

2018 WL 4829660 (N.J.Super.Ch.) (Trial Order)  
Superior Court of New Jersey, Chancery Division.  
Essex County

GREWAL, et al.,  
v.  
PURDUE PHARMA L.P., et al.

No. ESX-C-245-17.  
October 2, 2018.

**Letter Opinion**

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Thomas M. Moore, Judge.

\*1 Dear Counsel:

Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company (collectively, “**Purdue**”), have moved to dismiss the Complaint for failure to state a claim upon which relief can be granted under *Rule* 4:6-2(e). The Court heard oral argument on July 9, 2018. This letter opinion shall be the Court's order and opinion on this motion.

***1. FACTS AND PROCEDURAL HISTORY***

Plaintiffs Gurbir Grewal, the Attorney General of New Jersey, and Paul Rodriguez, the Acting Director of the New Jersey Division of Consumer Affairs, (collectively, “**the State**”) filed this action on October 31, 2017.<sup>1</sup> The Complaint alleges that Purdue's marketing violated the New Jersey Consumer Fraud Act (“**the CFA**”), the New Jersey False Claims Act (“**the FCA**”), and created a public nuisance. Purdue filed a motion to dismiss in lieu of an answer on February 2, 2018. The Court heard oral argument on July 9.

***A. PURDUE'S ALLEGED MARKETING SCHEME***

Purdue “manufactures, promotes, sells, and distributes” opioid prescription drugs, including OxyContin, *Compl.* ¶ 28. The State alleges that Purdue's marketing contributed to the current opioid crisis. The State seeks “to hold Purdue accountable for its key role in the opioid epidemic and demand the company's contribution to the expensive solutions, including addiction treatment and prescriber education, that are necessary to abate the crisis.” *Id.* at ¶ 1. The State contends that Purdue, starting in the late 1990s, tried “to change the perception of opioids to permit and encourage the use of these drugs not just for acute and palliative [end of life] care, but also long-term, for chronic conditions like back pain, migraines, and arthritis.” *Id.* at ¶ 5 (brackets added). The State defines chronic pain as “non-cancer pain lasting three months or longer.” *Id.* The State claims that before Purdue's marketing push, opioids were ordinarily used only to treat short-term acute pain and palliative care “because they were considered too addictive and debilitating for long-term use.” *Id.* at ¶ 4.

The State alleges that Purdue's marketing campaign changed the medical consensus about the use of opioids. *Id.* at ¶ 7. It asserts that, now, more than ninety percent of prescription opioids are for chronic pain conditions. *Id.* The State claims that Purdue's marketing affects doctors that it has not targeted because it successfully established “opioids as a first-line treatment for chronic pain.” *Id.* at ¶ 180. Purdue's opioids allegedly account for more than sixty percent of the brand-name opioid prescriptions that the State reimbursed through its Medicaid and workers' compensation programs and employee and retiree health plans. *Id.* at ¶ 12; *see id.* at ¶ 176.

The State alleges that Purdue's marketing consisted of: (1) direct marketing to prescribers by advertising and in-person sales calls, (2) “generating a biased and methodologically defective body of scientific research, the purpose of which was to support, rather than objectively investigate, the use of opioids for chronic pain,” and (3) marketing opioids to physicians and consumers through unbranded websites, third-party “front” groups, and opinion leaders. *Id.* at ¶ 6. Such groups and opinion leaders included pain advocacy groups, professional societies, and physicians. *Id.* Purdue allegedly financed these websites, groups, and individuals. *Id.*

\*2 The State alleges that, beginning in 1996, Purdue marketed OxyContin “as the solution to the problem of chronic pain.” *Id.* at ¶ 35. It convinced prescribers that “the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven.” *Id.* The State asserts that “Purdue knew its claims about long-term opioid use lacked scientific support.” *Id.* at ¶ 36. The State claims that the Food and Drug Administration (“FDA”) approved labeling of Purdue's opioids does not address long-term use, which the State defines as more than twelve weeks. *Id.* The State asserts that the clinical study for OxyContin's efficacy was a two-week study. *Id.* However, Purdue allegedly “marketed OxyContin with the understanding and expectation that health care providers—believing the drug to be appropriate for long-term use—would prescribe it to their chronic pain patients over periods of months and even years.” *Id.* The State asserts that Purdue targeted general practitioners, who were the most likely to treat patients with chronic pain and the “least likely to have the training and experience to evaluate Purdue's marketing and patients' pain conditions.” *Id.* at ¶ 37. The State contends that this targeting “laid the groundwork for today's epidemic of opioid abuse, injury, and death.” *Id.*

Purdue allegedly made deceptive statements in its marketing that understated the risk of addiction. *Id.* at ¶¶ 39-40. Additionally, Purdue claimed that OxyContin was effective for a full twelve hours and “less likely than other opioids to create a cycle of crash and cravings that fuel addiction.” *Id.* at ¶¶ 41-42. Its competitors sold less expensive opioids which were prescribed in four or six hour doses. *Id.* at ¶ 41.

In 2007, Purdue and three of its then-executives “pleaded guilty to federal criminal charges for certain deceptive conduct in the sale and marketing of opioids.” *Id.* at ¶ 8. The State alleges that after the guilty pleas, Purdue did not correct its prior misrepresentations and instead “echoed the deceptions for which it was cited in 2007 and made diverse other misrepresentations.” *Id.* at ¶ 74. The State asserts that Purdue

has falsely and misleadingly presented the risks of opioids by (a) continuing to downplay the serious risk of addiction, including by claiming that signs of addiction merely reflect undertreated pain; (b) overstating the effectiveness of screening tools in preventing addiction, giving prescribers unwarranted confidence that they can safely prescribe opioids; (c) denying or failing to disclose the dangers of opioids at higher doses, which increase the risk of addiction, overdose, and death; and (d) exaggerating the effectiveness of abuse-deterrent opioid formulations to prevent abuse and addiction. Purdue also has misrepresented the benefits of opioids, falsely claiming that long-term opioid therapy is appropriate and effective—and, in particular, will improve patients' function and quality of life—without disclosing that there is no good evidence to support these claims. Purdue further has misleadingly promoted OxyContin as providing a full 12 hours of pain relief, when in fact the effect wears off well before 12 hours in many patients—causing patients to experience a “crash” and fueling a cycle of higher-dose prescribing (which Purdue expressly encouraged) and addiction.

[*Id.* at ¶ 10; *see id.* at ¶¶ 11, 79-158.]

### ***B. PURDUE'S ALLEGED TARGETING OF THE ELDERLY***

The State alleges that Purdue targeted the elderly and opioid-naïve patients to expand its market share and increase its profits. *Id.* at ¶¶ 159-72. The State asserts that Purdue's training materials and sales goals for its sales representatives, its sales representatives' notes, and its sales managers' reports reference "Purdue's efforts to persuade doctors to start prescribing its ER/LA opioids to elderly patients." *Id.* at ¶ 160. Purdue instructed its sales representatives to persuade doctors to convert elderly patients from non-steroidal anti-inflammatory drugs, such as Tylenol, or other opioids to Purdue's opioid products. *Id.* at ¶ 161. Part of the persuasion strategy was to suggest starting the patient at a low dosage, which, according to the State, implies that a low dose was safe. *Id.* at ¶¶ 162, 167-68. Additionally, Purdue knew that it was likely the dosage would need to be increased as the patient developed a tolerance for the opioid. *Id.* at ¶ 168. Purdue also allegedly targeted nursing homes and focused its marketing on educating physicians about Medicare Part D coverage for opioids. *Id.* at ¶¶ 163-64.

### ***C. ALLEGED INJURIES TO THE PUBLIC AND THE STATE***

\*3 The State claims that Purdue's marketing has caused "an epidemic of addiction, abuse, overdose, and other injuries, with their attendant societal costs." *Id.* at ¶ 173. The State asserts that Purdue's marketing has caused increase in opioid use, which "has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in New Jersey." *Id.* at ¶ 182; *see id.* at ¶ 184. The State claims that "[p]atients receiving opioid prescriptions for chronic pain account for the majority of overdoses." *Id.* at ¶ 185 (citing a 2016 report by the Centers for Disease Control and Prevention). Further, up to eighty percent of heroin addicts used prescription opioids before using heroin. *Id.* at ¶ 196.

Through its health programs, the State has paid hundreds of millions of dollars for opioid prescriptions, many of which, it asserts, "were not medically necessary and would not have been written but for Purdue's fraudulent scheme." *Id.* at ¶ 173; *see id.* at ¶ 237. Moreover, the State has paid for additional medical treatment and prescription drugs for conditions and injuries caused by chronic opioid use. *Id.* at ¶ 202. The State funds the New Jersey Medicaid program, the State employee and retiree health plans, and the State employee workers' compensation program. *Id.* at ¶¶ 202, 204-16, 223-25. The State argues that most long-term use of opioids to treat chronic pain is not medically necessary as defined by the State's health programs. *Id.* at ¶¶ 217, 219, 228, 234-35. Alternatively, if the prescriptions were medically necessary because of accepted professional and community standards, the State argues that Purdue's deceptive marketing caused the change in these standards. *Id.* at ¶¶ 218, 229. The State alleges that it has incurred additional and consequential costs to pay for additional medical care and drugs for patients who used opioids long-term for chronic pain, such as the costs of rehabilitation. *Id.* at ¶¶ 222, 231-32.

The State asserts that its payment for the prescriptions and medical services was the "foreseeable and intended consequence of Purdue's fraudulent marketing scheme." *Id.* at ¶ 236. Moreover, the State alleges that Purdue intended physicians to prescribe and the government to pay for long-term prescriptions to treat chronic pain. *Id.* The State contends that, but for the deceptive marketing campaign, "the State would not have been presented with, or paid, claims for opioids to treat chronic, moderate pain." *Id.* at ¶ 237. The State asserts that "prescribers would have more accurately understood the risks and benefits of long-term opioid use and would not have prescribed opioids as medically necessary or reasonably required to treat chronic pain." *Id.* at ¶ 238. Additionally, the State claims that it and its municipalities has suffered increased costs for law enforcement because of the rise in the criminal market for opioids. *Id.* at ¶ 199.

### ***D. PURDUE'S ALLEGED KNOWLEDGE AND CONCEALMENT***

The State alleges that Purdue knew its marketing was false and misleading. *Id.* at ¶ 245. It claims that Purdue had access to studies, prescription data, and incident reports, “which made clear the harms from the long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers.” *Id.* The State accuses Purdue of taking “steps to avoid detection of and to fraudulently conceal its deceptive marketing and unlawful and fraudulent conduct, and also to conceal or minimize questions or concerns raised by prescribers about addiction.” *Id.* at ¶ 246. Purdue allegedly disguised its role in the marketing by “funding and working through biased science, unbranded marketing, third party advocates, and professional associations.” *Id.* at ¶ 253. The State contends that it “purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Purdue's false and misleading messages about the risks and benefits of long-term opioid use for chronic pain.” *Id.*

\*4 The 2007 settlement with the federal government included a Corporate Integrity Agreement. *Id.* at ¶ 247. The Agreement “requires Purdue to establish written procedures governing the response to requests for information about ... withdrawal, drug tolerance, drug addiction or drug abuse of Purdue's products.” *Id.* (internal quotation marks omitted). The State alleges that Purdue has violated the Agreement by “deflecting questions from prescribers about the risk of addiction.” *Id.* at ¶ 248. Moreover, the State accuses Purdue of fraudulently concealing or underrepresenting prescriber questions about addiction in its sales representatives' meeting notes or instructing its representatives not to raise to topic of addiction. *Id.* at ¶¶ 249-51. Additionally, Purdue did not start noting addiction materials that it gave to prescribers prior to October 3, 2016. *Id.* at ¶ 252.

Finally, the State asserts that “Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids.” *Id.* at ¶ 259. Contrary to Purdue's public statements, the State accuses Purdue of continuing to supply these providers with its products. *Id.* at ¶¶ 259-60.

The State argues that it “did not know the existence or scope of Purdue's fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.” *Id.* at ¶ 261.

### ***E. COUNTS OF THE COMPLAINT***

The Complaint has five counts. The first three counts allege violations of the CFA, *N.J.S.A. 56:8-1 et seq.* Count One asserts that Purdue's marketing violated the CFA because of making false or misleading statements, causing false or misleading statements to be made or disseminated, omitting or concealing material facts, and failing to correct prior misrepresentations and omissions. *Id.* at ¶ 269; *see id.* at ¶¶ 270-71. The State seeks a permanent injunction prohibiting Purdue from engaging in these acts and practices, disgorgement “of any money acquired or retained as a result of these practices,” restitution of money acquired from these practices, civil penalties for each CFA violation, and attorneys' fees and costs. *Id.* at p. 93

Count Two alleges that Purdue's marketing constitutes an unconscionable commercial practice under the CFA. *Id.* at ¶¶ 276-77. The State contends that Purdue's marketing “unethically deprived prescribers of the information they needed to appropriately prescribe, or not prescribe, these dangerous drugs.” *Id.* at ¶ 278. The State seeks a permanent injunction prohibiting Purdue from engaging in these acts and practices, disgorgement “of any money acquired or retained as a result of these practices,” restitution of money acquired from these practices, civil penalties for each practice, and attorneys' fees and costs. *Id.* at p. 95.

Count Three alleges that Purdue's targeting of the elderly is an unconscionable commercial practice under the CFA. *Id.* at ¶¶ 283-85. The State seeks restitution of money acquired from this practice, enhanced civil penalties under *N.J.S.A. 56:8-14.3* for each deceptive and unconscionable commercial practice directed at the elderly, and attorneys' fees and costs. *Id.* at p. 96.

Count Four asserts a claim under the FCA, *N.J.S.A. 2A:32C-1 et seq.* The State accuses Purdue of, “through its deceptive marketing of opioids for chronic pain, presented or caused to be presented false or fraudulent claims and knowingly used or caused to be used false statements to get false or fraudulent claims paid or approved by the State.” *Id.* at ¶ 291. The State alleges that Purdue's deceptive statements to prescribers caused the prescribers to write medically unnecessary prescriptions, which the State paid for. *Id.* at ¶¶ 292-95. Additionally, the State has paid consequential health care costs that were caused by the unnecessary prescriptions. *Id.* at ¶ 296. The State seeks an injunction prohibiting Purdue from engaging in conduct that violates the FCA, maximum penalties for each false or fraudulent claim that Purdue caused to be presented to the State for payment, treble damages, and attorneys' fees and costs. *Id.* at p. 99.

\*5 Count Five asserts a public nuisance claim. The State alleges that Purdue's marketing caused “a public nuisance by unreasonably interfering with a right common to the general public that harms the health, safety, peace, comfort, or convenience of the general community.” *Id.* at ¶ 298; *see* ¶ 302. Specifically, the State contends that Purdue's conduct has caused

(a) widespread dissemination of false and misleading information about the risks and benefits of opioids to treat chronic pain; (b) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on New Jersey families and communities; (d) increased health care costs for individuals, families, employers, and the State; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, criminal market for opioids; and (g) greater demand for emergency services and law enforcement paid for by the State at the ultimate cost of taxpayers.

[*Id.* at ¶ 300.]

The State argues that the nuisance was foreseeable to Purdue because it knew of the lack of evidence behind its marketing claims, it could foresee “a vastly expanded market for chronic opioid therapy” as a result of its conduct, and it was on notice and aware that broader use of opioids was causing the injuries that the State has described. *Id.* at ¶ 304. The State seeks an order requiring Purdue to provide for the abatement of the nuisance, enjoining Purdue from further contributing to the nuisance, and “awarding damages to redress the consequential damages resulting from” the nuisance. *Id.* at pp. 101-02.

## II. ARGUMENTS

### A. PURDUE'S MOTION TO DISMISS

Purdue moves to dismiss the Complaint for six reasons:

1. Federal law preempts the State's claims because the claims conflict with the FDA's decisions regarding what Purdue should tell doctors and patients about its products;
2. New Jersey law forecloses the State's public nuisance claim;
3. Portions of all claims are time-barred;
4. The State does not plead the alleged fraud with particularity;
5. The State does not allege that Purdue controlled third-party publications and statements; and
6. The State has not pleaded and cannot plead causation.

*Purdue's Br.* 3-4.

### 1. Preemption

Purdue argues that the federal law preempts the State's claims because “any claim arising from Purdue's promotion of opioid medications as safe and effective for its FDA-approved indications necessarily conflicts with the FDA's jurisdiction over drug labeling, and specifically its approval of those indications.” *Purdue's Br.* 12 (internal quotation marks and citation omitted). Purdue claims that it has marketed its medications for their FDA-approved uses and consistent with FDA's policies. *Id.* at 16. Purdue asserts that the FDA has approved Purdue's medications for long-term use to treat chronic pain. *Id.* at 10. Further, Purdue contends that the FDA-approved labels on the medications expressly address the misrepresentations alleged by the State. *Id.*

Purdue applies its preemption analysis to each category of the State's allegations. First, the FDA has approved Purdue's medications for long-term use to treat chronic pain. *Id.* at 12-13. Additionally, in 2012, it denied a petition from the Physicians for Responsible Opioid Prescriptions (“PROP”), which sought to limit the use of opioids in non-cancer patients to ninety days. *Id.* at 13; *see id.* at 2.

\*6 Second, the State alleges that Purdue promoted the concept of pseudoaddiction and implied there was scientific evidence to support it. *Id.* at 14 (citing *Compl.* ¶¶ 10, 86, 97). Purdue characterizes pseudoaddiction as drug-seeking behavior that mimics addiction from patients receiving inadequate pain relief. *Id.* at 14. Purdue contends that the FDA-approved label embodies the concept of pseudoaddiction. *Id.*

Third, the State alleges that “Purdue misrepresented that addiction risk screening tools allow doctors to identify and safely prescribe opioid medications to patients predisposed to addiction. *Id.* (citing *Compl.* ¶¶ 10, 101-06). Purdue argues that federal law preempts this claim because the FDA-mandated Risk Evaluation and Mitigation Strategy (“REMS”) requires Purdue to provide risk-benefit information to physicians. *Id.* at 7-8. REMS directs physicians “to understand and appropriately use screening tools for addiction or abuse to help assess potential risks associated with chronic opioid therapy and to help manage patients using ER/LA opioid analgesics.” *Id.* at 14 (internal quotation marks and citation omitted).

Fourth, “[t]he State alleges that Purdue misrepresented the dangers of opioid medications at higher doses.” *Id.* (citing *Compl.* ¶ 10). Purdue maintains that federal law preempts this allegation because it undermines the FDA's decision in response to the PROP petition, which concluded that the available information does not demonstrate a causal relationship between dosage and adverse events. *Id.* at 14-15.

Fifth, “[t]he State alleges that Purdue misrepresented the effectiveness of abuse-deterrent opioid formulations to prevent abuse and addiction.” *Id.* at 15 (internal quotation marks omitted) (quoting *Compl.* ¶ 10). The FDA-approved labeling states that the ingredients are “intended to make the tablet more difficult to manipulate for misuse and abuse.” *Id.* (internal quotation marks and citation omitted). Purdue concludes that its claims about the abuse-deterrent opioids are consistent with the FDA-approved labeling. *Id.* Further, the FDA reviewed the data regarding the abuse-deterrent OxyContin and concluded that it is expected to “deter certain types of misuse.” *Id.* (internal quotation marks and citation omitted). Moreover, FDA's policies encourage expanding access to abuse-deterrent formulations. *Id.*

Sixth, the State alleges “that Purdue misrepresented that OxyContin lasts for 12 hours.” *Id.* (citing *Compl.* ¶¶ 10, 41-42, 79, 83, 107, 145-58). Purdue contends that federal law preempts these allegations because the FDA has approved OxyContin for twice daily dosing. *Id.* (citing *Compl.* ¶ 147). Additionally, the FDA rejected a 2004 petition from the Attorney General of Connecticut, which claimed that OxyContin was not a twelve-hour drug and should be dosed more frequently. *Id.* at 15-16.



## ***2. Foreclosure of Public Nuisance Claim***

Purdue argues that New Jersey law forecloses the State's public nuisance claim because of the Supreme Court's decision in *In re Lead Paint Litigation*, 191 N.J. 405 (2007) (“*Lead Paint*”). Purdue contends that *Lead Paint* prevents the State from sustaining “a public nuisance claim against Purdue for the lawful manufacture and promotion of FDA-approved medications.” *Purdue's Br.* 17. Purdue maintains that “no New Jersey court has ever allowed a public nuisance claim to proceed against manufacturers for lawful products that are lawfully placed in the stream of commerce.” *Id.* (internal quotation marks omitted) (quoting *Camden Cty. Bd. of Chosen Freeholders v. Beretta U.S.A. Corp.*, 273 F.3d 536, 540 (3d Cir. 2001) (“*Beretta*”). Purdue argues that any claims relating to harms caused by products must be brought under the New Jersey Products Liability Act (the “PLA”). *Id.* at 20 (citing *Lead Paint, supra*, 191 N.J. at 436-37). Purdue contends that the PLA subsumes the State's other causes of action to the extent they seek to impose liability for harms caused by products. *Id.* at 20 n.37 (citations omitted).

\*7 Additionally, the State does not have a right to damages because a public entity only has the right to abate. *Id.* at 18-19. If the State wants damages, it must prove a special injury. *Id.* Here, Purdue argues that the State only identifies injuries that are general to the public at large. *Id.* at 19-20.

Finally, Purdue contends that the State's public nuisance claim also fails because the causal chain is too attenuated. *Id.* at 20 (citing *Beretta, supra*, 273 F.3d at 541). Purdue argues that it does not control the conduct of health care providers or drug dealers, and that the State has not pleaded otherwise. *Id.* at 21.

## ***3. Statute of Limitations***

Purdue argues that some of the State's allegations concern conduct that occurred beyond any applicable statute of limitations. *Id.* at 21-22. Purdue contends that, at most, a ten-year statute of limitations applies to the State's claims. *Id.* at 22. Purdue maintains that many of the State's allegations concern conduct that occurred before October 31, 2007. *Id.* (citing *Compl.* ¶¶ 6, 35-72, 85-98). Purdue argues that the discovery rule does not apply because the State could have discovered the alleged misconduct before October 31, 2007. *Id.* at 23-24. The State had access to the publications that allegedly contained misrepresentations. *Id.* at 23. Further, the State also had access to information regarding the prescriptions that it paid for. *Id.* at 24. Additionally, the FCA does not apply retroactively to conduct before its effective date of March 13, 2008. *Id.*

## ***4. Pleading Fraud with Particularity***

Purdue argues that the State does not meet the heightened pleading requirements of *Rule* 4:5-8 for its fraud allegations. *Id.* at 25 (citing *Compl.* ¶¶ 173, 236-38, 246, 261, 276, 291, 294-96). Purdue contends that the State's allegations about Purdue's marketing are “conclusory broad-brush assertions.” *Id.* (citing *Compl.* ¶¶ 6, 10, 14-15). Purdue argues that the State does not plead who made false statements, who received the false statements, what false statements were made, when the false statements were made in New Jersey, where the wrongful conduct occurred, where the false statements were made, why the statements were false, or how Purdue's acts affected prescriptions that the State paid for. *Id.* at 25-26. According to Purdue, the State's allegations do not connect the alleged misrepresentations to a New Jersey doctor, patient, or prescription, which Purdue argues makes these allegations conclusory. *Id.* at 26 (citing *Compl.* ¶¶ 83-84, 86, 90, 107).

## ***5. Control Over Third Parties***

Purdue argues that the State “improperly attempts to hold Purdue legally responsible for statements made by third parties.” *Id.* at 27 (citing *Compl.* ¶¶ 44-54, 58, 60-72, 94-98). The State has not proven “an apparent agency relationship” between Purdue and these third parties. *Id.* (citation omitted). The State has not alleged that Purdue exercised control over these third parties; it merely alleges that Purdue funded, sponsored, or influenced them. *Id.* at 28. Purdue contends that funding is insufficient as a matter of law to attribute statements of third parties to it. *Id.* (citing *Gen. Bldg. Contractors Ass'n, Inc. v. Pennsylvania*, 458 U.S. 375, 395 (1982)).

## 6. Causation

The State's FCA claims are based on Purdue's conduct causing doctors to prescribe opioids, which caused the State to pay for these prescriptions. *Id.* at 28-29 (citing *Compl.* ¶¶ 5-7, 17, 33, 35, 37-38, 60, 77, 102, 173-74, 176, 202-04, 237, 293, 295). Purdue contends that this alleged causal chain is too attenuated and that the learned intermediary doctrine breaks the chain of causation. *Id.* at 29. Purdue makes three arguments in support of its position. First, the State fails to allege that a New Jersey doctor heard, read, received, or relied on Purdue's alleged misrepresentations. *Id.* Instead, the State relies on conclusory allegations. *Id.* (citing *Compl.* ¶¶ 1, 5, 86).

\*8 Second, the State's claims are “too attenuated as a matter of law to support liability.” *Id.* According to Purdue, “any connection between the alleged misconduct and the prescriptions depends on multiple independent intervening events and actors,” such as prescribers, patients, and the State. *Id.* at 30-31. Some of the State's allegations add another link: third party physicians and groups. *Id.* at 31 (citing *Compl.* ¶¶ 44, 47, 50, 61-63, 180, 218).

Third, the learned intermediary doctrine breaks any causal connection because of prescribing physicians' independent medical judgment. *Id.* at 31-32.

## B. THE STATE'S OPPOSITION

### 1. Preemption

The State argues that federal law does not preempt its claims because Congress has not expressed its intent to preempt state laws on the subject matter of drug regulation, federal legislation does not occupy the field of drug regulation, complying with both the federal and state laws is possible, and complying with the state laws would not frustrate a clear federal purpose or objective. See *id.* at 7. Moreover, the federal Food, Drug, and Cosmetic Act preserves state law unless it “presents a direct and positive conflict with the federal regulation of drugs.” *Id.* at 8 (internal quotation marks omitted) (quoting *Wyeth v. Levine*, 555 U.S. 555, 567 (2009)). The State contends that its allegations do not conflict with federal law because Purdue's alleged misrepresentations were either inconsistent with the FDA-approved labeling or addressed topics that the labeling did not cover. *Id.* at 12, 26-27. Therefore, there is no conflict between the federal and state laws. *Id.* at 19.

The State responds to each of Purdue's arguments about the specific categories of allegations. First, Purdue's alleged misrepresentations about long-term use are inconsistent with the FDA-approved labeling and are not covered by the 2012 PROP petition that the FDA denied. *Id.* at 19-20 (citing *Compl.* ¶¶ 134, 137, 139).

Second, Purdue's alleged misrepresentations about pseudoaddiction go beyond the labeling. *Id.* at 20-21 (citing *Compl.* ¶¶ 63-64, 84, 86, 89-91, 97-98).

Third, Purdue's alleged misrepresentations about addiction risk screening tools go beyond the FDA's REMS by suggesting that the tools prevent addiction and overdose. *Id.* at 21-22 (citing *Compl.* ¶¶ 101-05).



Fourth, the State alleges that Purdue encouraged prescribers to start patients on low doses of opioids and increase the dosage over time without disclosing the risks associated with higher doses. *Id.* at 22 (citing *Compl.* ¶¶ 107-12). The State contends that this failure to disclose is unrelated to the citizen petition that the FDA rejected regarding setting a maximum daily dose. *Id.* at 23.

Fifth, the State alleges that Purdue stated or implied to prescribers that “Purdue’s abuse-deterrent formulations were (1) more difficult to abuse; (2) less likely to be diverted; (3) rendered inactive if crushed; (4) disliked by drug abusers; and (5) helping to thwart addiction.” *Id.* at 23 (citing *Compl.* ¶ 131). The State argues that these representations are contrary to the FDA-approved labeling. *Id.* at 23-24. The State contends that, at most, the labeling allows Purdue to say that the formulations will make it more difficult to snort or shoot crushed tablets. *Id.* at 24. The formulations would not affect oral abuse, which the State asserts is the most common type of abuse. *Id.* (citing *Compl.* ¶ 86). Further, the FDA’s preference for abuse-deterrent formulations is not inconsistent with the FDA’s “insistence that companies accurately portray the limitations of those formulations.” *Id.* at 24-25.

\*9 Sixth, the State alleges that “Purdue misrepresented that OxyContin provides a full 12 hours of pain relief.” *Id.* at 25 (citing *Compl.* ¶¶ 145-58). The State asserts that Purdue knew that OxyContin did not provide such relief. *Id.* at 25-26 (citing *Compl.* ¶ 150). The State argues that neither the prescribing information nor the FDA-approved labeling state that each dose provides twelve hours of continuous pain relief. *Id.* at 25.

## 2. Statute of Limitations

The State argues that its claims are not time-barred for four reasons. First, under the FCA, the State may recover for reimbursement claims made after the statute’s effective date that are based on Purdue’s conduct before the effective date. *Id.* at 27-28 n.15 (citing *State ex rel. Hayling v. Correctional Med. Servs., Inc.*, 422 N.J. Super. 363, 372 (App. Div. 2011)).

Second, the pre-2007 allegations provide essential background information about Purdue’s marketing scheme. *Id.* at 27.

Third, Purdue’s ongoing failure to correct past misrepresentations that were made before the limitations period “constitutes an actionable series of omissions of material facts under the CFA” and “constitute new violations.” *Id.* at 28. The State alleges that Purdue built on its pre-2007 misrepresentations and continued to omit risks of opioids and the lack of evidence supporting long-term opioid therapy for chronic pain. *Id.* at 32 (citing *Compl.* ¶ 74). The State argues that Purdue’s failure to correct these misrepresentations has caused them to persist and continue to influence prescribers and consumers. *Id.* at 32-33. The State contends that Purdue’s failure “to correct its prior misrepresentations in later interactions with prescribers ... constitut[es] a knowing omission of material facts from the prescriber’s consideration, just as if Purdue were omitting the disclosure of a newly discovered material fact.” *Id.* at 33.

Fourth, the Complaint contains many allegations of misrepresentations within the limitations period, such as:

1. Misrepresentations that OxyContin provides twelve hours of relief. *Id.* at 29 (citing *Compl.* ¶¶ 145-46, 153-57).
2. Promoting the concept of pseudoaddiction. *Id.* at 29-30 (citing *Compl.* ¶¶ 86, 91, 97).
3. Misrepresentations regarding abuse-deterrent formulations of opioids. *Id.* at 30 (citing *Compl.* ¶¶ 120-33).
4. Misrepresentation of addiction statistics for children treated with opioids. *Id.* (citing *Compl.* ¶ 86).
5. Misrepresentations about the efficacy of screening tools to manage opioid addiction. *Id.* (citing *Compl.* ¶ 105).
6. Omitting the risks of opioids while discussing the risks of non-opioid pain medications. *Id.* (citing *Compl.* ¶ 113).

7. Omitting the risks of dosage increases. *Id.* (citing *Compl.* ¶ 114).
8. Misrepresenting that opioids increase a patient's functioning. *Id.* at 31 (citing *Compl.* ¶ 141).
9. Misrepresenting the benefits and efficacy of opioids when it promoted chronic opioid therapy for the elderly and the opioid naive. *Id.* (citing *Compl.* ¶¶ 159-63, 167-69).

### ***3. Fraud Pleaded with Particularity***

The State argues that its CFA, FCA, and public nuisance claims are adequately pleaded.

#### ***a. CFA***

The State contends that its CFA claims are adequately pleaded for two reasons. First, the law does not require the State to show who the statements were made to, the dates and locations of the statements, or that the statements were relied upon. *Id.* at 35. New Jersey courts have held that a detailed description of a deceptive scheme is sufficient to survive a motion to dismiss. *Id.* at 36-37 (citing *Talalai v. Cooper Tire & Rubber Co.*, 360 N.J. Super. 547, 564 (Law Div. 2001)). The State need not “allege precise facts regarding every instance of potentially unlawful conduct.” *Id.* at 36 (citation omitted).

\*10 Second, the Complaint provides enough details of Purdue's deceptive conduct to allow Purdue to deny, disprove, or explain the allegations. *Id.* at 37-39 (citing various portions of the Complaint).

#### ***b. FCA***

The State notes that there are no published New Jersey opinions that establish the pleading standard for the FCA. *Id.* at 39-40. It suggests that the Court should use Third Circuit precedent under the federal False Claims Act. *Id.* at 40. The Third Circuit does not require a plaintiff to plead the specifics of each false claim. *Id.* at 40-41 (citing *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 155-58 (3d Cir. 2014)). The State argues that the *Foglia* approach is appropriate when a plaintiff “alleges a long-running scheme involving numerous claims submitted over the course of several years.” *Id.* at 41. It also “provides the responding party sufficient notice to deny or disprove the claims asserted against it, and that standard comports with the Legislature's instruction that the FCA must be ‘liberally construed to effectuate its remedial and deterrent purposes.’” *Id.* (quoting *N.J.S.A. 2A:32C-17*).

The State argues that the Complaint adequately alleges that “Purdue's deceptive conduct *induced health care providers* to prescribe opioids in a manner that violates material conditions of State-sponsored reimbursement programs, and that the submission of legally false claims for payment of those prescriptions was the reasonably foreseeable and intended result of that conduct.” *Id.* at 42 (emphasis in original) (citing *Compl.* ¶¶ 202-44). The Complaint provides specific examples of false claims submitted for reimbursement. *Id.* at 43 (citing *Compl.* ¶¶ 219, 233). It also provides criteria for identifying the false claims among the millions of claims for opioids under the State's health programs. *Id.* at 44 (citing *Compl.* ¶¶ 220-21, 235).

Additionally, the State contends that some federal courts accept methods of proof other than claim-by-claim analysis, such as statistical sampling and extrapolation. *Id.* at 45. The State expects to prove its false claims allegations through these methods with expert testimony. *Id.*

***c. Public Nuisance***

The State argues that the heightened pleading standard of *Rule* 4:5-8(a) does not apply to its public nuisance claim. *Id.* at 46. It notes that Purdue does not cite any cases that apply a heightened pleading standard to a public nuisance claim. *Id.* The State contends that the Complaint adequately pleads a public nuisance claim because its allegations, if proven, would be an interference with the public's health, safety, peace, comfort, and convenience. *Id.* at 46-48 (citing various portions of the Complaint).

***4. Causation***

The State argues that it has adequately pleaded causation for each claim to the extent required by law. *Id.* at 48. Additionally, it contends that the learned intermediary doctrine does not defeat its claims. Finally, the State maintains that it sufficiently alleges that Purdue exercised controlled over unlawful promotional activity.

***a. CFA***

The State argues that causation is not required for a CFA claim brought by the government.<sup>2</sup> *Id.* at 49 (citations omitted).

***b. FCA***

\*11 The State contends that it has adequately alleged that Purdue's deceptive conduct resulted in physicians submitting medically unnecessary claims for reimbursement. *Id.* at 49. The State argues that the actions of third parties do not necessarily break the chain of causation. *Id.* at 50. It maintains that the proper standard for causation is whether Purdue's scheme was a substantial factor in influencing the physicians to file false claims. *Id.* (citing *United States ex rel. Bergman v. Abbott Labs.*, 995 F. Supp. 2d 357, 359, 368 (E.D. Pa. 2014)). The physicians' intervening acts do not defeat causation if "it is 'foreseeable that claims could be submitted'" because of Purdue's conduct. *Id.* at 51 (quoting *Bergman, supra*, 995 F. Supp. 2d at 369).

Here, the State argues that the Complaint alleges that "Purdue's unlawful marketing and promotional activities were a 'substantial factor' that foreseeably caused physicians to make express or implied false certifications about the medical necessity of opioid treatment, resulting in claims submitted to the State for reimbursement." *Id.*; *see id.* at 51 -53 (citing *Compl.* ¶¶ 32, 81-105, 113, 177, 179, 219, 233, 236). The State accuses Purdue of directly targeting physicians so that they would prescribe Purdue's opioids and submit prescriptions to the State for reimbursement. *Id.* at 54. Thus, the State contends that a reasonable trier of fact could "conclude that Purdue's conduct caused physicians to issue medically unnecessary opioid prescriptions." *Id.* at 53. The State notes that Purdue does not cite any false claims cases to support its causation argument. *Id.*

***c. Public Nuisance***

The State argues that the proper standard of causation for a public nuisance claim is whether the defendant's conduct is a substantial factor in creating the nuisance, even if there are other intervening causes. *Id.* at 55-56 (citing *James v. Arms Tech., Inc.*, 359 N.J. Super. 291, 311 (App. Div. 2003)). Here, the State alleges that Purdue's marketing and promotional activities were a substantial factor in causing the nuisance. *Id.* at 57 (citing *Compl.* ¶¶ 298, 301-04).

***d. Learned Intermediary Doctrine***

The State argues that the learned intermediary doctrine does not defeat its claims for two reasons. First, the doctrine is limited to failure to warn claims under the PLA. *Id.* at 59 (citations omitted). The State contends that it is not asserting a failure to warn claim. *Id.*

Second, if the doctrine does apply, it does not defeat the State's claims because Purdue made misrepresentations to physicians and patients. *Id.* at 60 (citing *Perez v. Wyeth Labs.*, 161 N.J. 1, 19 (1999)).

#### *e. Control Over Promotional Activity*

For two reasons, the State argues that it has sufficiently pleaded that Purdue controlled unlawful promotional activity. *Id.* at 62. First, the Complaint alleges that Purdue directly distributed third-party material to physicians and used these materials in promoting its products. *Id.* at 62-63 (citing *Compl.* ¶¶ 67, 69-71, 97, 112).

Second, Purdue allegedly “funded, assisted, encouraged, and even exercised direct editorial oversight over material created by third-party organizations.” *Id.* at 62; see *id.* at 63-64 (citing ¶¶ 61-66, 69-72, 95, 97-113). The State contends that whether an agency relationship exists is a question for the trier of fact unless the facts are undisputed and there are no conflicting inferences. *Id.* at 63-64 (citing *Luchejko v. City of Hoboken*, 207 N.J. 191, 211 (2011); *Miller v. Linde*, 33 N.J. Super. 41, 43 (App. Div. 1954)).

Third, Purdue allegedly “published misleading material—in-house—through its own unbranded marketing under the banners *Partners Against Pain* and *In the Face of Pain*.” *Id.* at 65 (citing *Compl.* ¶¶ 88-104).

#### *5. Foreclosure of Public Nuisance Claim*

\*12 The State argues that the PLA does not foreclosure the State's public nuisance claim for four reasons. First, the State is not suing because of harm caused by a product. *Id.* at 66. The PLA defines harm as personal injury or property damage. *Id.* (citing *N.J.S.A. 2A:58C-1(b)(2)*).

Second, the State argues that *Lead Paint* differs from this action in the following ways:

1. *Lead Paint* did not involve a fraudulent marketing or promotional scheme;
2. Lead paint was an ordinary, unregulated consumer product when it was sold;
3. A statute addressing the lead paint problem placed responsibility for the problem on property owners, not paint manufacturers;
4. The evidence did not show that the manufacturers' conduct, at the time they distributed the paint, “bears the necessary link to the current health crisis;” and
5. The municipalities sought vindication of personal injuries and property damage.

*Id.* at 67-68 (citations omitted).

Third, the State contends that this action is similar to *James*, which held that the plaintiff's failure to warn allegations did not turn the entire complaint into a PLA action. *Id.* at 69 (citing *James, supra*, 359 N.J. Super. at 304). Additionally, the Appellate Division held that the plaintiff's public nuisance claim was based on “defendants' affirmative conduct in promoting and distributing firearms.” *Id.* (citing *James, supra*, 359 N.J. Super. at 328).

Fourth, the State argues that it need not show a special injury because a special injury is only required when a private party sues for damages. *Id.* at 71 (citing *Lead Paint, supra*, 191 N.J. at 426). The State seeks abatement, which includes requiring Purdue to pay the costs of the abatement and to reimburse the State for costs it incurred in addressing the nuisance. *Id.*

The State also rejects Purdue's suggestion, which was in a footnote of its moving brief, that the PLA forecloses the State's other claims. *Id.* at 70. The State argues that the CFA and FCA claims do not seek to redress harm caused by a product under the PLA. *Id.* Additionally, the FCA claim does not require a showing of harm as the PLA defines harm. *Id.* (citation omitted).

### **C. PURDUE'S REPLY**

#### **1. Preemption**

Purdue argues that the State's claims are preempted for three reasons. First, Purdue's marketing is consistent with the FDA-approved indications and labeling for its products. *Purdue's Reply Br.* 2. The FDA has approved OxyContin for “daily, around-the-clock, **long-term opioid treatment** and for which alternative treatment options are inadequate.” *Id.* at 2-3 (emphasis in original) (internal quotation marks and citation omitted). The approval covers long-term treatment for chronic pain. *Id.* at 3.

Second, the State “cannot maintain a claim that a prescription medicine's labeling or marketing consistent with FDA-approved labeling is inadequate or misleading unless the manufacturer could have unilaterally changed the labeling to address the alleged inadequacy or misleading statement.” *Id.* (citing *Purdue's Br.* 10-14, 11 n.22).

Third, the State's claims would require Purdue to act in direct conflict with FDA mandates. *Id.* at 5.

#### **2. Foreclosure of the Public Nuisance Claim**

Purdue argues that New Jersey case law and the PLA foreclose the State's public nuisance claim because “the State cannot bring a public nuisance claim against Purdue for the manufacture and promotion of a lawful product.” *Id.* at 5.

##### **a. Case Law**

\*13 Purdue contends that case law bars the State's public nuisance claim for three reasons. First, *Lead Paint* requires the State to proceed as a private plaintiff and show a special injury because it is seeking damages. *Id.* at 6 (citing *Lead Paint, supra*, 191 N.J. at 435; *State's Br.* 71, n.34).

Second, under *Beretta*, the State's claim is “too attenuated to attribute sufficient control to the manufacturers to make out a public nuisance claim.” *Id.* at 7 (internal quotation marks omitted) (quoting *Beretta, supra*, 373 F.3d at 541).

Third, *Lead Paint* trumps *James* because it was decided later, was a New Jersey Supreme Court decision, and the facts of this action are more similar to *Lead Paint*. *Id.* at 8. Additionally, the Appellate Division in *Lead Paint* had relied heavily on *James* but was reversed by the Supreme Court. *Id.*

##### **b. The PLA**

Purdue contends that the PLA subsumes the public nuisance claim because the PLA “encompass[es] virtually all possible causes of action relating to harms caused by consumer and other products.” *Id.* at 9 (brackets in original) (internal

quotation marks omitted) (quoting *Lead Paint, supra*, 191 N.J. at 436-37). Purdue maintains that “the PLA is paramount when the underlying claim is one for harm caused by a product.” *Id.* at 11 (internal quotation marks omitted) (quoting *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 66 (2008)). Purdue argues that the PLA covers all claims “for harm caused by a product, *irrespective of the theory underlying the claim*, except actions for harm caused by breach of an express warranty.” *Id.* at 9 (emphasis in original) (internal quotation marks omitted) (quoting N.J.S.A. 2A:58C-1(b)(3)). Purdue contends that the Complaint seeks to redress harm as defined by the PLA. *Id.* at 9-10 (citing *State's Br. 1; Compl.* ¶¶ 173, 195, 279, 300).

### 3. FCA Claim

Purdue argues that the State has failed to state an FCA claim against it because the allegations do not meet the particularity requirement of *Rule 4;5-8(a)*. Purdue contends that the State has failed to show that Purdue's marketing resulted in the submission and reimbursement of medically unnecessary opioid prescriptions. *Id.* at 13. Purdue claims that the State does not provide any specific examples of medically unnecessary opioid prescriptions. *Id.* at 11. Purdue maintains that “[b]road, conclusory allegations of a fraudulent ‘scheme’ are insufficient to state FCA claims.” *Id.* at 12 (citing *United States v. Eastwick College*, 657 F. APP'X 89, 95 (3d Cir. 2016)). Purdue argues that the “alleged availability of different methods of proof at trial does not relieve the State of its present pleading burden.” *Id.* (citation omitted). Purdue distinguishes *Foglia* because in that case it was only the defendant who had access to the documents that could prove or disprove the case. *Id.* at 13 (citing *Foglia, supra*, 754 F3d at 158). Here, the State possesses such documents. *Id.* at 13-14 (citing various portions of the Complaint).

### 4. Causation

Purdue argues that the State has not and cannot adequately plead causation for its FCA and public nuisance claims. Moreover, the learned intermediary doctrine severs any causal chain.

#### a. FCA

Purdue contends that the State fails to adequately plead causation for its FCA claim for four reasons. First, the State cannot show that Purdue's conduct was the proximate cause of an FCA violation. *Id.* at 15. But-for causation is insufficient under the FCA. *Id.* at 14. The State has failed to adequately plead that any New Jersey physician prescribed a State-reimbursed opioid based on Purdue's misrepresentations. *Id.* at 15.

\*14 Second, the causal chain is too attenuated and is broken by physicians' independent decisions to prescribe the drugs. *Id.*

Third, the foreseeability of medically unnecessary prescriptions does not establish “proximate cause because the State needs to show directness between Purdue's misrepresentations and the false claim. *Id.* at 16.

Fourth, the State cannot base its FCA allegations on the long-term use of the opioids because the FDA approved Purdue's opioids for long-term use. *Id.* at 17-18.

#### b. Public Nuisance

Purdue argues that the State fails to adequately plead causation for its public nuisance claim for three reasons. First, the State relies on *James*, which Purdue contends is no longer valid. *Id.* at 18.



Second, *James* concerned an illegal and unregulated firearms market. *Id.* This action concerns a highly regulated pharmaceutical market. *Id.*

Third, the drugs at issue require a physician's prescription. *Id.* The Attorney General's

office stated in 2017 that “irresponsibly run doctors' offices are ground zero for the abus[e] [of] prescription drugs.” *Id.* at 18-19 (brackets in original) (internal quotation marks and citation omitted). By contrast, in *James*, the firearms manufacturers controlled the “creation and supply of th[e] illegal market.” *Id.* at 19 (brackets in original) (internal quotation marks and citation omitted).

### *c. The Learned Intermediary Doctrine*

Purdue argues that the learned intermediary doctrine severs the causal chain for three reasons. First, contrary to the State's argument, the doctrine is not limited to the PLA because the Legislature did not abrogate the common law. *Id.* at 19.

Second, Purdue contends that the State overreads *Perez*, which stated that the only exception to the learned intermediary doctrine is when a company advertises directly to consumers. *Id.* at 20 (citing *Banner v. Hoffman-La Roche, Inc.*, 383 N.J. Super. 364, 376 (App. Div. 2006)). Here, the State does not allege that Purdue conducted mass advertising to consumers. *Id.* at 21.

Third, Purdue provided adequate warnings physicians through the FDA-approved labeling, which included a “black box warning” about the dangers of addiction, abuse, misuse, overdose, and death. *Id.* at 20. A black box warning is the most serious warning required by the FDA. *Id.*

## *5. Particularity*

Purdue reiterates that the State fails to plead its allegations of fraud with particularity because it does not provide the who, what, when, and where details. *Id.* at 22. The State's only allegations with “a semblance of the particularity required to satisfy Rule 4:5-8(a) either fall outside of the applicable statute of limitations, fail to connect the alleged conduct to any date or New Jersey doctor, patient, or prescription, or fail to show any misleading statement.” *Id.* Purdue distinguishes *Talalai*, which the State cited, by contending that the case does not hold that granular pleading is always impracticable. *Id.* at 23. Finally, Purdue repeats that the State has the records that would “show the ‘specificities of any particular wrongs.’” *Id.*

## *6. Control Over Third-Party Statements*

Purdue argues that the State has not pleaded any basis to hold it liable for the statements of third parties. *Id.* at 24. The State alleges that Purdue funded or sponsored third-party materials, but Purdue contends that retention of control is critical in determining whether an agency relationship exists. *Id.* (citing *Lucheiko, supra*, 207 N.J. at 212). Purdue argues that Purdue's allegations of funding and sponsorship of third-party materials are conclusory and “insufficient to meet the State's pleading obligations.” *Id.* at 25.

## *7. Statute of Limitations*

\*15 Purdue reiterates that allegations predating October 31, 2007 are time-barred. *Id.* at 25. Purdue argues that the State does not assert a legal theory that would toll or renew the statute of limitations for the allegations. *Id.* Further, Purdue contends that the State does not plead the discovery rule. *Id.* at 26.

Additionally, Purdue argues that the State's continuing violation argument is meritless because it is not grounded in continued wrongful acts. *Id.* (citations omitted). According to Purdue, continued ill effects from an original violation do not constitute a continuing violation. *Id.* (citation omitted). Purdue maintains that “whether third parties continued to be misled by Purdue's alleged uncorrected misrepresentations ... is irrelevant to the *State's* claims against Purdue, its knowledge of the misconduct, and the operation of the statute of limitations against it in this action.” *Id.* at 26-27 (emphasis in original).

### III. ANALYSIS

#### A. LEGAL STANDARD FOR A MOTION TO DISMISS

When reviewing a complaint that is faced with a motion to dismiss for failure to state a claim upon which relief can be granted under *Rule* 4:6-2(e), the Court's “inquiry is limited to examining the legal sufficiency of the facts alleged on the face of the complaint.” *Printing Mart-Morristown v. Sharp Electronics Corp.*, 116 N.J. 739, 746 (1989) (citation omitted). The plaintiff is “entitled to every reasonable inference of fact.” *Id.* (citation omitted). The Court does not evaluate the plaintiff's ability to prove its allegations. *Id.* (citation omitted). However, the plaintiff must set forth the essential facts supporting his or her cause of action. *Scheidt v. DRS Techs., Inc.*, 424 N.J. Super. 188, 193 (App. Div. 2012) (citation omitted). Conclusory allegations are not sufficient. *Id.* (citation omitted).

If the Court relies on materials outside of the pleadings, the motion to dismiss converts into a motion for summary judgment. *R.* 4:6-2. However, the conversion does not occur when the materials relied on are referred to in the pleadings. *E. Dickerson & Son, Inc. v. Ernst & Young, LLP*, 361 N.J. Super. 362, 365 n.1 (App. Div. 2003) (citation omitted). Here, the parties agree that the motion to dismiss standard applies to this motion. *Purdue's Br.* 8-9; *State's Br.* 4-6.

#### B. PREEMPTION

##### 1. Legal Standard

Under the Supremacy Clause of the federal Constitution, “state laws that conflict with federal laws are ‘without effect.’” *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013) (citation omitted); see *U.S. Const.*, Art. VI, cl. 2. Preemption may be express or implied. *In re Reglan Litie.*, 226 N.J. 315, 328 (2016) (citation omitted). Implied preemption consists of field preemption or conflict preemption, the latter of which may be relevant here. Conflict preemption occurs “where compliance with both federal and state regulations is a physical impossibility or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *hi* at 329 (internal quotation marks and citations omitted). When Congress legislates in a field in which states have exercised their police powers, courts assume that Congress did not intend to supersede the states' police powers “unless that was the clear and manifest purpose of Congress.” *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (internal quotation marks and citation omitted). The Food, Drug, and Cosmetic Act preserves state laws unless there is “a direct and positive conflict” with the Act. *Id.* at 567 (internal quotation marks and citation omitted).

##### 2. Application

\*16 Here, the Court finds that the State's allegations do not conflict with federal law. The State does not claim that the FDA-approved labeling was inadequate. Nor does the State seek to change the labeling. The State alleges that Purdue's

marketing was inconsistent with or not covered by FDA approvals. *See State's Br.* 16-27. At this stage of the litigation, the Court must accept the allegations as true and give the State all reasonable inferences. If the State is successful on the merits, Purdue would not be forced to violate federal law. Thus, it would be possible for Purdue to comply with both New Jersey and federal laws. Therefore, the Court rejects Purdue's preemption argument.

### **C. THE PLA'S EFFECT ON THE STATE'S PUBLIC NUISANCE CLAIM**

Purdue argues that the PLA subsumes the State's public nuisance claim. It also suggested in a footnote in its initial brief and at oral argument that the PLA subsumes the State's CFA and FCA claims. *Purdue's Br.* 20 n.37. The State included a short response to the argument in its opposition brief. *State's Br.* 70. Purdue did not argue these issues in its reply brief. The Court declines to rule on whether the PLA subsumes the State's CFA and FCA claims because the issues were not fully briefed.

#### **1. The PLA**

The Legislature enacted the PLA in 1987 after finding “that there is an urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products.” *N.J.S.A. 2A:58C-1(a)*. The Legislature did not intend the PLA to “codify all issues relating to product liability, but only to deal with matters that require clarification.” *Id.* The Legislature sought to “re-balance the law in favor of manufacturers.” *Rowe v. Hoffman-La Roche, Inc.*, 189 N.J. 615, 623 (2007) (internal quotation marks and citation omitted). It “intended to limit the liability of manufacturers so as to balance[] the interests of the public and the individual with a view towards economic reality.” *Id.* at 623- 24 (brackets in original) (internal quotation marks and citation omitted).

The PLA defines harm as

(a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.

[*N.J.S.A. 2A:58C-1(b)(2).*]

A product's manufacturer or seller is liable in a product liability action for manufacturing defects, design defects, or a failure “to contain adequate warnings or instructions.” *N.J.S.A. 2A:58C-2*. Under the PLA, [a]n adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.

[*N.J.S.A. 2A:58C-4.*]

In other words, “[a] failure to warn, or a failure to warn properly, can constitute a defect in a product sufficient to support an action in strict liability.” *Becker v. Baron Bros.*, 138 N.J. 145, 151-52 (1994) (citation omitted).

The PLA defines “product liability action” as “any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty.” *N.J.S.A. 2A:58C-1(b)(3)*. Our Supreme Court has noted that this language “is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products.” *Lead*

*Paint, supra*, 191 N.J. at 436-37 (citing *N.J.S.A. 2A:58C-1(b)(3)*). The Legislature “manifested its intent to replace all pre-existing claims by ‘one unified, statutorily defined theory of recovery for harm caused by a product.’” *McDarby v. Merick & Co., Inc.*, 401 N.J. Super. 10, 96 (App. Div. 2008) (quoting *Lead Paint, supra*, 191 N.J. at 436). New Jersey courts have held that the PLA may subsume other causes of action when the allegations underlying those causes of action fall within the definition of a product liability action. *Lead Paint, supra*, 191 N.J. at 436-37 (public nuisance); *McDarby, supra*, 401 N.J. Super. at 95-99 (CFA); *Sinclair, supra*, 195 N.J. at 65-66 (CFA); *Bailey v. Wyeth, Inc.*, 424 N.J. Super. 278, 328-333 (Law Div. 2008) (CFA); *DeBenedetto v. Denny's, Inc.*, 421 N.J. Super. 312, 318-23 (Law Div. 2010) (CFA).

## 2. Public Nuisance

### a. Definition

\*17 The Supreme Court discussed the definition of public nuisance at length in *Lead Paint*. *Lead Paint, supra*, 191 N.J. at 421-29. It noted that “[o]ur modern concepts of public nuisance are set forth in the *Restatement (Second) of Torts*.” *Id.* at 424. Section 821B defines public nuisance as “an unreasonable interference with a right common to the general public.” *Restatement (Second) of Torts* § 821B(1). Circumstances that may constitute an unreasonable interference are (a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or

(b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or

(c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect on the public right.

[*Id.* at § 821B(2).]

### b. The State's Claim

The State alleges that Purdue's conduct has caused the following injuries to the public:

(a) widespread dissemination of false and misleading information about the risks and benefits of opioids to treat chronic pain; (b) a distortion of the medical standard of care for treating chronic pain, resulting in pervasive overprescribing of opioids and the failure to provide more appropriate pain treatment; (c) high rates of opioid abuse, injury, overdose, and death, and their impact on New Jersey families and communities; (d) increased health care costs for individuals, families, employers, and the State; (e) lost employee productivity resulting from the cumulative effects of long-term opioid use, addiction, and death; (f) the creation and maintenance of a secondary, criminal market for opioids; and (g) greater demand for emergency services and law enforcement paid for by the State at the ultimate cost of taxpayers.

[*Compl.* ¶ 300.]

Purdue's alleged wrongful conduct consisted of “(a) overstat[ing] the benefits of chronic opioid therapy, including by misrepresenting OxyContin's duration of efficacy and by failing to disclose the lack of evidence supporting long-term use of opioids; and (b) obscur[ing] or omit[ing] the serious risk of addiction arising from such use.” *Id.* at ¶ 301.

The Court finds that the PLA subsumes the State's public nuisance claim because the claim falls within the definition of a product liability action. See *N.J.S.A. 2A:58C-1(b)(3)*. The State alleges that Purdue's marketing did not adequately portray the benefits and risks of its opioids. See *McDarby, supra*, 401 N.J. Super. at 95-96 (the plaintiff's CFA claim alleged that a manufacturer misrepresented the safety of a drug and failed to be truthful while marketing the drug to

prescribing physicians). The PLA covers an inadequate warning or instruction to a consumer or physician. *N.J.S.A. 2A:58C-4*; *Becker, supra*, 138 *N.J. at* 151-52. Additionally, the State's claimed injuries stem from “personal physical illness, injury or death; ... pain and suffering, mental anguish or emotional harm;” and other losses deriving from these injuries. *N.J.S.A. 2A:58C-1(b)(2)*; see *Compl.* ¶ 300. The roots of the State's claimed injuries are the physical effects of the opioids on patients.

The Court rejects the State's argument that *James* governs in this action. *James* is distinguishable because, in that case, the plaintiff (the City of Newark) accused firearms manufacturers of encouraging an illegal firearms market by not adequately supervising their distribution and producing and selling more firearms than were needed by the legitimate gun market. *James, supra* 359 *N.J. Super. at* 306. The plaintiff alleged that the manufacturers knew or should have known that irresponsible people would obtain the firearms and commit crimes, which would result in violence, injuries, and death. *Id.* The plaintiff would suffer damages because of these crimes. *Id.* The Court finds that the claims in *James*, unlike here, did not involve misrepresentations or omissions regarding the dangers of the product at issue. In other words, the alleged injuries in *James* did not arise from a failure to adequately warn or instruct a consumer about the product. Moreover, the trial court had dismissed the plaintiff's claim under the PLA and claim that the defendants' failed to adequately warn of the firearms' dangerous propensities. *Id. at* 328. Here, the State alleges that Purdue did not properly represent the benefits and risks of its opioid medications, which caused injuries like addiction and overdoses. The Court concludes that the allegations in this action are similar to the allegations in *Lead Paint*, *McDarby*, *Sinclair*, *Bailey*, and *De Benedetto* because they concern a products liability action as defined by the PLA. *N.J.S.A. 2A:58C-1(b)(2)-(3)*.

\*18 Therefore, the Court dismisses the State's public nuisance claim with prejudice for failure to state a claim upon which relief can be granted under *Rule* 4:6-2(e).

## **D. TIME-BARRED CLAIMS**

### **1. Statute of Limitations**

Purdue argues that “the State's claims are subject to, at most, a ten year statute of limitations period for any alleged wrongful act.” *Purdue's Br.* 22. Thus, it contends that any acts or omissions before October 31, 2007 are time-barred. *Id.* The State argues that “Purdue's failure to correct its prior misrepresentations constitutes a series of material and actionable omissions during the relevant time period.” *State's Br.* 32. The State alleges that Purdue's “misrepresentations have persisted and have continued to influence and prescribers and consumers to this day.” *Id. at* 32-33.

The general statute of limitations for civil actions commenced by the State provides that [e]xcept where a limitations provision expressly and specifically applies to actions commenced by the State or where a longer limitations period would otherwise apply, and subject to any statutory provisions or common law rules extending the limitations periods, any civil action commenced by the State shall be commenced within ten years next after the cause of action shall have accrued.

[*N.J.S.A. 2A:14-1.2(a)*.]

The CFA does not contain a statute of limitations within the statute itself. Rather, it uses the six-year general limitation from *N.J.S.A. 2A:14-1. Mirra v. Holland America Line*, 331 *N.J. Super.* 86, 90 (*App. Div.* 2000). The CFA's statute of limitations provides that

[a] civil action under this act may not be brought:

a. More than six years after the date on which the violation of the act is committed; or

b. More than three years after the date when facts material to the right of action are known or reasonably should have been known by the State official charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last.

[*N.J.S.A. 2A:32C-11.*]

Here, the Court finds that all alleged acts or omissions that occurred prior to October 31, 2007 are time-barred. The State cites no authority for its argument that failing to correct a prior misrepresentation constitutes a new, independent violation. The State does not explain how merely failing to correct a prior misrepresentation is a new violation. Additionally, the Court finds that Purdue's "mere failure to right a wrong and make plaintiff whole cannot be a continuing wrong which tolls the statute of limitations," or else "the exception would obliterate the rule." *Russo Farms v. Vineland Bd. of Educ.* 144 N.J. 84, 114 (1996) (internal quotation marks and citation omitted). If Purdue repeated these alleged misrepresentations within the limitations period, the repeated misrepresentation may constitute an act or omission that violates the CFA or FCA. However, the mere failure to correct a prior misrepresentation is not a new act or omission.

The Court will, however, allow the State to keep allegations of conduct prior to October 31, 2007 in the Complaint to provide context for the later conduct. However, these acts or omissions are time-barred and Purdue's mere failure to correct these alleged misrepresentations is not a continuing or new violation.

## 2. FCA's Effective-Date

\*19 Purdue argues that the FCA does not apply retroactively. *Purdue's Br.* 24. The State counters that the Legislature intended to permit "causes of action occurring after the effective date of the statute that are premised upon either completed acts of fraud or ongoing conduct." *State's Br.* 27-28 n. 15 (internal quotation marks omitted) (quoting *Hayling, supra*, 422 N.J. Super. at 372).

The FCA was enacted on January 13, 2008 but did not take effect until March 13, 2008. *Hayling, supra*, 422 N.J. Super. at 367, 369. In *Hayling*, the Appellate Division held that "the NJFCA is not retroactively applicable to conduct occurring prior to its effective date." *Id.* at 369-70 (citation omitted); see *id.* at 376.

The portion quoted by the State concerned testimony of the FCA's co-sponsor, Assemblyman Herb Conaway, Jr. Mr. Conaway had testified before the Assembly Judiciary Committee, where he described the FCA as New Jersey's whistle blower statute which tracks the federal law that allows private individuals with the knowledge of *past or present fraud* to the federal, and in this case, state government to sue on behalf of the government to recover the losses to the public for fraudulently obtained public monies.

[*Id.* at 372 (emphasis in original) (internal quotation marks and citation omitted).]

The plaintiff in *Hayling* argued that this testimony constituted legislative intent to apply the FCA retroactively. *Id.* The Appellate Division rejected this argument. *Id.* It "decline[d] to give any interpretive weight to the Assemblyman's testimony as construed by *Hayling*." *Id.* at 373 (citation omitted). Instead, it said that "it is far more reasonable to construe the phrase in which the word 'past' is found as an expression of the Legislature's intent to permit statutory causes of action occurring after the effective date of the statute that are premised upon either completed acts of fraud or ongoing conduct." *Id.* at 372. The court noted that Mr. Conaway's comments were not an official sponsor's statement and were not included in the Assembly Judiciary Committee's statement for the bill. *Id.* at 373.



The quotation cited by the State is dictum because the Appellate Division held that the FCA “provides clear evidence of the Legislature’s intent that the Act be applied prospectively.” *Id.* at 371. As such, the court needed “no further analysis to buttress [its] conclusion that the motion judge properly decided this issue.” *Id.* The portion of the opinion cited by the State was on page 372 of the opinion. Thus, it was not part of the holding.

Here, the Court rejects the State’s argument that Purdue’s conduct before the FCA’s effective date may subject it to liability under the FCA. The FCA’s language does not make the statute effective until March 13, 2008. *Id.* at 367, 369. Purdue’s liability would come under section 3 of the FCA for knowingly presenting or causing to be presented “a false or fraudulent claim for payment or approval” or knowingly making, using, or causing “to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State.” *N.J.S.A. 2A:32C-3(a)-(b)*. Purdue’s misrepresentations allegedly caused health care providers to present medically unnecessary claims for reimbursement to the State. Thus, the State is seeking to hold Purdue liable under the FCA for misrepresentations it made before the FCA’s effective date for reimbursement claims that were made after the effective date. The Court finds that the FCA’s language does not impose liability for knowingly causing the presentation of a false or fraudulent claim or knowingly causing the making or use of a false record or statement if the conduct occurred before the effective date. Purdue did not have notice of the potential FCA liability when its conduct allegedly occurred. Additionally, as the Court determined above for the statute of limitations issue, Purdue’s conduct was not a continuing wrong. Therefore, the Court concludes that Purdue is not liable under the FCA for its conduct that occurred before March 13, 2008.

## ***E. PARTICULARITY***

### ***1. Legal Standard***

\*20 For allegations of misrepresentation or fraud, *Rule 4:5-8(a)* provides that the “particulars of the wrong, with dates and items if necessary, shall be stated insofar as practicable. Malice, intent, knowledge, and other condition of mind of a person may be alleged generally.” *R. 4:5-8(a)*. The purpose of the rule “is to require the pleader to state the facts which are relied on as constituting the wrong with enough particularity to enable the person charged to deny or disprove or explain these facts. It was not intended to encourage motions to strike pleadings or motions for judgment on the pleadings.” *Evangelista v. Public Service Coordinated Transport*, 7 *N.J. Super.* 164, 168-69 (App. Div. 1950) (analyzing the former Rule 3:9-1).

### ***2. CFA Claims***

*Rule 4:5-8(a)* applies to CFA claims, so they must “be pled with specificity to the extent practicable.” *Hoffman v. Hampshire Labs. Inc.*, 405 *N.J. Super.* 105, 112 (App. Div. 2009). The CFA provides that [t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any such person has in fact been misled, deceived or damaged thereby, is considered to be an unlawful practice.

[*N.J.S.A. 56:8-2.*]

The Attorney General may prosecute the CFA. He “must prove that the Act has been violated, but does not have to prove that the victim of the fraudulent conduct had in fact been misled, deceived or damaged thereby.” *Meshinsky v. Nichols Yacht Sales, Inc.*, 110 *N.J.* 464, 473 (1988) (internal quotation marks and citation omitted). The Attorney General may bring a “broader category of actions” than a private plaintiff. *Thiedemann v. Mercedes-Benz USA, LLC*, 183 *N.J.* 234,

250 (2005). This category “encompasses circumstances where there is no ascertainable loss to an individual but there exists an industry practice that the State seeks to curtail.” *Id.*

The Court finds that the State has adequately pleaded its CFA claims. The Court agrees with the State that these details are matters of discovery. This action is similar to *Talalai*, where the Law Division held that the plaintiffs adequately pleaded their CFA claims. There, the defendant argued that the plaintiffs did not meet the standard of *Rule* 4:5-8(a) because the complaint did not “include any information regarding the dates plaintiffs purchased their Cooper tires, the types of tires purchased, how much they paid, where they bought the tires, whether they still use them, or any other identifying information regarding them.” *Talalai, supra*, 360 N.J. Super. at 555. The court held that these items were matters of discovery. *Id.* at 564. The complaint had included “a detailed description of the alleged faulty manufacturing process and the fact that the defendant [did] not disclose this information to consumers.” *Id.*

Here, the Court finds that the Complaint provides enough details of Purdue's marketing scheme to survive a motion to dismiss. *See State's Br.* 37-38 (citing various portions of the Complaint). There are enough details for Purdue to deny, disprove, or explain the allegations. The Court rejects Purdue's contention that the State, rather than Purdue, “has access to any records that would purport to show the ‘specificities of any particular wrongs.’” *Purdue's Reply Br.* 23; *see id.* at 13-14. The Court disagrees because Purdue would possess or have access to the records detailing the who, what, when, and where of its representatives' conduct. *See Purdue's Br.* 25-26. These alleged misrepresentations were not made directly to the State. As mentioned above, the State need not prove reliance, so the recipient of Purdue's messages is not critical at this stage.

### 3. FCA Claims

- \*21 The FCA imposes joint and several liability for a civil penalty on a person who
- a. Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
  - b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State.

[N.J.S.A. 2A:32C-3(a)-(b).]

The parties did not present any published opinions from New Jersey courts concerning the pleading requirements for the New Jersey FCA. However, the State acknowledges that courts in other jurisdictions have required heightened pleading in false claims litigation. *State's Br.* 39. The Court agrees that *Rule* 4:5-8(a) should apply to FCA claims.

The Court finds the Third Circuit's interpretation of the federal FCA to be instructive on this issue. *Federal Rule of Civil Procedure* 9(b) is similar to *Rule* 4:5-8(a). It requires a party alleging fraud or mistake to “state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.” *Fed. R. Civ. P.* 9(b). The Third Circuit does not require a plaintiff to “identify a specific claim for payment at the pleading stage of the case to state a claim for relief.” *Foglia, supra*, 754 F.3d at 156 (emphasis in original) (internal quotation marks and citation omitted). The plaintiff “must provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.” *Id.* at 157-58 (internal quotation marks and citation omitted). The plaintiff must allege “[s]ufficient facts to establish a plausible ground for relief.” *Id.* at 158 (internal quotation marks and citation omitted).

Here, the Court finds that the State has adequately pleaded FCA claims. The State has alleged that Purdue's marketing misrepresented its drugs, which caused prescribers to write medically unnecessary prescriptions. *See State's Br.* 42-44

(citing various portions of the Complaint). The State asserts that medically unnecessary prescriptions are not eligible for reimbursement under its health programs. *See Compl.* ¶¶ 205, 212, 215, 217-18, 226, 228-29. The Court finds that this theory is plausible. Whether the State should have known that the prescriptions were medically unnecessary is an inappropriate question for a motion to dismiss. As previously stated in the Court's analysis for the CFA claims, Purdue possesses or has access to the information regarding its representatives' conduct. It is true that the State has or should have the records for the actual reimbursement claims. However, Purdue's liability stems from the alleged misrepresentations that it made to health care providers. The State needs more information from Purdue during discovery to help it identify the false claims. As with the CFA claims, the Court finds that these details are matters of discovery.

## **F. CONTROL OVER THIRD PARTIES**

### **1. Legal Standard**

\*22 The New Jersey Supreme Court has ruled that “[a]n agency relationship is created when one party consents to have another act on its behalf, with the principal controlling and directing the acts of the agent.” *Sears Mortgage Corp. v. Rose*, 134 N.J. 326, 337 (1993) (citations omitted). An agreement specifying the relationship is unnecessary because “the law will look to their conduct and not to their intent or their words as between themselves but to their factual relation.” *Id.* (internal quotation marks and citation omitted). The trier of fact determines whether an agency relationship exists unless one of the litigants establishes the standard to obtain summary judgment. *See Miller v. Linde*, 33 N.J. Super. 41, 43-44 (App. Div. 1954) (citations omitted).

### **2. Application**

The Court is applying the motion to dismiss standard, which assumes that the State's allegations are true and gives the State every reasonable inference of fact. The published decisions cited by the parties were reviewing decisions made at the summary judgment or trial stages. *Sears Mortgage Corp.*, *supra*, 134 N.J. at 336-37; *Miller*, *supra*, 33 N.J. Super. at 43; *Gen. Bldg. Contractors Ass'n, Inc.*, *supra*, 458 U.S. at 378, 380-82; *Luchejko*, *supra*, 207 N.J. at 195; *Baldassarre v. Butler*, 132 N.J. 278, 287-88 (1993).

The Court finds that the State has adequately pleaded that Purdue controlled third party publications and events. The State alleges that Purdue controlled the unbranded marketing platforms named *Partners Against Pain* and *In the Face of Pain*, which “disseminate[d] misleading messages about the risk of addiction.” *Compl.* ¶ 87; *see id.* ¶¶ 88, 92; *State's Br.* 65. These allegations satisfy the motion to dismiss standard. The State alleges that Purdue funded or sponsored symposiums and continuing medical education seminars. *Compl.* ¶¶ 105, 113. The Court finds that, at the motion to dismiss stage of this action, it is reasonable to infer that Purdue had control over the messaging at these events. Additionally, the State alleges that Purdue funded organizations that disseminated misleading material. *Id.* at ¶¶ 65-67, 70-72, 95, 97-98. The Court finds that, at the motion to dismiss stage of this action, it is reasonable to infer that Purdue had control over the statements made by these organizations.

## **G. CAUSATION**

Purdue argues that the State's FCA claim fails for two reasons. First, the learned intermediary doctrine breaks the causal chain. Second, the State does not adequately plead but-for causation. Third, the allegations do not adequately plead proximate causation.

### **1. Learned Intermediary Doctrine**

Purdue argues that “the learned intermediary doctrine alone breaks any causal connection.” *Purdue's Br.* 31. Under the learned intermediary doctrine, “a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities.” *Niemiera v. Schneider*, 114 N.J. 550, 559 (1989) (citation omitted). The manufacturer must give “proper warning of the danger or side effects of the product.” *Id.* at 562. The warning must include the “risks attendant to” the drug. *Perez, supra*, 161 N.J. at 14 (citation omitted).

Here, assuming that the learned intermediary doctrine applies to the causation analysis, the Court finds that the doctrine does not break the causal connection. The State alleges that Purdue misrepresented the benefits and risks of its drugs. These alleged misrepresentations were inconsistent with the warnings on the FDA-approved labeling. If these allegations are true, the warning to the health care providers would not have been proper or adequate. Therefore, the Court rejects Purdue's argument that the learned intermediary doctrine breaks any causal connection.

## 2. But-For Causation

\*23 Purdue contends that the Complaint does not adequately plead but-for causation because “the State fails to allege that, prior to prescribing a State-reimbursed opioid medication, any New Jersey doctor ever read, heard, or otherwise received—let alone relied on—any purported misrepresentation made by Purdue.” *Purdue's Br.* 29 (emphasis in original). For the reasons stated above in section 111(E)(3), the Court finds that the State has adequately pleaded but-for causation. One can reasonably infer from the allegations in the Complaint that the State would not have reimbursed some prescriptions if Purdue's representatives had not made misrepresentations to physicians.

## 3. Proximate Causation

Purdue argues that the allegations do not adequately plead proximate causation because the causal chain is too attenuated. *Purdue's Br.* 29. The parties did not cite published opinions from New Jersey state courts on the issue of causation under the New Jersey FCA. However, the Court agrees with the State that Third Circuit cases interpreting the federal FCA are instructive. The Third Circuit and the Eastern District of Pennsylvania have held that the FCA applies the substantial factor test. An “illegal marketing scheme must be a ‘substantial factor’ in influencing third parties, such as physicians[,] to file false claims.” *Bergman, supra*, 995 F. Supp. 2d at 368 (citation omitted). Under the substantial factor test, “the intervention of a force which is a normal consequence of a situation created by the actor's ... conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about.” *United States ex rel. Schmidt v. Zimmer*, 386 F.3d 235, 244 (3d Cir. 2004) (ellipses in original) (internal quotation marks and citation omitted) (quoting *Restatement (Second) of Torts* § 443).

*Bergman* is similar to the allegations in this action. The plaintiff alleged that the defendant “falsely and misleadingly market its prescription drug TriCor for off-label and medically unnecessary uses.” *Bergman, supra*, 995 F. Supp. 2d at 359; see *id.* at 361. Plaintiff alleged that the defendant knew and hoped that its marketing scheme “would cause the submission of many thousands of false claims to be submitted to” government funded health insurance programs. *Id.* at 362. The district court denied defendant's motion to dismiss the plaintiff's federal FCA issues. *Id.* at 370, 372.

Here, the Court finds that the State's allegations meet the substantial factor test. The Complaint sufficiently alleges that Purdue marketed its prescription drugs to health care providers. *State's Br.* 52-53 (citing *Compl.* ¶¶ 32, 85-105, 113, 177). The State alleges that Purdue intended its marketing scheme to increase the amount of prescriptions for its drugs. *Compl.* ¶ 236. Moreover, the State's payment for some of these prescriptions was a foreseeable and intended consequence. *Id.* In other words, the end result—State-reimbursed prescription claims—allegedly was anticipated and desired by Purdue. The Court concludes that it is a reasonable inference that the prescribing of these drugs, the filling of these prescriptions, the submission of the reimbursement forms, and the State's payment of the claims for reimbursement are foreseeable

and normal consequences of such marketing efforts. At the pleading stage, the Court does not find that this causal chain is too attenuated.

#### ***IV. DECISION***

For the foregoing reasons, the Court grants in part Purdue's motion to the following extent:

1. Count Five of the Complaint is dismissed with prejudice;
2. For Count Four, Purdue's conduct before March 13, 2008 is time-barred; and
3. For all counts, Purdue's conduct before October 31, 2007 is time-barred.

**\*24** The Court denies the remainder of Purdue's motion. An order memorializing this decision has been prepared by the Court and shall be entered today.

Dated: October 2, 2018

<<signature>>

Hon. Thomas M. Moore, J.S.C.

#### Footnotes

- 1 At the time of filing, Christopher Porrino was the Attorney General and Sharon Joyce was the Acting Director of the New Jersey Division of Consumer Affairs.
- 2 Purdue agrees with this point in its reply. *Purdue Reply Br.* 14 n.4.