tr. 164:16-165:9.
[60] Pl.'s Ex. 20, TEVA_MDL_A_01575978.

Tying the above "misleading" statements to a changing opioid landscape, State's experts Drs. Courtwright and Ballantyne will testify "that addiction risks had been established *prior to the efforts of [Cephalon] to change the prescribing consensus*."[61] For example, Dr. Courtwright will testify that "[t]he . . . efforts of manufacturers . . . to promote prescription opioids in [chronic nonmalignant pain] occurred before, during, **and after 2000-2003,** years in which the prescription-opioid addiction epidemic attracted widespread publicity and official notice, **and during which scientists and physicians produced further evidence of the dangers of exposing opioid-naïve patients to prescription painkillers**.").[62] And while it is not the Court's job to decide whether such promotional material and strategies crosses the ever-shrinking line from "objective" to "misleading/false," it reiterates that the trier of fact is uniquely suited to resolving such material disputes.

Further, the State presents overwhelming evidence showing that Cephalon promoted off-label use of its fentanyl drugs right out of the proverbial gate. This evidence includes (but is by no means limited to): a 2002 *Actiq* Marketing Plan disclosing efforts to "position" *Actiq* as a "valid, first-line treatment option for [breakthrough] and episodic pain[.]";[63] a 2007 *Fentora* Marketing Plan detailing the same,[64] and a 2004 FDA letter summarizing warnings the agency had recently given to Cephalon regarding off-label promotion of *Actiq*: "[The Division of Drug Marketing, Advertising, and Communications (DDMAC)] expressed significant concerns about the increasing

[61] Pl.'s Opp'n Mem. at 17 (emphasis added).
[62] Pl.'s Ex. 47, Summary of Expert Opinions of Dr. David T. Courtwright (emphasis added); *see also* Pl.'s Ex. 48, Expert Report of Jane C. Ballantyne, at 17-31.
[63] Pl.'s Ex. 03, 2002 Actiq Marketing Plan, TEVA_MDL_A_00454816, 03248942. Tellingly, the second page of this 2002 "plan" cites "increased scrutiny of opioid prescribing" involving "abuse of OxyContin" as an existential concern to Actiq's bottom line, despite the fact that "OxyContin is not a direct competitor of ACTIQ[.]" *Id.* at 03248906.
[64] Pl.'s Ex. 13, 2007 Marketing Plan, TEVA_MDL_A_00360982.

off-label use of Actiq . . . DDMAC reminded Cephalon off-label promotion is illegal and, especially with a drug with a risk profile like Actiq, raises significant public health concerns. As discussed . . . DDMAC expressed concerns that Cephalon's training and detailing practices appear to encourage the off-label use of Actiq rather than discourage it."). Pl.'s Ex. 9, TEVA_MDL_A01584980.

For its part, Cephalon responds to this trove of evidence by correctly noting that off-label promotion, while subject to federal enforcement actions, "is not inherently 'false or misleading.'"[65] Of course, the operative word here is "inherently," as the federal criminal charges at issue in *Caronia* and similar cases[66] have no legal bearing on the State's common law tort claims. Because Cephalon has not *satisfactorily* addressed its off-label promotion of branded *Actiq* and *Fentora*, none of the State's causes of action based on false and misleading marketing may be disposed of completely.

The Court credits the State's analogy in its opposition memoranda that "the change in medical acceptance of opioids was not a simple on-off switch[.]"[67] Indeed, it stands in contradiction with the nature of science itself to claim that the medical community's consensus on long-term opioid use was so uniform throughout the decade of the 2000s that strong countervailing currents were never apparent to Cephalon. This is particularly the case when: (1) Cephalon's own internal marketing reports from the first half of the decade warned of "increased scrutiny of opioid

[65] Def. Cephalon's Mem. at 12, quoting *United States v. Caronia*, 703 F.3d 149, 165 (2d Cir. 2012).
[66] *See also Ind./Ky./Ohio Regional Council of Carpenters Welfare Fund v. Cephalon, Inc.*, No. 13-7167, 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014) ("*Carpenters*") ("[W]hile Cephalon's actions may well constitute improper off-label promotion under the FDCA and its regulations, . . . it does not follow that the promotion is fraudulent.").
[67] Pl.'s Opp'n Mem. at 18.

prescribing,"[68] and (2) competent evidence is proffered to suggest that Cephalon's marketing team viewed itself as an active participant in shaping the national conversation on high-strength opioid use for non-cancer pain.[69] Regardless, the State has satisfied its burden on the clearly disputed issue of whether Cephalon's marketing was "false" within the larger medical and pain management context of the early-to-mid 2000s. As such, the issue is not appropriate for summary judgment.

ii. TIRF-REMS - Misleading Marketing

While Cephalon couches its discussion of the procedural and consent requirements for prescribing/filling branded fentanyl (i.e., TIRF-REMS) within its expansive *legal causation* section, the Court sees fit to touch briefly upon the topic in its 'false marketing' analysis. More specifically, the Court takes note of the December 2011 "Special Report"[70] by Cephalon on *Fentora* and *Actiq* risk evaluation and mitigation strategies.[71] This "Report" features studies on fentanyl tablet efficacy in chronic pain patients *without* cancer (a non-FDA-approved use of fentanyl by default[72]). Importantly, the "Report" appears to walk something of a tightrope between touting the effectiveness of the TIRF-REMS program for limiting prescribing/dispensing to "appropriate patient[s]" on one end,[73] and promoting studies seeking to increase the pool of "appropriate patients" on the other (e.g., the study entitled *Breakthrough Pain in Cancer and Noncancer Patients: An Overview* by Dr. Arvind Narayana).[74] The natural inquiry that follows is: "appropriate patients" according to whom? Certainly not the FDA which, at all times material, has

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[68] Pl.'s Ex. 03, 2002 Actiq Marketing Plan, TEVA_MDL_A_03248906.
[69] *See generally* Pl.'s Ex. 13, 2007 Marketing Plan, TEVA_MDL_A_00360982.
[70] *See* n.25 *supra* for extended discussion on proper attribution of the "Special Report."
[71] *See* Pl.'s Ex. 15 at 1 ("Supported by Cephalon, Inc. Frazer, Pennsylvania").
[72] *See* Pl.'s Ex. 15, "*Breakthrough Pain in Cancer and Noncancer Patients: An Overview*," TEVA_MDL_A_01208121.
[73] Pl.'s Ex. 15, at TEVA_MDL_A_01208125 ("Prescribing and dispensing *Fentora* and ACTIQ **only to appropriate patients**[.]") (emphasis added).
[74] *See id.* at TEVA_MDL_A_01208121.

only indicated *Fentora* and *Actiq* for "the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[75]

While Cephalon highlights the TIRF-REMS program to negate the causation prong of the State's false marketing theory, the Cephalon-branded "Special Report," purportedly created to raise awareness of TIRF-REMS, may constitute misleading marketing *in its own right*. The State has therefore proffered competent evidence to create a factual question as to whether the nominally prophylactic TIRF-REMS program doubled as false and/or misleading marketing. As it stands, the "Special Report" certainly appears to suggest the propriety of non-FDA-approved, off-label use of *Actiq* and *Fentora*, and is meant for dissemination to a prescriber (i.e., not internal) audience.[76]

(b) Cephalon's Control of Third-Party Entities

Like Teva USA, Cephalon argues that it did not exercise control sufficient to create an agency relationship over the various third-party entities, CME programs, "key opinion leader[s]," and the resulting content of any publications that it funded.[77] Also like Teva USA, Cephalon's funding of any third-party entities or CMEs was expressly conditioned on independence from Cephalon as provided for in the contracts at issue.[78] As such, Cephalon argues that it would be a

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[75] *HIGHLIGHTS OF PRESCRIBING INFORMATION*, U.S. Food & Drug Administration (last revised December 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021947s024s025lbl.pdf.

[76] While Defendant Teva USA, in their memoranda, objects to the "Special Report['s]" classification as "marketing material" (*see* Def. Teva's Reply Mem. at 6), the determination of what constitutes "marketing material" is a factual determination appropriate for the trier, not for the Court on summary judgment.

[77] Def. Cephalon's Mem. at 22.

[78] *See* Def. Cephalon's Ex. 20, Independent Educational Program Grant Agreement with AAPM, TEVA_MDL_A_01169010 (Nov. 28, 2006) (Section 8(b) provides that "neither Cephalon nor its agents shall control the content of the Program"); Ex. 21, Independent Educational Program Grant Agreement with MediCom Worldwide, Inc., TEVA_MDL_A_00502973 (Nov. 6, 2008) (Section 7(b) provides that "neither Cephalon nor its agents shall control the content of the Program").

clear violation of basic agency law principles to hold it liable for misleading third-party statements. *See General Building Contractors Association, Inc,* 458 U.S. at 395 (funding alone is insufficient to make organization an agent of funder); *Rosati v. Kuzman,* 660 A.2d 263, 265 (R.I. 1995).[79]

For their part, the State argues that the various "independence clauses" in Cephalon's block grant contracts "describe what perhaps should have happened, not what did happen."[80] Therefore, the question for the Court is: *has the State presented competent evidence showing that Cephalon*[81] *potentially had and/or exerted control of these third-party entities*?[82]

For now, the Court answers this sub-question in the **affirmative**. Among the competent circumstantial and testimonial evidence, the State proffers on Cephalon's alleged third-party control includes:

(1) Testimony describing Cephalon's couching of its CME-sponsoring efforts under its commercial/marketing division.;[83]

(2) Testimony from the same (presumably Cephalon sales rep) affirming that Cephalon was using CMEs to influence prescribers: "Q: They were using CMEs to influence prescribers, right? . . . A: That was industry standard at the time.";[84]

(3) A 2004 *Actiq* internal planning presentation relaying that CME programs were part of a broader effort to "[t]arget[] and [c]ommunicat[e] to [p]rescribers.";[85]

(4) Deposition testimony by Dr. Russell Portenoy, a "key opinion leader" and Cephalon witness that, in his experience, opioid manufacturers funded third-party groups that amplified their marketing messages.;[86]

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[79] ("The essence of an agency relationship is the principal's right to control the work of the agent, whose actions must primarily benefit the principal.") (citation omitted).
[80] Pl.'s Opp'n Mem. at 9.
[81] As opposed to, say, Teva USA or the Actavis Generic Entities.
[82] *See Toledo v. Van Waters & Rogers, Inc.*, 92 F. Supp. 2d 44, 55 (D.R.I. 2000) ("Again, control is the linchpin of an agency relationship.") (citation omitted).
[83] Pl.'s Ex 33, Williams Tr. 200:16-19, 227:22-229:6 ("So, again, during this timeframe in 2003, the CME function was part of the commercial function.").
[84] *Id.* at 200:12-24.
[85] Pl.'s Ex. 34, TEVA_MDL_A_03252903, at 26-28.
[86] Pl.'s Ex. 31, Portenoy, Tr. 151:22-153:24 ("Q: And based on your personal knowledge and experience, you would agree that opioid manufacturers pay honorary, fees and grants in a way that elevates specific messages that comport with their preferred messages correct? . . . A: Yes, that's

(5) The State's proffered marketing expert's (Dr. Perri) testimony that program sponsors (such as Cephalon) exert a "subtle form of control" over third-party created content vis-à-vis their "elective" funding decisions.[87]

While the above evidence might not ultimately be found to rise to the level of an agency relationship,[88] the third-party grant contracts at issue, despite Cephalon's protest to the contrary, were not written in a vacuum free from all traces of influence and control. Further, the "existence and scope of an agency relationship is essentially a factual determination[,]" and, thus, an issue for the jury. *Calenda v. Allstate Insurance Co.*, 518 A.2d 624, 628 (R.I. 1986) (internal quotations omitted).

(3) Actavis Entities

As manufacturers of *only* generic medicines—separate from manufacturers of *branded* opioids such as Teva USA and Cephalon—the Actavis Entities maintain that they "did not engage in any marketing at all, much less any false marketing."[89]

The Actavis Entities maintain that since there is (1) no evidence that they promoted the safety or efficacy of their generic medicines anywhere (let alone Rhode Island) and (2) no expert for the State capable of giving any competent opinion about the marketing of any Actavis Entity, misleading or otherwise, then summary judgment is appropriate on all claims. Moreover, the

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my . . . I agree with that. . . Q: Based on your personal knowledge and experience with opioid manufacturers, would you agree that research grants by opioid manufacturers to researchers working in academic centers after a drug is approved for marketing, almost always align with the manufacturers' interest in demonstrating the benefits of the drugs they manufacture with the intent - - with the intention of publishing results that could yield hire [*sic*] sales in the future? . . . A: Yes, I agree with that.").

[87] Pl.'s Ex. 32, Perri Tr. 207:2-18 ("So you get to pick who you hire, and you get to pick - - to decide what programs you fund. So, to a degree, they do have a level of control.").

[88] Rhode Island courts have held that there are three elements to an agency relationship: (1) the principal must manifest that the agent will act for him; (2) the agent must accept the undertaking; and (3) the parties must agree that the principal will be in control of the undertaking. *See Lawrence v. Anheuser-Busch, Inc.*, 523 A.2d 864, 867 (R.I. 1987).

[89] Def. Actavis' Mem. at 2.

Actavis Entities maintain that the State's attempts to conflate "the act of marketing [the availability of generic medicine] with false marketing" should not enable them to skirt summary judgment.[90] For its part, the State directly counters that "contrary to representations [by] the . . . Actavis [Entities], they did engage in promotional activities for their generic opioids."[91]

The questions for the Court to decide are as follows: (1) Does the State offer competent evidence of *any* marketing of generic opioids attributable to the Actavis Entities beyond simply announcing the availability of a generic option?; and (2) could that marketing, viewed in the light most charitable to the State, reasonably be viewed as misleading or fraudulent so as to create a dispute of material facts?

(a) Opioid Marketing by Actavis Entities

In order to demonstrate the State's scarce evidence of *any* opioid marketing attributable to the Actavis Entities, the Actavis Entities point to Dr. Kolodny's deposition in which he "reference[s] a product availability announcement . . . that he contends is misleading because of an image of someone finishing a race."[92] Conversely, the State frames this availability announcement as an "advertisement," and further describes the "runner" (a silhouette composed entirely of ticker tape-style Actavis slogans) as "suggest[ing] functional improvement by . . . raising his or her arms while breaking finishing tape as if winning a running race."[93] If this poorly

[90] *Id.* at 6.
[91] Pl.'s Opp'n Mem. at 12.
[92] Def. Actavis' Mem. at 12. *See also* Def. Actavis' Ex. 16, Kolodny Tr. 122:25-123:18.
[93] Pl.'s Mem. at 12; *see also* Pl.'s Ex. 42, ALLERGEN_MDL_00480175. The remainder of the front-page of the announcement that does not consist of FDA-mandated "Important Safety Information" reads as follows: "Actavis is proud to launch Oxymorphone Hydrochloride Extended-Release Tablets, CII 7.5 mg and 15 mg strengths, immediately available. It is AB rated to Opana . . . ER (oxymorphone hydrochloride) Extended-Release tablets and is indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time. At Actavis, we are working to meet the demand for high quality lower-cost alternatives to brand name pharmaceuticals." *Id.*

illustrated graphic constituted the State's sole evidence of Actavis Entities' opioid marketing, then the State's characterization of the advertisement would likely not sustain their burden of proving "a disputed issue of material fact" (i.e., false marketing) by "competent evidence." *American Express Bank, FSB*, 945 A.2d at 299. However, that is not the situation.

Plaintiff's exhibits 42 through 46, which will be discussed in greater detail below, constitute the State's proffered evidence of false or misleading advertising on the part of the Actavis Entities. To be sure, not all these materials relate to increasing the sales of generic opioids, much less doing so in a false or misleading manner (e.g., Plaintiff's Exhibit 45 highlights Actavis' zero carbon footprint vis-à-vis its geothermal energy manufacturing facility).[94] However, within this corpus exists enough front- and back-end marketing material, dealing with increasing the volume of Actavis Entities' generic opioid sales, to take us to question two of the Court's analysis.

(b) False and Misleading Marketing

Cognizant that the judicial officer's role in summary judgment is issue spotting, the Court will not—and indeed *cannot*—weigh the State's evidence to decide whether it crosses the threshold from puffery to falsity. That task is uniquely left to the trier of fact. However, having examined the evidence in the light most favorable to the State, the Court concludes that there are issues of material fact regarding the falsity of the Actavis Entities' marketing endeavors.

For example, in addition to the above-discussed "runner" advertisement (which *could* be said to trivialize the medical risks of extended opioid use), the State has produced an e-mail from the Senior Manager of Products & Communication for Actavis. This e-mail touts that, in addition

[94] "Actavis has the world's only pharmaceutical manufacturing facility completely powered by geothermal energy." Pl.'s Ex. 45. At hearing on Defendants' Motion for Summary Judgment, counsel for the State admitted that he had to "fall on his sword" and concede that the geothermal energy flyer should never have made it in the State's evidence pack.

to Actavis' online and phone awareness campaign to raise "promotional awareness of" their generic opioids, they "are continuing to search for unique opportunities to highlight and promote our Oxymorphone!"[95] The e-mail itself begins: "Actavis is currently running a two-part Oxymorphone marketing program with McKesson Drug Company." A fair inference is that this specific Actavis Entity was affirmatively engaged in a marketing endeavor, rather than any sort of solo effort on the part of Distributor McKesson Drug Company (as Actavis's Memoranda claims).

Further, while Director of Generic Marketing, Jinping McCormick, stated in his videotaped deposition that the Actavis Entities were primarily engaged in "awareness marketing" for generic opioids, material issues of fact exist regarding what he described as Actavis' "*more than so-called typical*" multi-channel marketing effort for oxymorphone.[96] Finally, an extended e-mail exchange (over the "oxymorphone sell sheet") between John Hansen of McKesson and McCormick (1) could be read as McCormick trying to elide mandatory safety information for the sake of spatial economy;[97] and (2) could also be read as promoting higher strength opioid prescriptions that, for reasons unclear, were once discontinued but are now back on the market.[98] While the Actavis Entities may argue that this "oxymorphone sell sheet" "belong[ed]" to distributor McKesson,[99]

[95] Pl.'s Ex. 43, September 27, 2011 e-mail from David Myers.
[96] Pl.'s Ex. 44, McCormick Tr. 74:11-75:2 (emphasis added).
[97] "John, . . . For the one-page fax, [limiting it to one page] will be a challenge as the safety information is mandatory. If the information is developed by McKesson, i.e. no Actavis Logo, but only order information (McKesson ECONO#), would the requirement be different?" Pl.'s Ex. 46, at Acquired_Actavis_00379711.
[98] "Here are some suggested talking points to pharmacists: . . . Doctors are starting to write these strengths again. [W]e think it might be helpful for you to have a bottle on the shelf[.]" Pl.'s Ex. 46, at Acquired_Actavis_00379712.
[99] *See* Def. Cephalon's Reply Mem. at n.7 ("The State also cites an email exchange referencing an 'oxymorphone sell sheet[.]' . . . That is an advertisement *belonging* to distributor McKesson, not any Actavis Generic Entity.").

their own Director of Generic Marketing was intimately involved in both its creation and eventual distribution.

The State additionally points to a February 2010 letter from the FDA to then Chief Executive Officer at Actavis US, Doug Boothe. The letter, which is summarized in Dr. Perri's Expert Report, details the FDA's concerns over Actavis' "omission or minimization of serious risks[] [and] broadening of indication or failure to state the full indication" of certain prescriptions, including *Fentora*.[100]

The Court concedes that both the quantity and quality of marketing evidence the State possesses on the Actavis Entities appears thin, especially compared with the "trove" of promotional evidence the State has amassed against Teva USA. However, construing the above evidence in the light most favorable to the State, this Court finds that genuine issues of material fact remain to be decided regarding whether the Actavis Entities engaged in misleading or negligent marketing activities for their generic opioids. At trial, the Actavis Entities will have ample latitude to call attention to the State's lack of Actavis-specific marketing material and correspondence. It will then be up to the jury to determine whether this lacuna of material proves fatal to the State's misleading marketing claim against the Actavis Entities.

(c) Failure to Disclose & Preemption

Neither the Actavis Entities nor the State dispute that federal law preempts state-law tort claims against generic pharmaceutical manufacturers based on their alleged failure to add to, alter, or augment their FDA-approved warning labels. *See* Pl.'s Opp'n at 28 ("[T]he State does not contend th[e] [Actavis Entities] were required to amend generic product labels in a manner

[100] Pl.'s Ex. 55, Perri Report at 130-31, citing to 2/18/2010 FDA Warning Letter to Mr. Boothe, ACTAVIS0799203. *See also* ACTAVIS0238310.

inconsistent with the branded equivalents."); *see also Pliva, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (holding that federal law preempts state laws imposing on generic drug manufacturers a duty to alter a drug's label). Rather, as the Actavis Defendants themselves note, all of "the State's claims are . . . based . . . on allegations of false or misleading *marketing*," not *labelling* (broadly defined).[101] *See also* Pl.'s Opp'n at 28 ("Rather, each Teva Defendant affirmatively made false statements concerning their opioids; no federal or state law required them to do so."). The Ohio Multidistrict Litigation (MDL) rejected similar attempts by defendant manufacturers to narrowly construe plaintiffs' arguments as seeking a simple label change:

> "The Court decline[s] to read Plaintiffs' allegations so narrowly. The Court f[inds] that the state law claims were 'not premised upon inappropriate labeling or a fraud on the FDA, **but rather fraudulent marketing in the promotion and sale of their opioids**' (Summit R & R at 50); Plaintiffs were not seeking to enforce the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), but their allegations were 'of the type that would traditionally be brought as state law claims [prior to the enactment of the FDCA]' . . . and the argument that state law imposed a duty to monitor the sale of opioids with due care was not inherently 'inconsistent with the purposes of the FDCA, and thus not preempted.'" *In re National Prescription Opiate Litigation*, No. 1:17 MD 2804, 2019 WL 4178591, at *2 (N.D. Ohio Sept. 3, 2019) (some internal citations omitted) (emphasis added).

As allegedly fraudulent marketing and promotional activities go well beyond the protection of any federal statute or case law (e.g., the federal "sameness" requirement), and as the Court has already ruled that issues of material fact remain in dispute concerning the Actavis Entities' allegedly fraudulent marketing endeavors, summary judgment is unwarranted on this issue.

[101] Def. Actavis' Mem. at 11; *see e.g.*, 21 U.S.C. § 355(j)(2)(A) ("Abbreviated New Drug Applications").

C

Failure to Identify and Report Suspicious Orders

(1) Introduction

To the State's second theory of liability—that Defendants are legally responsible for harms caused by their failure to identify, report, and stop suspicious orders shipped to Rhode Island—all Defendants counter with the following. First, each complied with overlapping CSA and DEA regulations in the form of a statutorily mandated SOM system and, regardless, the CSA only requires that DEA-registered manufacturers report suspicious orders placed by ***distributors***, not pharmacies.[102] Second, the State cannot identify a single shipment by any Defendants into Rhode Island that was purportedly "suspicious." And third, since "suspicious orders" is a statutorily defined term[103] requiring both context and data-driven analysis, the inability of the State's experts to flag even one "suspicious order" associated with any of the Defendants closes this avenue of liability.[104] Any additional arguments unique to a particular defendant or defendant group will be discussed below.

As a housekeeping matter, this Court previously determined that both the federal and state CSA simply do not contain a "no shipping" duty in their "text . . . or . . . associated regulations." May 5, 2020 Decision Denying State's Motion for Summary Judgment at 7 (Gibney, P.J.).[105]

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[102] *See* 21 C.F.R. § 1301.74(b).

[103] *See* 21 C.F.R. § 1301.74(b) ("The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.").

[104] *See* Def. Teva's Mem. at 23-26.

[105] "Moreover, the State has not proved the existence of the alleged 'no shipping' duty such that it is entitled to summary judgment as a matter of law. The State claims that the federal and state CSAs create an explicit duty for the Defendants to refrain from shipping suspicious orders until due diligence ensures that they will not be diverted to illegal channels. This requirement does not appear in the text of the CSAs or the associated regulations." *Id.* at 6-7.

Additionally, in its Combined Opposition Memorandum of Law, the State neglects to provide the Court with any examples of alleged SOM-system failures.[106] Rather, in the cross-referencing style that characterizes the innerworkings of these summary/partial summary judgment motions, the State points the Court back to its Motion for Partial Summary Judgment for competent circumstantial evidence of Defendants'[107] failure to identify and report suspicious orders. The Court will now discuss the evidence the State attributed to each Defendant.

(2) Teva USA

In its memoranda, the State details the following examples of shipping and/or SOM-malfeasance connected to Teva USA:

(1) A September 2012 letter and report on Teva Pharmaceuticals' SOM system from third party consultant, Cegedim Relationship Management, stating that: "Teva [USA] has a *rudimentary* SOM system."[108] This letter/report also stated that "Teva [USA] has never identified a suspicious order and thus no orders have ever been reported to the DEA," and that Teva's system, "SORDS" (short for Suspicious Orders) was not "from a statistical standpoint . . . sufficiently sensitive to customer ordering practices to result in any meaningful analysis of customer order practices." *Id.*

(2) This same report noted that: (i) investigation of "pended" orders is: "not well documented";[109] (ii) there are fewer than ten "pended" orders to review each week;[110] review is conducted primarily by customer support personnel;[111] and prior "holds" placed on accounts are "not clearly visible to staff when conducting a[] [later] investigation regarding a 'pended' order[.]" The report recommended that "Teva [USA] should develop and use sources of information regarding what their wholesaler/distributor customers sell further 'downstream[]' [and] . . . incorporate[] [that practice] into their SOM program."[112]

(3) Formerly of AmerisourceBergen, Kevin Kreutzer was hired by Teva USA in January 2013 as SOM Manager. He was fired after just three months for, according to his testimony,

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[106] *See generally* Pl.'s Opp'n Mem. at 20-24.
[107] *See* Pl.'s Mem. for Partial Summ. J. at 6-8. The State withdrew its Motion for Partial Summary Judgment but asked the Court to incorporate its filings for the motion into the record as filings for the Defendants' Motions for Summary Judgment.
[108] Pl.'s Mem. for Partial Summ. J., Ex. K, Cegedim Letter at TEVA_MDL_A_01060005 (emphasis added).
[109] *Id.* at TEVA_MDL_A_01060010.
[110] *Id.*
[111] *Id.*
[112] *Id.* at TEVA_MDL_A_01060011.

directly contacting a downstream customer regarding a "pended" order when protocol dictated that he had to go through "customer service."[113]

(4) Teva USA only approved its first written standard operating procedures (SOPs) for its SOM system in 2014. These SOPs largely maintained the existing system of involving customer service in every aspect of an SOM investigation.[114]

(5) When Teva USA revised SOP-8277 entitled "Suspicious Order Monitoring — DEA Order Holds," it did not curtail the involvement of its Sales Department. For example, sec. 6.2.5 provides that "[i]f a customer does not satisfactorily respond to a Customer Services inquiry [regarding the reason for an increase/change in ordering pattern], the **appropriate Sales Associate** will be contacted and instructed to obtain an explanation from the customer." [115]

(6) Teva USA's non-party parent company audited Teva USA's DEA compliance department in 2015 and prepared a critical report which, among other findings, stated that: (i) of 10,000 orders of Schedule II products, 95 percent were automatically released;[116] (ii) Teva USA's DEA Department was in "noncompliance with DEA requirements" and at "High Risk" for DEA regulatory action; and (iii) Teva USA's SOM program was likewise at "Moderate Risk" for such action.[117]

(7) Between 2013 and 2018, Teva USA reported twenty-eight orders from eleven pharmacies, only five of which involved Schedule II Opioids.[118] These collected reports do appear to indicate that Teva USA, at least on occasion, shipped Schedule II opioids *directly* to pharmacies. Conversely, Teva USA contends the low number of DEA reports generated by it demonstrates that it very rarely shipped opioids directly to pharmacies. Regardless, it does raise a rather important question of fact.

Since the Court at this stage can neither weigh evidence nor make credibility determinations, it cannot ignore the material facts currently in dispute over whether Teva USA failed to maintain effective controls against diversion. Moreover, assuming Teva USA's then-existing SOM system facially comported with FDA-required diversion controls,[119] that alone is not sufficient to grant summary judgment. The State's causes of action against Teva USA are all

[113] Pl.'s Mem. for Partial Summ. J., Ex. L, Kreutzer Tr. 270:1-24.
[114] Pl.'s Mem. for Partial Summ. J., Ex. N, Section 6.
[115] *See* Pl.'s Mem. for Partial Summ. J., Ex. O (emphasis added).
[116] With the remaining 5 percent placed on hold to be manually checked.
[117] Pl.'s Mem. for Partial Summ. J., Ex. P, TEVA_MDL_A_02475564. Further, the report flagged that suspicious orders were cleared through the SOM program based on the decisions of a single person (Tomkiewicz). *Id.*
[118] Pl.'s Mem. for Partial Summ. J., Ex. Q, Collected Reports.
[119] 21 U.S.C. § 823(a); 21 C.F.R. § 1301.71(a); 21 C.F.R. § 1301.74(b).

common law tort claims (i.e., public nuisance, negligence, unjust enrichment, and fraud). Just as Rhode Island does not recognize negligence *per se*,[120] compliance with the statute(s) does not provide a per se defense against a negligence claim. Rather, viewed in the light most favorable to the non-moving party, the State has proffered ample evidence that Teva USA's SOM controls may have been calibrated in favor of closing the sale (at best),[121] and engineered to fail its purported purpose (at worst).

The Court takes note that the State's evidence of Teva USA's SOMs due diligence failures aligns with that submitted by plaintiffs to the Ohio MDL Court. That Court, after determining plaintiffs had offered competent evidence that manufacturers' SOMs/due diligence procedures lacked "key components . . . necessary to maintain effective controls against diversion[,]" reasoned that "a jury could reasonably conclude the manufacturers, and each of them, failed to maintain effective controls against diversion." *In re National Prescription Opiate Litigation*, 2019 WL 4178591, at *3.[122] Similarly, the State here has brought forward evidence in the form of third-party reports, parent company reports, ex-employee/executive accounts, internal documents, and quantitative data to suggest that Teva USA's SOMs/due diligence protocols lacked key components necessary to prevent diversion.[123] For now, the State's second theory of liability as to Teva USA survives summary judgment.

[120] *See Salcone v. Bottomley*, 85 R.I. 264, 267, 129 A.2d 635, 637 (1957) ("[T]he violation of a statute or an ordinance is not negligence *per se* but is to be used by the trier of fact[] merely as an aid in determining that issue on consideration of all the evidence.") (internal citations omitted).
[121] By positioning the sales department as the first and, in some instances, *only* line of defense against diversion. *See* Pl.'s Mem. for Partial Summ. J., Ex. O.
[122] This Court notes that the Ohio MDL iudge is applying a stricter summary judgment standard (i.e., "a reasonable jury") than that used by Rhode Island courts.
[123] *See generally* Pl.'s Mem. for Partial Summ. J., Exs. K-Q.

(3) Cephalon

In addition to the arguments in the introduction to this section above, Cephalon asserts as a defense that it never sold quantities of *Actiq* and *Fentora* outside of production quotas set by the federal government and, as such, it cannot be held liable "for ***lawfully*** selling ***lawful*** products in ***lawful*** amounts[.]"[124] The Court finds that the State has proffered enough evidence to undercut Cephalon's '*within DEA-approved quotas*' defense.[125] Vice President of Oncology Marketing at Teva, Fred Vitale, testified that manufacturers requested a quota from the DEA *in line with* prior sales data that they received.[126] From there, Teva's former Senior Director of DEA Compliance and Supply Chain Integrity,[127] Dennis Ferrell, testified that the DEA's quota allocations were partly based on two-year monthly sales averages directly linked to manufacturer's promotional efforts and, more importantly, that the DEA generally acceded to manufacturers' quota demands.[128] As an example of this process, Noramco Inc. (a pharmaceutical arm of Johnson & Johnson), in a letter to the DEA, requested a higher manufacturing quota cap: "The current Oxycodone manufacturing quota will be consumed by **mid July 2009**. Additional quota is requested as soon as possible to ensure continuous supply of oxycodone to our customers."[129]

Turning to the State's proffered evidence of alleged shipping and/or SOM-malfeasance against Cephalon, the Court notes that (nearly) all examples derive from the 250-page Expert Report of Ruth Carter.[130] In her report, Ms. Carter painstakingly details the diversion system

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[124] Def. Cephalon's Mem. at 25 (emphasis in original).
[125] I.e., that Cephalon never sold quantities of *Actiq* and *Fentora* outside of production quotas set by the federal government and, as such, Cephalon cannot be held liable for lawfully selling lawful products in lawful amounts. *See* Def. Cephalon's Mem. at 25.
[126] *See* Pl.'s Ex. 52, Vitale Tr. 1106-1107, 1143:18-1144:6.
[127] And, before that, Senior Director of Security Operations.
[128] Pl.'s Ex. 53, Ferrell Tr. 261:7-262:13; 289:11-23.
[129] Pl.'s Ex. 54, NORAMCO-PA_000785205 (emphasis in original).
[130] *See* Ruth Carter Declaration and Report, Ex. 22 (June 1, 2021).

deficiencies for each defendant manufacturer, including Cephalon. As to Cephalon, Ms. Carter concludes that:

> "Cephalon's suspicious order monitoring system was insufficient to maintain effective controls against diversion. Cephalon **utilized an 'excessive orders' system operated** by the Logistics Manager which failed to: evaluate orders in real time based upon the definition of a suspicious order (e.g., unusual size, frequency, or pattern); **consider available data regarding its direct customers** or its customers' customers ([i.e., chargeback data]) . . .[;] **utilize trend analysis and modify its [SOM] system based on changing diversion trends**; **conduct due diligence** (know your customer questionnaires, site visits of customers and customers' customers); or **stop shipment of suspicious orders**."[131]

Additionally, Ms. Carter notes that even in those rare instances where a suspicious order was flagged, Cephalon simply "did not conduct the appropriate due diligence to determine if the order was legitimate" before shipping.[132] Taken together, Ms. Carter concludes that Cephalon's SOMs were "mechanical and cursory," "totally ineffective[,]" and representative of their nationwide corporate policy, "including in Rhode Island."[133]

Admittingly, the Court would prefer additional primary sources from Cephalon itself to fully decide whether the State has introduced evidence sufficient to survive summary judgment on their Cephalon-specific SOM-malfeasance theory.[134] However, the Court also observes that the excerpts of Ms. Carter's report dealing with pre-2011 Cephalon are cogent, chronologically organized, and buttressed by references to internal Cephalon material.[135] As to pre-acquisition instances of Cephalon's SOM failure per 21 U.S.C. § 823(a), 21 C.F.R. § 1301.71(a), and 21 C.F.R.

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[131] *Id.* at 73 (emphasis added).
[132] *Id.*
[133] *Id.* at 74.
[134] For comparison, in terms of evidencing Teva USA's SOM deficiencies, the State proffers Pl.'s Mem. for Partial Summ. J., Exs. K-Q. Additionally, the State's recently submitted "Supplemental Memorandum . . . In Opposition Cephalon [*sic*], Inc's Motion for Summary Judgment" (filed Jan. 18, 2022) deals exclusively with the State's false marketing theory against Cephalon and makes no mention of their alleged SOM's failures.
[135] The legitimacy of which is not in dispute by the parties.

§ 1301.74(b), the State (as the nonmoving party) has satisfied their "affirmative duty to demonstrate . . . a genuine issue of fact" on this particular legal theory. *McGovern v. Bank of America*, N.A., 91 A.3d 853, 858 (R.I. 2014).

(4) Actavis Entities

In their Motion for Partial Summary Judgment, the State alleges the following examples of shipping and/or SOM-malfeasance on the part of the Actavis Entities:

- The 2000-2012 rudimentary Actavis SOM system was severely limited in that it *only* flagged orders that were disproportionally larger in *size*, not in order frequency or order pattern.[136] As such, an order would only appear suspicious in Actavis' system if it was: (i) 25 percent over the customer's rolling average, and (ii) met the 25 percent threshold increase for 40 percent of abused type drugs. *Id.*[137]

- Former Senior Manager of Actavis's Customer Service Department, Nancy Baran, recalled just one order between 2008 and 2017 that was ever deemed to be suspicious and subsequently reported to the DEA. Further, the system did not incorporate any downstream customer information available to Actavis, nor did it differentiate among NDC codes for drugs with a higher risk of diversion.[138]

- A 2009 e-mail from the same Nancy Baran to former Vice President-Chief Legal Officer, John LaRocca, upon the latter's request for information stating that: "I believe our [order monitoring] process is *not* current and there is *significant* room for improvement."[139] This same e-mail also disclosed that the SOMs "process as it stands today dates back to November of 2000 when the Suspicious Order Report was developed[,]" and that "[a]s far as I can tell, there have been little or no changes to the report since that time."[140]

- Actavis did not investigate suspicious orders at the pharmacy level.[141]

- On September 12, 2012, five Actavis employees were informed by DEA personnel (at their Arlington, Virginia office) that its products were being distributed in Florida in quantities and circumstances highly suggestive of diversion. Actavis rejected the DEA's

[136] Pl.'s Mem. for Partial Summ. J. at 9.
[137] Under this system, it's conceivable that a customer, whose monthly usage is 3,000 units, could order 2,999 units *daily*. *Id.*
[138] Pl.'s Mem. for Partial Summ. J., Ex. U, Baran Tr. 303:7-304:10.
[139] *See* Aug. 08, 2009 e-mail from Nancy Baran to John LaRocca, Re: "Suspicious Orders," ALLERGAN_MDL_02081243 (emphasis added).
[140] *Id.*
[141] Pl.'s Mem. for Partial Summ. J., Ex. X.

recommendation at the time to voluntarily reduce their oxycodone manufacturing quota. *Id.* [142]

For their part, the Actavis Entities counter that: (i) this opposition is devoid of *any* specific evidence about (or instances of) diversion monitoring failures;[143] (ii) there is no explicit connection made to the State of Rhode Island;[144] (iii) the State continues to obfuscate the distinction between the eleven separate Actavis Generic entities; and (iv) the 2012 Virginia DEA meeting featured only employees for Actavis Elizabeth, LLC and, moreover, was a collaborative meeting ("[t]erms used in the DEA memorandum—'educational,' 'informative,' 'suggested,' . . . 'partner"—are language consistent with a company doing its job") featuring data infrastructure not yet available to Actavis.[145] ("Moreover, with respect to identifying diversion, the memorandum describes how the DEA had identified problematic ***pharmacy*** behaviors using ARCOS data, which was not available to registrants like Actavis Elizabeth.") (emphasis in original).[146]

There is some merit to the Actavis Entities' refrain that the State's practice of indiscriminately pooling eleven Actavis entities together must come to an end. *See Doe v. Gelineau*, 732 A.2d 43, 44 (R.I. 1999) ("[T]he stakes are too high for [Rhode Island] courts [to] regularly . . . disregard the separate legal status of corporations."); *Miller v. Dixon Industries Corp.*, 513 A.2d 597, 604 (R.I. 1986) ("The mere fact that there exists a parent-subsidiary relationship between the two corporations is insufficient reason to impose liability on the parent for the torts of the subsidiary.").[147] However, the trial provides the forum for the State to get specific as to

[142] *Id.* Ex. ZF, US-DEA-00000001 and Ex. ZG, Clarke, at 104.
[143] Def. Actavis' Reply Mem. at 10.
[144] *Id.* at 8.
[145] *See id.* at 11.
[146] *Id.*
[147] Unlike its sister courts in New York, Massachusetts, California, and Illinois, Rhode Island case law does not explicitly mandate that the trial court must desegregate and evaluate the evidence

which of the eleven Actavis Entities it intends to bring evidence against. With all that said, the Court cannot ignore the material facts currently in dispute regarding the Actavis Entities' SOM system and its overall efficacy (or lack thereof). Simple logic dictates that if—as the State contends—Actavis' SOM systems then in place were deliberately calibrated to never flag suspicious orders, then *composite* evidence of increasingly higher numbers of opioids shipped could provide *competent* evidence that suspicious orders were indeed sent out.[148]

Ultimately, while the State's SOMs' evidence against the Actavis Entities is notably thinner than that amassed against Teva USA, the Court determines that there are issues of material fact in dispute. As discussed above with Teva USA, this reasoning tracks with that of the Ohio MDL Court.[149] Similarly, the State has brought forward evidence in the form of multiple Actavis employees who have testified that the Actavis Entities' SOMs/contingency systems lacked key components necessary to manage diversion.[150]

At trial, counsel for the Actavis Entities are free to grill the State's experts as to their inability and/or unwillingness to identify a single "suspicious order" that was shipped to Rhode Island. Indeed, in drafting these dispositive motions, counsel for manufacturers appear to have listed every possible permutation of what the State's experts *have not proven*.[151] At the summary

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separately to each named corporate defendant at the summary judgment stage. *See* Def. Actavis' Reply Mem. at 4-5.

[148] *See e.g.*, Pl.'s Mem. for Partial Summ. J., Ex. U, Baran Tr. 303:7-304:10 (Former Senior Manager of Actavis's Customer Service Department, Nancy Baran, recalled just one order between 2008 and 2017 that was ever deemed to be suspicious and reported to the DEA).

[149] This Court once again notes that the Ohio MDL judge is applying a stricter summary judgment standard (i.e., "a reasonable jury") than that used by state courts in Rhode Island.

[150] *See* Pl.'s Mem. for Partial Summ. J., Ex. U, Baran Tr. at 303:7-304:10; Pl.'s Mem. for Partial Summ. J., Ex. X; Pl.'s Mem. for Partial Summ. J. Ex. ZF, US-DEA-00000001; Ex. ZG, Clarke Tr. 104; *see generally* Pl.'s Mem. for Partial Summ. J. at 8-10.

[151] Reading the manufacturers' motions can, at times, indeed feel like some sort of dispositive "mad libs" where the bank of permissible terms and words to choose from includes: "failure," "single," "prove," "lack of," "Rhode Island," etc.

judgment stage, however, all that matters is what facts the State's evidence and experts can put in dispute. For now, it is enough that the State has pointed to competent evidence that suggests there was a complete failure by the Actavis Entities to maintain effective controls against diversion.

D

Causation

(1) Introduction

Each of the Defendants[152] strenuously contends that the State cannot, under either theory of liability (i.e., false/misleading marketing or SOM-diversion failures), show how Rhode Island citizens were either '*but-for*' or proximately harmed by the Defendants. In other words, even if the State can show how an *increase* in prescription opioids under either of these two theories *caused* harm to Rhode Island, the State cannot present any evidence that any of the Defendants caused the harm. More specifically, the Defendants repeatedly argued at every turn that the State failed to identify any Rhode Island prescriber who was misled by their marketing efforts or any suspicious order that reached Rhode Island.

First, and more basic, causation is indeed a required element of every claim advanced by the state: "**Causation** is a basic requirement in any **public nuisance action**; such a requirement is consistent with the **law of torts generally.**" *Lead Industries Association*, 951 A.2d at 450 (emphasis added); *Dextraze v. Bernard*, 253 A.3d 411, 416 (R.I. 2021) (applying the proximate causation principle to **negligence**). "To establish **a prima facie damages claim in a fraud** case, the plaintiff must prove that the defendant made a false representation **intending thereby to induce plaintiff to rely thereon** . . . " *Travers v. Spidell*, 682 A.2d 471, 472 (R.I. 1996) (emphasis

[152] Since the arguments and counter arguments of the parties and the analysis by the Court are similar for all Defendants, the Court in this section of the Decision will treat them collectively but where appropriate may refer to particular evidence that pertains to a particular defendant.

added) (internal citations omitted). *See also Cote v. Aiello*, 148 A.3d 537, 550 (R.I. 2006) (applying the causation principle to **unjust enrichment** vis-à-vis inducement of reliance.)

Second, it is axiomatic that causation, under Rhode Island law, "is typically a question of fact for the jury" (*Purdue Pharma L.P.*, 2019 WL 3991963, at *10.[153] Defendants correctly note, however, that *causation* is not simply a perfunctory, one-way turnstile at the pretrial motions stage. Indeed, there have been multiple occasions where our Supreme Court has ruled it proper to grant summary judgment for want of cause (in particular, *proximate* cause), either because causation was wholly lacking as a matter of law and evidence, or because causation had simply become too attenuated under the circumstances. *See Russian v. Life-Cap Tire Services, Inc.*, 608 A.2d 1145, 1147-48 (R.I. 1992) (trial judge's granting of summary judgment proper because Plaintiff failed to present evidence identifying actions or omissions of retailer or lessor as proximate cause of his fall, or evidence from which reasonable inference of proximate cause could be drawn).

It is against that legal backdrop that the Court begins its analysis of the Defendants' *causation* arguments; namely, that: (1) the State cannot show a causal link between any prescription of Defendants' medicine to their allegedly false or misleading marketing; (2) the State cannot show that any unreported "suspicious" orders placed with any Defendant reached Rhode Island; and (3) even if the State could identify such an order, it cannot prove that it caused any legal harm.

[153] *See also Hill v. State*, 121 R.I. 353, 355, 398 A.2d 1130, 1131 (1979) ("When reasonable minds could infer that causation exists, the question [of causation] ***must*** be submitted to the jury.") (emphasis added).

(2) Causation - False or Misleading Marketing

Defendants' argument that the State cannot show how an increase in opioids resulting from false and misleading marketing *actually* or *proximately caused* harm to Rhode Islanders fails on precedential, conceptual, and (already established) evidentiary grounds.

Put mechanically, the Court has already determined that the State has proffered sufficient evidence to create a genuine issue of material fact that all Defendants *did* market their opioids and such marketing was false, misleading, and/or in violation of FDA indications. Therefore, a material issue of fact exists which, according to our laws, "must be submitted to the jury" on the issue of causation. *Hill*, 121 R.I. at 355, 398 A.2d at 1131. This could be the end of the analysis right here. However, the Court wishes to further clarify the effect that its finding of competent evidence of false/misleading marketing has on the causation analysis *writ large*.

The marketing by Defendants did not target the proverbial "middle-men" distributors and, as such, must have targeted parties further downstream, such as pharmacies, doctors, and even patients. As a result, Defendants can no longer attempt to insulate themselves from conceptual liability by pointing to its static place on the far-left end of the opioids crisis flowchart (i.e., to the left of distributors). At least not when competent evidence exists to suggest that they actively tried to influence the events on the far right, patient's-side of the same flowchart.

As to how this equation relates to the remaining common law torts counts against Defendants, take *negligence* and *public nuisance* for instance, our Supreme Court tells us that the "proper inquiry regarding legal cause [in a negligence or public nuisance action] involves an assessment of *foreseeability*, in which [one] ask[s] whether the injury is of a type that a reasonable person would see as a likely result of [its] conduct." *Lead Industries Association, Inc.*, 951 A.2d at 451 (emphasis added) (citations omitted).

Viewing the evidence and all reasonable inferences in favor of the State, Defendants' off label marketing of their products to parties further downstream could foreseeably lead to the type of injury (i.e., the opioid crisis in Rhode Island) that a reasonable person would see as the likely result. It is true, as Defendants note, that legal "[l]iability cannot be predicated on a prior and remote cause which merely furnishes the condition or occasion for an injury resulting from an intervening unrelated and efficient cause[.]" *Clements v. Tashjoin*, 92 R.I. 308, 314, 168 A.2d 472, 475 (1961) (citations omitted). However, competent evidence of false or misleading marketing to downstream parties on the part of *any* opioid manufacturer functionally erases the spatial and temporal proximity gap between the opioid drug maker and the tragic end effect. It is certainly not as though the manufacturers simply made these opioids and left them to collect dust on a warehouse shelf. Regardless, these "evaluative applications of legal standards [(i.e., foreseeability)] to the facts" belong in the purview of the jury and, as such, summary judgment is not appropriate on the issue of whether Defendants' allegedly false marketing was the legal or proximate cause of any opioid-related harm. "Not only ordinary fact questions, but also evaluative applications of legal standards (such as the concept of legal foreseeability) to the facts are properly jury questions. In any case where there might be reasonable difference of opinion as to evaluative determinations . . . the question is one for the jury." *Marshall v. Perez Arzuaga,* 828 F.2d 845, 849 (1st Cir. 1987) (internal quotations omitted).

It is not hyperbolic to note that the Summary Judgment Memoranda of the Defendants stretch on for pages listing (seemingly) every possible permutation of what the State's experts do *not* attempt to show regarding false/misleading marketing and causation: "[A] meaningful data-driven analysis of the specific false or misleading statements (if any) made by Teva USA, whether they were viewed by Rhode Island prescribers, and, if so, whether they were misled by them into

writing a harmful prescription."[154] The Court again takes this opportunity to remind the parties that there is an important distinction between what Defendants *feel* the State's experts should show regarding causation, and what the experts actually *need* to show to survive summary judgment. Competent evidence pointing to "the existence of a disputed issue of material fact" (*causation* itself constituting an issue of fact) is traditionally left for the trier to decide." *Johnson*, 945 A.2d at 299 (citations omitted).

In satisfying its burden on summary judgment, the State has proffered aggregate evidence in the form of expert testimony that (i) marketing claims by the Defendants were misleading; (ii) misleading marketing claims led to increased sales of opioids; and (iii) these increased sales of opioids resulted in numerous public harms (i.e., increases in overdoses, health spending, maternal opioid dependency, etc.) that are foreseeable consequences of the original false marketing claims.

More specifically, Dr. Ballantyne will discharge part (i) of this causal chain. "Teva [(Defendants)] marketed opioids as improving function and quality of life despite a lack of evidence supporting this claim. These claims helped tip the scales in the risk-benefit calculus, but they lacked a scientific basis."[155] Also, "[t]he practice by Teva of promoting off-label use of fentanyl products is, in my opinion, its most egregious misbehavior."[156]

Dr. Perri will shoulder the load from there regarding part (ii): "The aggressive marketing strategies and tactics Defendants used **were effective at gaining market share and durably expanded the overall market for opioids which was confirmed by [the manufacturer's] own**

[154] Def. Teva's Mem. at 28-29.
[155] Pl.'s Ex. 48, Ballantyne Report at 46.
[156] *Id.* at 54. *See also* Pl.'s Ex. 55, Perri Report at 110 ("For example, one Actiq sales training included communication of a 'PCS Sales Force Mission Statement' . . . While this was likely intended to be motivational for the pain care sales team, it frames how Cephalon viewed its marketing of Actiq. Further it supports the proposition of an 'aggressive' approach to Actiq sales.").

marketing metrics. **This led to a dramatic rise in utilization of opioids** in the United States, including in the state of Rhode Island." Pl.'s Ex. 55, Perri Report at 178 (emphasis added). *See also id.* at 111 ("Defendants designed their marketing strategy for opioids to turn drug features into drug benefits, create desirable positioning in Customers' minds, **and stimulate prescriptions for opioids**. These activities are consistent with marketing principles, but not with a concern for patient safety or industry standards.") (emphasis added).[157]

Drs. Cutler and Young will escort the baton across the metaphorical finish line that is part (iii). Dr. Cutler states that "[t]he growth in illicit opioid mortality after 2010 was not uniform across all areas . . . the highest rates of illicit opioid mortality are in eastern states, **with the highest rates in Ohio, West Virginia, Pennsylvania, and New England.**" He further states that "my analysis establishes that it was the widespread availability of prescription opioids, not other economic and social trends, that caused the large nationwide increases in opioid-related mortality and significant increases in other opioid-related harms[.]"[158] Dr. Young presents a graph showing percent of treatment admissions for pregnant women with reported opioid use in Rhode Island peaking between 2010 and 2014.[159] Based on this aggregate expert evidence, the State has shown the "existence of a disputed issue of material fact" that increased sales of prescription opioids, brought in part by Teva USA's false/misleading marketing, which proximately caused harm to the State of Rhode Island. *Estate of Giuliano v. Giuliano*, 949 A.2d 386, 391 (R.I. 2008).

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[157] *See also* Pl.'s Ex. 48, Ballantyne Report at 53 ("[Cephalon and Teva] have also promoted the idea of early pain intervention on the grounds that persistent pain causes medical harm, an idea that has some support in the case of acute pain, but no support in the case of chronic pain. In fact, in the case of opioids, encouraging early dosing can lead to more frequent use, greater tolerance, and higher doses.").

[158] *See* Pl.'s Ex 56, Cutler Report at 36 and 95 (emphasis added).

[159] *See also* Pl.'s Ex. 57, Young Report at 6.

At hearing, Defendants' counsel was adamant that, for the purposes of establishing causation, so-called "aggregate proof" was tantamount to "no proof." However, in rejecting a similar, hyper-specific (i.e., *'Plaintiffs have failed to identify a single shipment'*) causation challenge by manufacturer defendants, the Ohio MDL Court likewise determined that aggregate proof is sufficient to present triable issues of fact to the jury:

> "[T]he Manufacturers assert Plaintiffs have failed to identify a single order they should not have shipped. . . . **For reasons similar to those [dealing with misleading marketing] above, the Court finds Plaintiffs' aggregate proof of causation sufficient to overcome summary judgment**. In particular, given the massive increases in the supply of prescription opioids into the Track One Counties, combined with evidence that suggests there was a complete failure by Defendants to maintain effective controls against diversion, a factfinder could reasonably infer that these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs." *In re: National Prescription Opiate Litigation*, No. 1:17-md-2804, 2019 WL 4178617, at *3 (N.D. Ohio Sept. 3, 2019) (emphasis added).

A similar conclusion was reached by the Superior Court of California for Orange County utilizing the reports of an overlapping expert in the present matter.[160]

> "As discussed, **the [State] [is] not required to provide individualized proof** and Defendant [Manufactures] have not shown that the case study methodology and marketing principles utilized by Dr. Perri . . . are improper or not generally accepted in his field of expertise. Dr. Perri's report and opinions that Defendants' marketing and promotions resulted in a change in thinking about opioids, expanded the opioid markets and increased their use are explained and supported by numerous authorities and evidence, including depositions, Defendants' marketing plans, sales training manuals . . . [.] Additionally, although Dr. Perri states that he assumed Defendants' marketing was untrue, false, misleading and/or deceptive, he also explains that this assumption is consistent with case study methodology, other expert reports in the [Ohio] MDL litigation, and FDA warning letters. . . . **Dr. Perri's opinions and the circumstantial evidence may lead to the reasonable inference that Defendants' marketing and promotions are a substantial factor [in creating a public nuisance in the form of the opioid crisis]**." *People vs. Purdue*, Case. No. 30-2014-00725287, Court's Final Rulings on Motions for Summary Judgment/Adjudication (Cal. Sup. Ct., March 12, 2021), at https://news.sccgov.org/sites/g/files/exjcpb956/files/documents/2021.03.12%20Opioids%20Order%20re%20MSJs.pdf (emphasis added).

[160] Defendants, during oral argument, were quick to remind the Court that after a bench trial the California court found for the defendants. Just as quickly, the Court retorted that the same judge denied summary judgment.

Indeed, one ripple in the causation analysis the California Superior Court highlights is the ability of Defendant Manufacturers' own marketing plans/reports to buttress the (at times) attenuated chain of expert-attested cause-and-effect. The State provides just such a piece of evidence in their Opposition Memorandum: "Moreover, . . . Defendants' own documents acknowledge the causal impact of marketing on increased prescriptions, the root of the public nuisance. For example, a 2012 review of Fentora marketing found that promotional tactics were responsible for 30% of sales."[161]

Ultimately, if the trier of fact finds the State's multi-expert, baton handoff-based approach so disjointed such that it cannot conclude that Defendants' allegedly false marketing proximately caused harm to the State, then it will decide accordingly. For now, this Court agrees with both the logic and conclusion reached by its sister courts (i.e., the District Court for the Northern District of Ohio and the California Superior Court) in their own pretrial rulings: an expert-attested increase in sales resulting from false marketing could evidence a causal link to increased opioid harms in a state.

(3) Causation — TIRF-REMS

As a final argument against finding evidence for legal causation, Defendants Cephalon and Teva USA point to the "stringent requirements" of the TIRF-REMS program[162] as proof that "no Rhode Island prescriber could have been misled about the safety risks or efficacy of Actiq or

[161] Pl.'s Opp'n Mem. at 23; *see also* Pl.'s Ex. 30, TEVA_MDL_A_00755335.

[162] I.e., FDA-approved test, signed Patient Agreement, and written certification that prescriber "counseled [the] patient . . . about the ***risks, benefits, and appropriate use of the TIRF medicine***." Def. Cephalon's Ex. 13, TIRF REMS Access Program Patient-Prescriber Agreement Form (emphasis added).

Fentora[.]"[163] However, such a sweeping claim is neutralized by competent evidence that Cephalon's business model not only relied on improper off-label prescribing/consumption of fentanyl but, indeed, formed nearly the entire ethos for the marketing and sales structure of the two drugs:

> "Defendant Cephalon undertook its off-label promotional practices using a variety of techniques. It trained its sales force to disregard the restrictions of the FDA-approved label, and to promote the drugs for off-label uses. . . . **Cephalon also structured its sales quota and bonuses in such a way that sales representatives could reach their sales goals only if they promoted and sold the drugs for off-label uses**. . . . Defendant Cephalon employed sales representatives and retained medical professionals to speak to doctors about off-label uses of Actiq[.]"[164]

As such, Cephalon should not be allowed to use TIRF-REMS as intervening or superseding cover when evidence exists to suggest that Cephalon was involved in influencing prescribers/patients to disregard (and/or circumvent) the program's safeguards. Put more succinctly, it is *foreseeable* that patients and prescribers would ignore TIRF-REMS if that was the intended end effect of Cephalon's marketing. *See Walsh v. Israel Couture Post, No. 2274 V.F.W.*, 542 A.2d 1094 (R.I. 1988) (recognizing that an intervening act of negligence will not insulate an original tortfeasor if it appears that such intervening act is a natural and probable consequence of the initial tortfeasor's act).[165]

In addition, contrary to Cephalon and Teva USA's contention that TIRF-REMS provided a failsafe *notice* mechanism on both the dangers and limited indications of TIRF medicines, competent evidence suggests that these FDA-mandated warnings routinely failed to make their

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[163] Def. Cephalon's Mem. at 32 ("This [compliance with/awareness of TIRF-REMS] alone breaks the chain of causation.").
[164] Pl.'s Ex. 07, U.S. Department of Justice Press Release, *Pharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing*, *2 (Sept. 29, 2008).
[165] *See also Almeida v. Town of North Providence*, 468 A.2d 915, 917 (R.I. 1983) ("If, however, the intervening cause was not reasonably foreseeable, the intervening or secondary act becomes the sole proximate cause of the plaintiff's injuries.").

way into the hands of patients. For example, a 2003 Internal Audit of Cephalon's risk management program for *Actiq* revealed that Cephalon "is not in compliance with [its risk management] commitments" for the drug and, further, "over 75% of [new *Actiq*] patients interviewed" did not receive a TIRF-REMS-mandated "Welcome Kit."[166] This same Internal Audit also noted that there did not appear to be "any interventions to correct the violation."[167] Ultimately, even an 'impregnable' safe provides little security if one neglects to shut the door.

(4) Causation - Suspicious Order Monitoring Failures

For reasons similar to those stated above, the Court finds the State's aggregate proof of causation on its SOM failures theory sufficient to survive summary judgment. In coming to the same conclusion under the Ohio law, Judge Polster of the MDL reasoned that "given the massive increases in the supply of prescription opioids into the [Ohio counties participating in the MDL], ***combined with*** evidence that suggests there was a complete failure by Defendants to maintain effective controls against diversion, a factfinder could reasonably infer that these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs." *In re: National Prescription Opiate Litigation*, 2019 WL 4178617, at *3 (emphasis added). This Court has already determined that the second part of the MDL Court's causal 'equation' ("evidence that suggests . . . a complete failure by Defendants to maintain effective . . . diversion [controls] . . .") has been met by the State in the instant matter. As such, what remains is competent evidence of a "massive increase[] in the supply of prescription opioids" into Rhode Island. Such evidence is provided by Dr. Perri: "This [process of marketing opioids has] led to a dramatic rise in utilization of opioids in the United States, **including in the state of Rhode Island**."[168] Additionally, Dr. Cutler presents

[166] Internal Audit of Actiq Risk Management Program, 2nd Qtr 2003, TEVA_MDL_A_0115958.
[167] *Id.*
[168] *See* Pl.'s Ex. 55, Perri Report at 178 (emphasis added).

a chart showing a fourfold rise in shipments of prescription opioids in the U.S. between the "peak" crisis years of 2008-2012.[169]

Given the evidence of a massive increase in the supply of prescription opioids into Rhode Island (and New England more generally[170]), combined with already-established competent evidence suggesting complete and/or negligent failure by Defendants in their SOM protocols, a reasonable person could view Rhode Island's opioid/fentanyl crisis as a "foreseeable" consequence of their alleged conduct. *See Lead Industries Association Inc.*, 951 A.2d at 451. The State has therefore sustained its burden of proving by competent evidence the existence of a disputed issue of material fact on the issue of legal and proximate causation on their SOMs-failure theory of liability.

Finally, Defendants' fatalistic argument that the causal issues in this case are simply too multifaceted and attenuated, such that it should take the matter away entirely from the trier, holds no water. *See Hill v. State*, 121 R.I. 353, 355, 398 A.2d 1130, 1131 (1979) (specifically noting that "the issue of causation is almost always a question for the jury"). Causal evidence in the instant matter is not, as Defendants argue, akin to that in *Russian,* where the plaintiff repeatedly failed to identify (or hazard a guess at) the object that caused his slip and fall. *Russian*, 608 A.2d 1145. Here, the "cause" of the proverbial "fall" is very tangible, and comes paired with expert attestation and documentation—despite the State's inability or unwillingness to point to individual instances of proof.

[169] Pl.'s Ex. 56, at 5.
[170] On a national level, Dr. Cutler's chart/timeline shows a **572% increase** in morphine milligram equivalents being shipped from 1997 to 2011. *Id.*

E

The State's Causes of Action

Having discussed at length Defendants' evidentiary and causal challenges to the State's two underlying theories of liability, the Court now turns to Defendants' more "nuts-and-bolts" challenges to each of the State's four common law tort claims.

(1) Public Nuisance

The Defendants argue that because evidence of causation is lacking in the State's case, then, *ipso facto*, the State is unable to show either (1) an *unreasonable interference* with a right common to the public or (2) that any Defendant *controlled the instrumentality* of the nuisance.

In *Lead Industries*, the Supreme Court recognized the elements of a public nuisance as "(1) an unreasonable interference; (2) with a right common to the general public; (3) by a person or people with control over the instrumentality alleged to have created the nuisance when the damage occurred." *Lead Industries*, 951 A.2d at 446-47. Presiding Justice Gibney has already considered the matter in depth with due regard of the *Lead Industries* decision during the 12(b)(6) stage and recognized that "freedom from an overabundance of prescription opioids" is the *common public right* at issue. *Purdue Pharma L.P.*, 2019 WL 3991963, at *9. Further, misleading marketing constitutes one of the two "*instrumentalit*[*ies*]," under the exclusive control of the Defendants, which will go on to create the alleged nuisance. *Id.* at 10 (emphasis added).

While this Court believes Presiding Justice Gibney's decision constitutes law of the case, it reaches the same conclusion vis-à-vis its own analysis. While our Supreme Court in *Lead Industries* affirmed that public health is a public right, it concluded therein that the state's complaint was more akin to a products liability claim. It distinguished between a public right and an aggregation of private rights. It also noted that the General Assembly had placed responsibility

for abating the problem on landlords and property owners. While lead paint tragically affected the lives and development of many people, mostly children, the instrument related to actions that had long since happened because lead as an ingredient was removed from paint decades before suit was brought. The harm was also identifiable to specific individuals, namely, the residents of homes that have not had the lead paint abated.

While Defendants' counsel vigorously contended at hearing that this case similarly is a product liability case, this Court does not concur. The potential victims of the opioid epidemic are not so easily identified, nor are they confined to one private location (i.e., the home). Rather, the natural consequences from an overabundance of opioids spills out into neighborhood parks, dim alleys, city benches, and other places of public accommodation and stewardship.

The opioid crisis has devastatingly affected those addicted, but also everyone in the addicts' circle from family to friends to teachers, social workers, and health care providers. The crisis has taxed not only the public coffers but an entire network of healthcare and social services. Thus, Presiding Justice Gibney concluded that "freedom from an overabundance of prescription opioids is a public right." *Id.* at 9. This Court agrees. Since the interference with the public right is the overabundance of opioids, it is the Defendants who control the flow of the drugs. Whether their interference was "unreasonable" will be for the jury to decide.

After having properly *pled* a valid theory of causation at the 12(b)(6) stage, the State has now *evidenced* that theory at summary judgment. Considering further that the element of causation has always been a question for the jury, this Court sees no present reason to depart from Presiding Justice Gibney's cogent and well-supported analysis concerning the (i) common public rights at issue; (ii) control over the instrumentality of the nuisance; and (iii) the Defendant Manufacturers' relationship to the aforementioned. Rather, Defendants attempt to recast several key

determinations of Presiding Justice Gibney's analysis. As a representative example, they define the "alleged harm" of the nuisance as "addiction or overdose."[171] This characterization misstates the alleged harm, which Presiding Justice Gibney concluded was the opioid crisis itself.[172] *Purdue Pharma L.P.*, 2019 WL 3991963, at *9.

Presiding Justice Gibney engaged in the heavy mental lifting in her role as the 12(b)(6) gatekeeper of the State's claims, and this Court concurs in both the analysis and ultimate result.

(2) Fraud

To establish a prima facie fraud claim, "the plaintiff must prove that the defendant made a false representation intending thereby to induce plaintiff to rely thereon and that the plaintiff justifiably relied thereon to his or her damage." *Parker v. Byrne*, 996 A.2d 627, 634 (R.I. 2010) (internal quotations omitted). Defendants challenge the State's ability to show a disputed issue of material fact regarding both the *reliance* and *intent* prong. The latter prong is quickly dispatched, as this Court has above determined that the State's proffered evidence of false or misleading statements attributable to the Defendants competent for its false marketing theory and sufficient evidence to take claims based on that theory to trial.

As to the reliance prong, the Court credits the analysis done by Presiding Justice Gibney at the 12(b)(6) stage that "the **requisite particularity** for fraud-based allegations depends on the unique facts and circumstances of the case **and the requirement may be relaxed in situations that involve complex allegations of fraud over long periods of time**. *Purdue Pharma L.P.*, 2019 WL 3991963, at *14) (emphasis added) (citing *Women's Development Corp. v. City of Central Falls*, 764 A.2d 151, 161 (R.I. 2001) (stating that for the purpose of Rule 9(b), particularity

[171] Def. Cephalon's Mem. at 41.
[172] Or, more literally, the exposure to unchecked amounts of dangerous opioid drugs now present in the community.

depends on the nature of the case and on whether the complaint provides fair notice to the opposing party). However, the parties are now at the summary judgment stage.

The evidence here shows that Cephalon's sales model and quotas were contingent on prescribers and patients *relying* on Cephalon's manifestations that off-label use was safe, effective, and legal, to say nothing about any deliberately understated dangers of fentanyl more generally.[173] The same analysis applies to the direct marketing of Teva USA as well.[174]

(3) Negligence

In both their memoranda and at hearing, Defendants argue that the State's negligence claim fails for want of a duty owed: "[Defendant Manufacturers] had no duty to control the abuse, diversion, and misuse of FDA-approved opioids that they sold."[175] If there is no duty of care owed to the plaintiff (in this case the State), then a "defendant cannot be liable under a theory of negligence[.]" *Volpe v. Fleet National Bank*, 710 A.2d 661, 663 (R.I. 1998). Rather, that because Cephalon, Teva USA, and the Actavis Entities lacked control over the downstream actors who, they reason, "had to engage in some misconduct for the State to incur its alleged harms," it would constitute a gross expansion of negligence law to hold them responsible for a third party's conduct. Def. Cephalon's Mem. at 43 (citing *Flynn v. Nickerson Community Center*, 177 A.3d 468, 477 (R.I. 2018) (affirming grant of summary judgment for refusal to impose duty to prevent criminal conduct of others)).

[173] *See* Pl.'s Exs. 03, 09, 13 (at 00360982), 18, 19, 20, 47, 48 (at 17-31).
[174] *See* Pl.'s Exs. 30, 40, 41 (outsourced marketing presentation delivered to Teva USA suggesting that TIRF-REMS was used as a Trojan horse to promote branded *Fentora*; excerpts from 2015 *Pain Matters* program as well as Teva Employee, Matthew Day's testimony qualifying *Pain Matters* as "an unbranded *campaign* that healthcare professionals and doctors could access").
[175] Def. Cephalon's Mem. at 43.

It is well settled in this jurisdiction the determination of "[w]hether a defendant is under a legal duty in a given case is a question of law" and that the assessment of such is conducted on a "case-by-case basis." *Willis v. Omar*, 954 A.2d 126, 129, 130 (R.I. 2008) (citing *Martin v. Marciano*, 871 A.2d 911, 915 (R.I. 2005)). In conducting this analysis, the Court examines "all relevant factors, including the relationship of the parties, the scope and burden of the obligation to be imposed upon the defendant, public policy considerations, and notions of fairness." *Volpe v. Gallagher*, 821 A.2d 699, 705 (R.I. 2003) (internal citations omitted); *see also Banks v. Bowen's Landing Corp.*, 522 A.2d 1222, 1225 (R.I. 1987) (As "[n]o clear-cut rule exists to determine whether a duty is in fact present in a particular case [,]" the Court considers several factors "to aid in that determination.").

This Court has already ruled out breach of Defendants' CSA statutory duties[176] as constituting a *per se* breach of any common law state tort claims (e.g., public nuisance, negligence, etc.): "Holding that the Defendants are subject to . . . alleged duties under the two CSA statutes would not resolve any part of the State's [claim for] public nuisance . . . because the State would still have to prove that these statutory duties support its common law claim[]" May 5, 2020 Decision Denying State's Motion for Summary Judgment at *6 (Gibney, P.J.). However, relying particularly upon (i) public policy considerations and (ii) basic notions of fairness, the Court finds that the Defendants here owed duties to the State and its citizens to market, sell, and distribute their extremely potent drugs with care of a reasonably prudent drug manufacturer. Further, in the context of such duty, it is generally foreseeable that failing to establish or utilize competent SOM

[176] As pled under the federal and state CSA, as well as 21 C.F.R § 1301.74(b), §§ 21-28-3.04, 21-28-3.28, and 216-RICR-20-20-4.7.

protocols,[177] and/or engaging in false or misleading marketing of *Actiq*, *Fentora*, and opioids as a class,[178] could cause (or materially contribute to) the collection of harms commonly referred to as the "opioid crisis" in the state. *See Purdue Pharma L.P.*, 2019 WL 3991963, at *18.

(4) Unjust Enrichment

In its characterization of the State's common law unjust enrichment claim, Defendants again reframe the scope of the charge based on what they *think* the claim should encompass, not based on what it *actually* encompasses:

> "[T]he State also alleges that it conferred a benefit on Defendants, including Cephalon, by **paying for health care and other opioid-related expenses—which the State refers to as "externalities."** (SAC ¶ 428). But these services were conferred upon Rhode Island residents—not the State. They did not benefit Cephalon."[179]

Rather, breaking down the unjust enrichment tort to its bare essentials ((1) benefit conferred; (2) benefit appreciated; (3) inequitable to retain)[180], the Court reaffirms the unjust enrichment theory based upon the following set of evidenced factual circumstances: (1) Rhode Island paid Defendants for its opioid products;[181] (2) Defendant accepted the State's payment;[182]

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[177] *See generally* Pl.'s Mem. for Partial Summ. J., Exs. K-Q (evidence in the form of third-party reports, parent company reports, ex-employee/executive accounts, internal documents, and quantitative data to suggest that Teva USA's SOMs/due diligence protocols lacked key components necessary to prevent diversion); *see also* Pl.'s Mem. for Partial Summ. J., Ex. U, Baran Tr. 303:7-304:10; Pl.'s Mem. for Partial Summ. J., Ex. X; Pl.'s Mem. for Partial Summ. J. Ex. ZF, US-DEA-00000001; Ex. ZG, Clarke Tr. 104 (evidence in the form of multiple Actavis employees who have testified that the Actavis Entities' SOMs/contingency systems lacked key components necessary to manage diversion).

[178] *See* § 2 (1)-(3), *supra* (evidence of Defendants' alleged misleading and fraudulent marketing of *Actiq*, *Fentora*, and generic opioids).

[179] Def. Cephalon's Mem. at 45 (emphasis added).

[180] *See Bouchard v. Price*, 694 A.2d 670, 673 (R.I. 1997).

[181] At hearing on Defendants' Motions for Summary Judgment, counsel for the State represented that evidence would be submitted at trial regarding the State's payment for Defendants' opioids through various public insurance schemes.

[182] Also to be evidenced by the State at trial, as per counsel's representation at hearing on Defendants' Motions for Summary Judgment.

and (3) that, under the present circumstances, it would be inequitable for the Defendants to retain the benefit without paying the value of the harm it caused. This (proper) framing of the tort negates Defendants' argument at hearing that there is "no evidence" that the State paid Defendants any money (i.e., conferred any benefit) and is direct enough to sustain an unjust enrichment claim. *See Taylor Woodrow Blitman Construction Corp. v. Southfield Gardens Co*., 534 F. Supp. 340, 347 (D. Mass. 1982) ("Typically, unjust enrichment involves a direct benefit conferred on one party by another.").

(5) Punitive Damages

Since at least 1854, punitive or exemplary damages may be assessed when there is "evidence of such willfulness, recklessness or wickedness, on the part of the party at fault, as amounted to criminality…" *Hagan v. Providence and Worcester R.R. Co.*, 3 R.I. 88, 91 (1854). "Whether the[] facts are adequate to support an award of punitive damages is a question of law for the court to decide." *Sherman v. McDermott*, 114 R.I. 107, 108, 329 A.2d 195, 196 (1974). "Whether plaintiff is entitled to punitive damages, once the court has determined the case to be a proper one for such an award, is left to the discretion of the trier of fact." *Sherman*, 114 R.I. at 108-09, 329 A.2d at 196. *See also Peckham v. Hirschfeld*, 570 A.2d 663 (R.I. 1990); *Mark v. Congregation Mishkon Tefiloh*, 745 A.2d 777 (R.I. 2000).

Summary judgment is not a proper vehicle for the denial of punitive damages. *See Morin v. Aetna Casualty & Surety Co.*, 478 A.2d 964, 967 (R.I. 1984) (As "[s]ummary judgment is not a proper vehicle for the award of punitive damages[,]" conversely, neither is the procedure a proper vehicle for the *denial* of punitive damages.).

At hearing on the instant motions, counsel for the parties disclosed that each side has identified some 3,000 documents as potential exhibits for trial. Considering the scope of facts yet

to be developed, the Court will defer ruling on the matter of punitive damages until the appropriate point at trial.

V

Conclusion

For the reasons stated herein, the Court **DENIES** the Motions for Summary Judgment made by Teva USA, Cephalon, and the Actavis Entities. Counsel will confer and present the appropriate order.

RHODE ISLAND SUPERIOR COURT

Decision Addendum Sheet

TITLE OF CASE:	**State of Rhode Island v. Purdue Pharma L.P., et al.**
CASE NO:	**PC-2018-4555**
COURT:	**Providence County Superior Court**
DATE DECISION FILED:	**February 18, 2022**
JUSTICE/MAGISTRATE:	**Licht, J.**
ATTORNEYS:	
For Plaintiff:	**Etie-Lee Schaub, Esq.; Robert McConnell, Esq.; Fidelma Fitzpatrick, Esq.; Vincent Greene, Esq.; Kristin Hermiz, Esq.; Katie Menard, Esq.**
For Defendant:	**Wendy West Feinstein, Esq.; Tinos Diamantatos, Esq.; Chip Palmer, Esq.; Brian Ercole, Esq.; Adam Teitcher, Esq.**